

**DEPARTMENT OF AGRICULTURE****Animal and Plant Health Inspection Service****9 CFR Parts 92, 93, 94, 95, 96, and 98****[Docket No. 94-106-1]****RIN 0579-AA71****Importation of Animals and Animal Products****AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to amend the regulations concerning importation of animals and animal products. The proposed changes include a complete rewrite of 9 CFR part 92, subparts D (ruminants) and E (swine), a transfer of current part 92 to 9 CFR part 93, and the establishment of a new part 92. We are proposing to establish criteria for foreign "regions" based on risk class levels. The criteria would be used to establish importation requirements for particular animals and animal products from different regions outside of the United States. We believe this change is in accordance with international trade agreements entered into by the United States. We are also proposing to allow, under certain conditions, the unloading and reloading at the port of arrival of meat and other animal products otherwise prohibited entry into the United States. We believe this change is warranted because it would remove unnecessary restrictions on the importation of meat and other animal products into the United States.

**DATES:** Consideration will be given only to comments received on or before July 17, 1996.

**ADDRESSES:** Comments may be submitted as paper copies or by electronic mail. If you submit paper copies, please send an original and three copies of your comments to Docket No. 94-106-1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 94-106-1. We encourage the submission of copies by electronic mail, since this both facilitates our analysis of the comments and allows us to make the text of comments available to the public via the Internet. The e-mail address for comments on this proposed rule is 94-106-1@aphis.usda.gov. Please be sure to include your full name and organization in any comments you submit by e-mail. If your e-mail comment is a duplicate of a paper copy you have submitted, please

state this in the first line of your e-mail message. Comments submitted by e-mail will be posted to the APHIS Regionalization Proposal Web Page within a few days after receipt. This Web page also contains copies of the proposed rule in several formats and related information. The Web page URL is <http://www.aphis.usda.gov/PPD/> region. Both paper and e-mail comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690-2817 to facilitate entry into the comment reading room.

**FOR FURTHER INFORMATION CONTACT:** Dr. Gary Colgrove, Chief Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231, (301) 734-8590.

**SUPPLEMENTARY INFORMATION:****Background**

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has promulgated regulations regarding the importation of animals and animal products in order to guard against the introduction into the United States of animal diseases not currently present or prevalent in this country. These regulations are set forth in the Code of Federal Regulations (CFR), title 9, chapter 1.

Under the current regulations, with several exceptions, restrictions on the importation of animals and animal products are based on whether a particular disease exists in any part of the foreign country from which the animals or animal products originate or transit before importation into the United States. (In a few cases, restrictions are placed on the importation of animal products from countries where a certain disease is not known to exist, because of risk factors such as those countries' importation policies or proximity to countries where the disease exists.)

The current USDA policy of prohibiting or restricting importations based solely on whether a disease exists anywhere within a national entity does not take into account whether regions within a country, or regions made up of several countries, have in place adequate natural and man-made defenses against the introduction or spread of animal diseases in those regions. Nor, we believe, do the current regulations adequately address

variations in the risk of disease transmission both between regions where a disease exists and between those where the disease is not present. We believe that these policies unnecessarily prohibit or restrict the importation of animals and animal products in many situations where such importation can be carried out with insignificant risk of introducing disease agents into the United States.

Therefore, in this document, we are proposing to revise the regulations in six different parts of 9 CFR to establish importation criteria for certain animals and animal products based on the level of disease risk in specified geographical regions. We believe that these regulatory changes are consistent with and meet the requirements of international trade agreements that have recently been entered into by the United States, as discussed below under the heading "International Trade Agreements."

**Limits of This Proposed Rule**

It is important to note that the changes we are proposing at this time apply only to the importation of ruminants and swine, and their products. The importation of all other types of animals would continue to be governed by the current regulations, rather than by a regionalized, risk class approach. It is our intent, however, to extend, in future rulemaking, the regionalized, risk class approach to the importation of all animals and animal products that are subject to the regulations.

**International Trade Agreements**

Both the North American Free Trade Agreement (NAFTA) and the General Agreement on Tariffs and Trade (GATT) Uruguay Round agreements contain provisions establishing the rights and obligations of signatory countries concerning sanitary and phytosanitary (SPS) regulation. SPS measures are generally defined as governmental measures intended to protect human, animal, or plant life or health. The applicable provisions are, respectively: Articles 709 through 724 of the NAFTA ("NAFTA-SPS"); and the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures ("WTO-SPS").

Although the two agreements differ in a few respects, both NAFTA-SPS and WTO-SPS provide that:

A Member Country shall recognize the concepts of regions of low pest or disease prevalence, and shall ensure that its sanitary and phytosanitary measures are adapted to take into account the characteristics of regions from which products originate and to which products are destined. In doing so, the

Member should take into account relevant geography, ecology, methods of surveillance and effectiveness of control systems. [NAFTA-SPS, Article 716; WTO-SPS, Articles 6.1-6.2]

The changes being proposed in this regulation are intended to comply with U.S. obligations under NAFTA-SPS and WTO-SPS with respect to the importation of live animals and animal products.

#### Format Changes to 9 CFR

Because we are proposing to make significant substantive changes to the current regulations in order to incorporate provisions regarding both regionalization and the risk classification of exporting regions, we believe it is necessary, to aid readers of the regulations, to make several major formatting changes to 9 CFR. Although we are proposing to amend in some way parts 92, 93, 94, 95, 96, and 98, only two of those parts—parts 92 and 93—would require extensive structural reformatting. We would make a number of substantive changes to part 94, but that part would largely retain its current format. Parts 95, 96, and 98 would require fewer substantive changes and no format changes.

#### Parts 92 and 93

The regulations in current parts 92 and 93 govern the importation into the United States of certain live animals, in order to prevent animals infected with certain diseases from transmitting those diseases to livestock and poultry in the United States. The animals regulated by current part 92 include birds, poultry, horses, ruminants, swine, dogs, hedgehogs and possums. Current part 93 regulates the importation of elephants, hippopotami, rhinoceroses, and tapirs.

As part of the format changes we are proposing, we would move the regulations in current part 92 to part 93. Along with this relocation of the current part 92 regulations, we would make extensive changes to two of the subparts in current part 92—subpart D (ruminants) and subpart E (swine). These changes are discussed in detail below in this supplementary information.

The movement of current part 92 to part 93 would leave no regulations at part 92. We are proposing to fill the vacated part 92 with an entirely new set of regulations, which would include criteria for establishing geographical regions for the purpose of importing animals and animal products, and criteria for classifying regions according to the disease risk (risk assessment and classification) that animals and animal products from those regions would pose

to U.S. livestock if no import restrictions were in place. New part 92 would also include a list of restricted diseases for the purposes of the import regulations. Each of these provisions is discussed in detail below.

Additionally, new § 92.4 would include a listing of the risk classification APHIS has assigned to each region of the world for each restricted disease agent. The listing in this proposed rule consists, for the most part, of countries, because, under the existing regulations, disease status is determined on a country-by-country basis. However, this proposed rule would allow for application for regional status for areas smaller or larger than individual countries. The application process is discussed in this Supplementary Information under the heading "Application for Risk Class Recognition."

#### Proposed Part 92

As noted above, we are proposing to set forth in part 92 the criteria for classification of regions according to risk assessment as required by NAFTA and GATT. These criteria would be incorporated into the amended regulations in parts 93, 94, 95, 96 and 98, which contain restrictions on the importation of certain animals and animal products.

As revised, § 92.2 would list those disease agents and vectors of agents that would be restricted entry into the United States, either because they are not known to exist in the United States or because they are subject to Federal or cooperative Federal/State control or eradication programs in the United States. Some of the diseases that we are proposing to list in revised § 92.2 are already addressed in the current import regulations. In addition, we are proposing to add other specified diseases.

The diseases we would add to those already addressed in the regulations have, in many cases, been of concern even under the current regulations, but have not posed a significant practical risk because the countries in which they exist have also been countries in which rinderpest or foot-and-mouth disease (FMD) exists. The current regulations ban the importation into the United States of most animals and animal products from countries in which rinderpest or foot-and-mouth disease exists. In those cases where animals and animal products are allowed to be imported from these countries, they must meet stringent quarantine or processing requirements. These prohibitions and safeguards effectively

ban many animals and products affected with other diseases.

However, we believe that several factors now make it necessary to provide specific regulatory restrictions for certain diseases not currently addressed in the regulations. The first factor is this proposed revision of the import regulations, which would provide for regionalization and for various classification levels of disease risk. Under this proposal, for example, and unlike under the current regulations, the fact that FMD exists in one region of a country may not significantly restrict the importation of animals and animal products from another region of the same country, if the two regions are so separated and monitored that the risk of the disease being transferred from one region to the other is negligible. This is a departure from the current regulations, in which FMD in any part of country determines the FMD status of the entire country.

The second factor is the progress many countries have made in eradicating, or moving toward eradication of, rinderpest and FMD in specific regions. In countries where FMD exists, an increasing number of regions have eradicated or come close to eradicating the disease. Therefore, under this proposal, import restrictions due to FMD in one part of a country could no longer be relied upon to guard against the importation of diseases not specifically addressed in the regulations.

In addition to FMD and rinderpest viruses, other disease agents that are specifically addressed in current parts 92 and 94 are: In part 94, African swine fever virus, hog cholera (also known as classical swine fever virus), swine vesicular disease virus, velogenic Newcastle disease virus (also known as avian pneumoencephalitis or VVND virus), fowl pest (also known as fowl plague or highly pathogenic avian influenza), bovine spongiform encephalopathy, and Salmonella enteritidis phage type 4; in part 92, Akabane virus, bluetongue virus, epizootic hemorrhagic disease virus, contagious pleuropneumonia, surra caused by *Trypanosoma evansi*, fever ticks and other ticks, vesicular stomatitis, *Trypanosoma vivax*, dourine caused by *Trypanosoma equigenitalium*, glanders caused by *Pseudomonas mallei*, equine piroplasmiasis caused by *Babesia equi* or *B. caballi*, equine infectious anemia, contagious equine metritis caused by *Taylorella equigenitalis*, African horse sickness virus, Venezuelan equine encephalitis virus, epizootic lymphangitis caused by *Histoplasma farciminosum*, and *Taenia*

*multiceps* (also known as *Taenia coenurus*).

#### Additions of Exotic Diseases

In this document, we are proposing to add the following exotic diseases to the list of restricted diseases mentioned above. A description of the disease that would be added is included with each entry.

*African or wildebeest or alcephalene malignant catarrhal fever (MCF)* is caused by a herpesvirus found in Africa, and is primarily transmitted from carrier wildebeest to cattle when the wildebeest calve. Wildebeest are the primary reservoir of this virus. The "sheep-associated form" of MCF is present in most of the world, including the United States. Neither the wildebeest-transmitted form nor the sheep-associated form of MCF are known to spread directly from cattle to cattle, so the principal concern would be importation of wildebeest or other host species from Africa that could increase the spread and seriousness of the disease in cattle or native wildlife species, some of which have been shown to be susceptible. (Heuschele, W. P., 1992, *Foreign Animal Diseases*, U. S. Animal Health Assoc., Richmond, VA, 273-284.) Because it cannot be concluded with certainty that other ruminants cannot spread the disease, the restrictions of this proposal with regard to MCF would apply to all ruminants.

*Aino virus* is a Bunyavirus of the Simbu group that produces fatal deformities in cattle similarly to Akabane virus. It has been found in Australia and Asia, particularly in Japan and Taiwan. It is transmitted by various species of Culicoides and, because of the distribution of potential vectors in the southern United States, could potentially become endemic in that area if it were to become established. (Moriwaki, M. *et al.* 1977. *Natl. Inst. Anim. Heal. Qtrly, Jap.* 17(3):95-106.; St. George, T. D. *et al.* 1989, in *The Arboviruses: Epidemiology and Ecology*. Vol IV. Ed. Monath, T.P. CRC Press, Boca Raton, FL, 145-166.; Fukutomi, T. 1991. *J. Jap. Vet. Med. Assoc.* 44(1):17-19.)

*Bovine ephemeral fever*, also known as Kotonkan, Obadhiang, Puchong, or bovine epizootic fever virus, is an arthropod-borne viral disease of cattle and water buffalo in Africa, Australia and Asia. Affected cattle suffer severe loss of weight and condition, decreased milk production, and infertility in males. The reservoir hosts are not known, but water buffalo have been shown to have a prolonged viremia (Young, P.L., 1979, *Austl Vet J.*

55(7):349-350). It could be a potentially serious problem in the southern States of the United States because of the distribution of potential vectors. If it were to become established, there would be little likelihood that it could be eradicated. (St. George, T. D., 1992, *Foreign Animal Diseases*, U. S. Animal Health Assoc., Richmond, VA, 125-133.)

*Bovine infectious petechial fever*, also known as Ondiri disease, is caused by the rickettsia *Erlchia (Cytoctetes) ondiri* in cattle and results in high mortality, abortion, and reduced lactation. It is found primarily in east Africa, and a tick vector is suspected. Infected cattle can remain infected for many months. There may be potential ticks or other vectors in the United States that can transmit the rickettsial cause of this disease. (Davies, G. 1993. *Vet. Microbiol.* 34(2):103-121.)

*Brucella melitensis* has been eradicated from the United States, but is found in Mexico, Central and South America, southern Europe, Asia, and Africa. It is a serious disease, causing abortion in sheep and goats, and can also infect cattle. It is also a serious human health risk. (Alton, G.G., 1990, in *Animal Brucellosis.*, Ed. Neilson, K. and J. R. Duncan, CRC Press, Boca Raton, FL, 383-410.)

*Congo or Crimean hemorrhagic disease virus* is caused by tick-transmitted virus and causes fever, anorexia and depression in cattle and goats in Africa and Asia. It may cause a sporadic, severe, and often fatal disease in people. A tick-rodent-cattle cycle maintains the virus in nature. Birds are responsible for distributing infected ticks, but most birds are resistant. Infection has been reported in ratites. Transmission to humans has been reported to occur with direct contact with blood of infected cattle and ostriches. This group of viruses is not found in the Western hemisphere but could possibly become established, and would be virtually impossible to eradicate. (Lvov, D.K., 1994, in *Handbook of Zoonoses*, 2nd Ed. Section B., ed. Beran, G. W., CRC Press, Boca Raton, FL, 251-252.)

*Contagious agalactia of sheep and goats* caused by *Mycoplasma agalactiae* results in fever, malaise, arthritis, eye lesions, and, in females, mastitis and reduced milk production. Losses are due to high morbidity and loss of milk and meat production. It is found in parts of Europe, Asia, and North Africa and has been reported from Australia, South Africa, and South America. Low virulence strains are found in North America, but do not cause classical disease. Infected animals are the

primary reservoir. This is potentially a costly disease for the milk goat industry in the United States. (Maré, J., 1992, *Foreign Animal Diseases*, U. S. Animal Health Assoc., Richmond, VA, 140-145.)

*Globidiosis* is due to the protozoan parasites *Besnoitia besnoiti* that affect ruminants, causing damage to skin, subcutis, blood vessels, mucous membranes and other tissues. They cause large, thick-walled cysts and severe debilitation of the animal. Convalescence is slow, and permanent sterility can occur in male animals. Affected animals are lifelong carriers, but cats and other felines are the definitive carrier host. It is found in southern Europe, Africa, Asia, and South America, and is transmitted by several biting flies, many species of which exist in the United States. A related species, *Besnoitia bennetti* is rare, but has been found in the southern States of the United States, and can cause a chronic disease in horses. This species would not be considered a restricted agent. (Levine, N.D., 1985, *Veterinary Protozoology*, Iowa St. U. Press, Ames, IA, 256-259.)

*Goat pox* and *sheep pox* viruses cause acute to chronic generalized pox lesions, fever, and pneumonia with a long recovery and occasionally high mortality in sheep and goats. They are found in Africa, Asia, and parts of Europe. Besides loss of animal productivity, these viruses cause damage to hides and wool. The viruses are very resistant and can be carried on hides or wool. (House, J. A., 1992, *Foreign Animal Diseases*, U. S. Animal Health Assoc., Richmond, VA, 343-350.)

*Heartwater*, also known as Cowdriosis, is caused by a rickettsia *Cowdria ruminantium* and produces an acute disease of ruminants transmitted by ticks. It is primarily transmitted by ticks of the genus *Amblyomma*. It is one of the three most serious livestock diseases in Africa, and has been found on some of the islands of the Caribbean. Two native North American species of *Amblyomma* have been found capable of transmitting the disease. Some wild ruminant species in Africa are known to be carriers of the infection. This is potentially one of the most serious exotic disease threats to the U. S. livestock industry. (Mare, J., 1992, *Foreign Animal Diseases*, U. S. Animal Health Assoc., Richmond, VA, 218-228.)

*Japanese encephalitis virus* causes encephalitis in people and horses. Its primary reservoir is in birds and in swine, in which it causes stillbirths. It is transmitted by various species of

mosquitoes. It is primarily found in temperate and tropical eastern Asia. (Shope, R. E., 1992, Foreign Animal Diseases, U. S. Animal Health Assoc., Richmond, VA, 246-253.)

*Jembrana disease*, also known as Tabanan disease, is caused by a retrovirus related to Bovine Immunodeficiency-like Virus (Chadwick, B. J., 1995, J. Gen. Virol. 76(1):189-192). It causes a rinderpest-like disease of cattle and buffalo, and has caused heavy losses in Indonesia. Recovered cattle may be lifetime carriers. Ticks are thought to be a vector. (Hartaningih, N., et al., 1993, Vet. Microbiol. 38(1-2):15-23; ibid. 38(1-2):23-29; Darma, D.M.N., et al., 1994, Vet. Immunol. & Immunopath. 44(1):31-44.) This virus could be a serious disease problem in much of the world. Until the epidemiology is better known, great care should be taken to avoid importing animals that may carry this virus into the United States.

*Lumpy skin disease virus*, also known as Neethling virus, causes an acute or chronic disease in cattle characterized by skin nodules and lymphadenitis. The virus is similar to sheep pox and goat pox viruses. It is found throughout Africa and the Middle East. It is transmitted primarily by biting flies. Losses are primarily due to a prolonged recovery, with emaciation, lowered milk production, hide damage, and other secondary infections. The virus may persist for long periods on contaminated premises. The disease is very difficult to eradicate once it becomes established. (House, J. A., 1992, Foreign Animal Diseases, U. S. Animal Health Assoc., Richmond, VA, 264-272.)

*Melioidosis*, caused by the saprophytic soil bacteria *Pseudomonas pseudomallei*, affects people and a wide variety of animals and resembles glanders. It occurs widely throughout southeastern Asia and parts of the tropical Americas, including Puerto Rico. It is a serious public health problem in southeastern Asia and also causes serious loss of production in animals. Animals may be latently infected for many months. Once the soil becomes contaminated, it is virtually impossible to eliminate the organism. The soil of the southeastern States in the United States could readily become endemically contaminated with the organism. Care must be taken to be certain that imported animals are not the source of introduced contamination with the organism, as they would more likely result in soil contamination than infected humans. (Grove, M. G., Harrington, K. S., 1994, Handbook of Zoonoses, Section A, 2nd Ed., CRC Press, Boca Raton, FL, 155-165.)

*Near east encephalomyelitis* affects horses and domestic ruminants, causing a low-grade fever, nervous signs and death. The causative agent is uncertain, but a tick-borne virus is suspected. The disease is similar to Borna disease, which is found in Europe. The disease is found in the Middle East and Asia. (Robertson, 1976, Handbook on Animal Diseases in the Tropics, British Vet. Assoc., London, Eng, UK, 67-68.)

*Nairobi sheep disease virus*, also known as Dugbe or Ganjam virus, is transmitted by ticks to sheep and goats and is characterized by acute hemorrhagic gastroenteritis and high mortality. The disease is found in Africa and Asia (Ganjam virus). The primary reservoir is the tick *Rhipicephalus appendiculatus*, in which transovarial transmission of the virus occurs. Other ticks have been found able to transmit the virus, but cannot maintain the virus because they do not transmit it through their eggs. (Grocock, C. M., 1992, Foreign Animal Diseases, U. S. Animal Health Assoc., Richmond, VA, 285-292.)

*Parafilaria bovicola* is a filarial worm that causes hemorrhagic nodules on the skin, with bruise-like lesions under the skin and in muscle tissues. Several licking flies have been shown to be capable of transmitting the parasite, including some present in the United States. Although the parasite has been found in imported cattle in Canada, it does not appear to have become established. All regions of the world except Australia, New Zealand, North America, and South America appear to be affected with this parasite. Losses include damage to hides, and condemnation of meat from slaughtered animals. (Steen Bech-Nielsen, 1992, Foreign Animal Diseases, U. S. Animal Health Assoc., Richmond, VA, 293-302.)

*Peste des petits ruminants*, also known as goat plague, is a contagious disease due to a virus similar to rinderpest virus in sheep and goats. Rare cases have been described in cattle and swine, but these animals appear unable to transmit the disease to other animals. It occurs in Africa, the Middle East and southern Asia. Wild ungulates such as the white-tailed deer in the United States are susceptible. The virus could become established in sheep or goats in the United States and cause severe losses if it became established in white-tailed deer herds or other native North American wild ruminants. (Saliki, J. T., 1992, Foreign Animal Diseases, U.S. Anim. Health Assoc., Richmond, VA, 303-310.)

*Rift Valley fever virus* affects ruminants, dogs, cats and people. It

causes abortions and a fatal illness in young animals, and is transmitted by various species of mosquitoes, including native North American species. Its distribution has been limited to Africa. Animals do not remain carriers of the virus for long periods of time. (Peters, C. J. and K. J. Linthicum, 1994, in Handbook of Zoonoses, 2nd Ed., Section B., Ed. Beran, G. W., CRC Press, Boca Raton, FL, 125-138.)

*Teschen disease*, also known as polioencephalomalacia of swine, Talfan disease, or benign enzootic paresis, is an infectious nervous disease of pigs caused by an enterovirus similar to human poliomyelitis. It has been found only in Europe and parts of Africa. Control programs in Europe have virtually eliminated the virulent form of the virus in Europe. Similar enteroviruses of swine with low pathogenicity are found throughout the world, including North America. Infected swine may shed the virus for several weeks even though they may be asymptomatic. (Derbyshire, J. B., 1989, in Virus Infections of Porcines, Ed. M. B. Pensaert, Elsevier Science Publishers, B.V., New York, NY, 225-239.)

*Theileriosis*, also known as east coast fever, corridor disease, or Mediterranean fever, are a group of diseases that affect cattle and that occur primarily in Africa and the Mediterranean area. The causative agent of east coast fever, *Theileria parva*, and the causative agent of corridor disease, *T. lawrenci*, are limited in their distribution to Africa by the distribution of *Rhipicephalus* spp. ticks, which are the intermediate host. However, the existence of potential vectors in the United States could make introduction of this agent an animal health problem in this country. Mediterranean fever is caused by *T. annulata*, which is found in the Mediterranean area and eastern Europe and for which the intermediate host are ticks of the *Hyalomma* genus. Malignant theileriosis of sheep and goats is caused by *T. hirci*, and the intermediate host has been shown to be ticks of the genus *Rhipicephalus* and *Hyalomma*. It is similar to *T. annulata* in its distribution. (Young, A. S. and C. M. Grocock, 1992, Foreign Animal Diseases, U.S. Anim. Heal. Assoc., Richmond, VA, 177-187; 1976, Handbook on Animal Diseases in the Tropics, Ed. Robertson, A., British Vet. Assoc., London, Eng., 178-189.)

*Tick-borne encephalitis*, also known as louping ill or Central European encephalitis, is caused by a tick-transmitted group of viruses found in Asia and Europe. Louping ill primarily affects sheep with an acute, often fatal, encephalitis. Swine, cattle, horses, and humans may also be affected. There may

be ticks in the United States that could transmit these agents, but they have not been sufficiently researched. (Timoney, P. J., 1992, Foreign Animal Diseases, U.S. Animal Health Assoc. Richmond, VA, 254-263.)

*Tick-borne fever (TBF)*, due to the rickettsia *Ehrlichia (Cytoecetes)* phagocytophilia, affects domestic and wild ruminants, causing high fever, reduced lactation and abortion. It is transmitted by various ticks. It is found in Africa, Asia and Europe. The carrier state in cattle lasts for several months. The disease is seldom fatal but causes a severe immunosuppression that exacerbates other latent infections, such as Johne's disease. (Larsen, H. J. S. *et al.*, 1994, Res. Vet. Sci. 56(2):216-224.) It may be able to be transmitted by some native North American ticks, so care should be taken to prevent introduction. (Robertson, A., 1976, Handbook on Animal Diseases in the Tropics, Brit. Vet. Assoc. London, Eng. U.K. 88-90.)

*Wesselsbron virus* causes abortions, neonatal death and congenital abnormalities primarily in sheep, but also has caused mild disease in cattle, goats, pigs, equines, camels, rodents, dogs, and humans in sub-Saharan Africa. It is carried by many species of African wildlife and is transmitted by mosquitoes. This disease, if introduced into the United States, could probably become established. It is likely that mosquito vectors in the United States could easily transmit the virus. (Barnard, B.J.H., 1990, in Virus Infections of Ruminants, Ed. Dinter, Z. and B. Morein, Elsevier Sci. Publishers, New York, NY, 291-294.)

#### Additions of Domestic Diseases

In addition to import restrictions to guard against the importation into the United States of animal diseases from other countries, the regulations in 9 CFR contain requirements regarding livestock disease agents that exist in the United States but that are subject to Federal or cooperative Federal/State control or eradication programs. For ruminants and swine, these diseases include *Brucella abortus*, *B. suis* (9 CFR part 78), *Mycobacterium bovis* (9 CFR part 77), pseudorabies virus (9 CFR part 85), scabies (9 CFR part 73), and scrapie (9 CFR parts 54 and 79). With our proposed shift to a regionalized approach, we believe it is now necessary to specifically address these diseases in the import regulations.

#### Definition of Region

In §§ 92.1, 93.401, 93.501, 94.1, 95.1, and 96.1 of this proposed rule, we would define the term *region* to mean "any defined geographic land region

identifiable by geological, political, or surveyed boundaries." Under this definition, a region may be a national entity, part of a national entity, combined parts of several national entities, or a group of several national entities combined into a single trading block. Section 92.5 of this proposed rule contains procedures, discussed below under the heading "Application for Risk Class Recognition," for requesting establishment of a specific region.

#### Criteria for Risk Classification

As discussed above, this proposed rule is a departure from the current regulations in that a region would not be classified simply as one in which a specific disease is or is not known to exist. Rather, a region in which we have determined that a certain disease does not exist would be classified as one of three different risk class levels, depending on the risk that the disease might be introduced into the region. Likewise, under this approach, two separate risk classifications for regions in which a disease is known to exist would be established, as well as one additional risk class category for countries or regions that do not yet have specific classification as another risk class level. Therefore, under this proposed rule, regions would fall into one of six risk class levels or categories.

The six risk class levels would be titled "RN" or "negligible risk class regions," "R1" or "slight risk class region," "R2" or "low risk class region," "R3" or "moderate risk class region," "R4" or "high risk class region," and "RU" or "unknown or unclassified risk class region." The criteria for each risk class are set forth in § 92.3 of this proposal. A region classified as RN would present the least risk of disease transmission, with R1, R2, R3, and R4 presenting increasing risk of disease transmission. An RU region would be one that has not yet been classified.

It is important to note that each of the risk classifications would be based on unrestricted importation of animals and animal products—i.e., the risk of a disease being imported into the United States if no mitigating biosecurity measures were in place. Under this proposal, the actual biosecurity measures for the importation of animals and animal products become increasingly stringent as the risk class number increases. With these biosecurity measures in place, we believe that the disease risk from the importation of animals and animal products from each of the regions would be negligible, or equivalent to that of a Risk Class RN. In some cases, however, because of the virulent nature of the

disease in question, no importations of susceptible animals or animal products would be allowed from regions classified as Risk Class R3, R4, or RU.

Under this proposal, it is possible that a region would have two or more different classifications for different diseases that affect the same type of animal. For example, with regard to diseases that affect swine, a region could theoretically be classified as RN for African swine fever and R3 for hog cholera. In such a case, the risk classification with the more stringent restrictions (in this case R3 for hog cholera) would govern the importation of any swine from the region, in order to assure that the most protective restrictions are applied.

#### Criteria for Risk Classification

A region could seek a particular risk classification in one of two ways. The first option would be to demonstrate to APHIS that it meets a series of conditions, discussed below under the heading "Risk Class Criteria," regarding such factors as disease history, surveillance, geography, and infrastructure. Assessing disease risk based solely on such conditions is consistent with APHIS's current method of determining the risk that a particular disease exists in a country. It differs from our current approach in that it would be applicable to regions, rather than just to countries, and that it takes into account different levels of risk.

We recognize, however, that qualitative conditions can be used in developing a quantitative risk assessment (QRA) that estimates the probability of the existence of disease in numerical terms. We view such a QRA, conducted according to accepted scientific standards, as an alternative to assessing disease risk based solely on qualitative criteria, and have included such an option in § 92.3 of this proposed rule. Therefore, under this proposed rule, a region seeking a particular disease classification could do so either by meeting the qualitative criteria for that classification, or by conducting and submitting to APHIS a scientifically valid QRA determined by the Administrator to demonstrate that the probability of the existence in that region of a live animal infected with a particular disease does not exceed the risk limit we propose for that disease classification. The risk limit for each of the risk level classifications is discussed below.

Because determination of disease risk through a scientifically valid QRA would constitute a substantial departure from our current method of assessing the disease risk of an area, we encourage

comments from the public on whether such QRA's constitute a reasonable alternative to assessing risk solely based on qualitative criteria, and, if so, what methodologies would be acceptable in determining disease risk. We are proposing that a risk classification would be assigned by the Administrator based on a QRA only after the Administrator has reviewed the assessment and has determined that it was developed according to scientifically acceptable methods.

For each of the proposed risk classifications we discuss below, we set forth a risk limit we believe would be acceptable for that classification if a valid QRA were conducted. For instance, for a region to be classified as Risk Class RN (Negligible Risk), we propose that a QRA must conclude that fewer than 1 per 1 million ( $10^{-6}$ ) live animals in that region would be expected to be infected with a restricted agent. We have proposed these numerical limits based on the level of risk we believe should reasonably be expected in a region considered to be of "negligible," "slight," "low," "moderate," "high," or "unknown" risk, respectively. We recognize, however, that research and other data may be available from the public that will suggest that the numerical limits we are proposing be adjusted before this rule is made final. We encourage the submission of such information from the public.

A discussion of each of the risk class levels follows.

#### Risk Class RN Regions

Animals or animal products imported from a region classified as Risk Class RN would present a negligible risk of introducing or spreading a disease in the United States. The dictionary definition of "negligible" would apply, *i.e.*, "so small or unimportant or of so little consequence as to warrant little or no attention" (Webster's 3rd New International Dictionary, 1966, Rand McNally and Co. Chicago, Ill.).

To achieve Risk Class RN classification, the region would have to be one in which the restricted agent has not been diagnosed within the region during the lifetime of any currently living susceptible animals. The mere fact that the restricted agent has not been reported in a region would not be considered adequate evidence of absence of the disease, if it cannot be shown that surveillance in the region is in place to report, diagnose, and control any occurrences of the disease (passive surveillance). Occasional or periodic surveys for the restricted agent in the region (active surveillance) would be

beneficial but not necessarily required in all cases. The requirement for surveys could depend upon the disease and type of infrastructure in the region. For instance, although it may be necessary, in order to determine the initial classification of a region, to have a survey conducted to establish that a disease does not appear to be present, there may be no need for subsequent surveys as long as passive surveillance exists. This determination would be made by the APHIS evaluation team that evaluates the application for recognition of a region. Not requiring active surveillance in all cases in an RN region would be parallel to the situation in the United States, where as a rule routine surveillance testing is not done for exotic diseases but passive surveillance is maintained.

Additionally, for a region to be classified as RN, the restricted agent could not be known to exist within any defined region adjacent to the RN region, and any adjacent R1 or R2 regions (described below) for the disease would need to be separated from the RN region by natural or man-made physical barriers or protected borders. All border access points from adjacent R1 or R2 regions for the disease would need to be controlled to prevent movement of susceptible animals or animal products from the adjacent regions, except under conditions that have been reviewed and approved by the Administrator of APHIS. Movement of animals and animal products into the RN region from R1, R2, R3, R4 or RU regions for the disease would need to be done only under conditions that have been determined by the Administrator to achieve the same level of biosecurity as required for importation from R1, R2, R3, R4, or RU regions into the United States.

Also, in general, vaccination of any potential carrier animals for restricted disease agents must have been prohibited within the RN region during the lifetime of any currently living susceptible animals. However, vaccinations could be allowed for certain diseases such as vector-transmitted diseases, or for animals specifically vaccinated to meet import requirements of other regions, when the Administrator determines that such vaccination would not increase the risk of importing restricted agents into the United States. Whether such vaccination would be allowed would depend on the disease in question, the type of vaccine used, and factors such as whether the vaccinated animals are immediately exported from the region.

In a region classified as Risk Class RN, there would need to be resources and

commitment on the part of the animal health authorities governing the region and of the animal industry in question to respond to any occurrences of a restricted agent. We would interpret "respond" to mean taking action to rapidly control and eradicate any occurrences of the restricted agent that might occur.

If a QRA using scientifically accepted methods is done, the results for an RN region would need to show that fewer than 1 out of 1 million ( $1 \times 10^{-6}$ ) live animals would be expected to be affected with the restricted agent. Based on the standards of negligible risk employed by other Federal agencies, we believe that a region in which  $10^{-6}$  live animals would be expected to be infected could reasonably be classified as a region of negligible risk.

A region previously classified as Risk Class RN in which a restricted agent is determined to exist could be reclassified as Risk Class RN 3 years after all known infected and exposed reservoirs of disease in the region have been eliminated.

#### Risk Class R1 Regions

Animals or animal products imported without restriction from a region classified as Risk Class R1 would present a slight risk of introducing or spreading a disease in the United States. Again, the dictionary definition of the term would apply. "Slight" is defined as "small of its kind or in amount" (Webster's 3rd New International Dictionary, 1966, Rand McNally and Co. Chicago, Ill.). We would consider a region that presents a slight risk (Risk Class R1) to be essentially the same as one that presents a negligible risk (Risk Class RN), except that regions classified as R1 that have been previously affected with a particular disease may not have been without the presence of the disease for as long a period of time as an RN region, and R1 regions may be regions that share borders with, or trade extensively with, regions where the disease is known to exist. The likelihood of residual infection in the R1 region would be considered to be negligible.

Vaccination requirements would be the same as for Risk Class RN regions, except that there could be animals within the region that were vaccinated prior to the region being classified as Risk Class R1, provided they are under provisional quarantine. In § 92.1 of the proposed regulations, a *provisional quarantine* would be defined as restrictions placed on movements of vaccinated livestock where the restricted agent in question is not known to exist in livestock, but where

the possibility of exposure exists. Under a provisional quarantine, vaccinated livestock not known to be affected with the disease could be moved to affected regions, i.e., to regions having animals affected with the disease, or to regions that do permit vaccination.

Under the proposed regulations, a region classified as R1 could be adjacent to regions that are affected with the disease in question, but would need to be separated from those regions by natural or man-made physical barriers, or by protected borders. If border controls were not in place, affected animals, animal products, or vectors could move or be moved readily across the border. However, to guard against such movement, all border access points from adjacent R2, R3, R4 or RU regions would need to be controlled to prevent movement of susceptible animals or animal products from the adjacent regions, except under conditions that have been reviewed and approved by the Administrator.

In an R1 region, there must be active surveillance for the restricted agent in the region. However, as a matter of policy, we would not require that the surveillance be continuous, because, in a region classified as Risk Class R1, the concern would not be primarily with residual infection in the region or with vaccine masking of infection. Any infection that might be found in the region should be an introduced infection. Because the population in an R1 region would be susceptible and the disease would be one not familiar to the region, passive surveillance would be effective in detecting any occurrence of the disease. The requirement regarding adequate response to disease introduction that is discussed above under RN criteria would also apply to R1 regions.

If a QRA is done using scientifically accepted methods, the results for an R1 region would need to show that fewer than 1 per 100,000 ( $1 \times 10^{-5}$ ) live animals would be expected to be infected with the restricted agent.

A region previously classified as Risk Class RN or R1 in which a restricted agent is determined to exist could be reclassified as Risk Class R1 2 years after all known infected and exposed reservoirs of disease in the region have been eliminated.

#### Risk Class R2 Regions

Animals or animal products imported without restriction from a Risk Class R2 region would present a low risk of introducing or spreading a disease in the United States. A Risk Class R2 region would be one that has been affected with a particular restricted

agent in the past, but in which a sufficient period of time has passed (5 years for bovine spongiform encephalopathy and scrapie, 1 year for all other restricted diseases) with no reported cases of the disease to make it likely that active disease no longer exists in the region. In a Risk Class R2 region, the maximum annual herd incidence of the restricted agent over the past 5 years would need to be less than 0.1 percent, the likelihood of residual infection would be low and there would be a low risk of importation of affected animals, animal products or vectors from adjacent areas or trading partners.

Any adjacent R3, R4, or RU regions for the disease would need to be separated by natural or man-made physical barriers, or protected borders, and there would need to be suitable control of border access points from adjacent R3, R4, or RU regions for the disease to prevent movement of susceptible animals or animal products from the adjacent regions, except under conditions that have been reviewed and approved by the Administrator. Movement of animals and animal products into the R2 region from R3, R4, or RU regions for the disease could be done only under conditions that have been reviewed by the Administrator and that have been determined to achieve the same level of biosecurity as required for importation from R3, R4, or RU regions into the United States.

There would need to be a continuous active surveillance program in the region, as well as a passive surveillance system, and, as for an R1 region, there would need to be resources and commitment on the part of the animal health authorities governing the region and of the animal industry in question to respond to (i.e., rapidly control and eradicate) any occurrences of the restricted agent.

Vaccination may be allowed in the R2 region, under the same conditions as for an RN or R1 region, with additional vaccination allowed for those herds that are at greatest risk of exposure from animals from affected regions. Generally, however, as a matter of policy, vaccinated animals will not be allowed into the United States. Under our current regulations in parts 92 and 94, a country that permits vaccination would not normally be considered free of the disease in question.

If a QRA is done using scientifically accepted methods, the results for an R2 region would need to show that fewer than 1 per 10,000 ( $1 \times 10^{-4}$ ) live animals would be expected to be infected with the restricted agent.

#### Risk Class R3 Regions

Animals or animal products imported without restriction from a Risk Class R3 region would present a moderate risk of introducing or spreading a disease in the United States. Such a region would meet the definition of a "low prevalence region" under the GATT agreement. (GATT, Side Agreement on the Application of Sanitary and Phytosanitary Measures, Annex A, Item 7; also GATT Implementing Act, Dec. 1994, Sanitary and Phytosanitary Measures, Section 1, Paragraph f). In an R3 region, a restricted agent may have been diagnosed within the previous year, but the annual herd incidence of the disease over the previous 5 years may not have exceeded 0.1 percent.

Any adjacent R4 and RU regions for the disease would need to be separated by natural or man-made physical barriers or protected borders, and all border access points from adjacent R3, R4, or RU regions for the disease would have to be strictly controlled to prevent movement of susceptible animals or animal products from the adjacent regions, except under conditions that have been reviewed and approved by the Administrator. Movement of animals and animal products into the region would need to be carried out only under conditions that have been reviewed by the Administrator and that have been determined to achieve the same level of biosecurity as required for importation from R4 or RU regions into the United States.

Vaccination would be allowed under the same conditions as for an R2 region. Such a region would need to have an active control and surveillance program, with the goal of eradicating the disease in question.

The results of a QRA for an R3 region, if done, would need to show that fewer than 1 per 1,000 ( $1 \times 10^{-3}$ ) live animals would be expected to be infected with the restricted agent.

#### Risk Class R4 Regions

Animals or animal products imported without restriction from a Risk Class R4 region would present a high risk of introducing or spreading a disease in the United States. A "high risk" region would be one in which a control and surveillance program exists, but in which the prevalence of the restricted agent is excessively high or where the program does not have the goal of eradication. In an R4 region, a restricted agent has been diagnosed during the previous year, and the annual herd incidence of the disease over the past 5 years may have exceeded 0.1 percent in 1 or more years or may be unknown.



The R4 region would need to maintain a passive and active surveillance system for restricted disease agents, but the level of surveillance may not fully meet standards for an R3 region.

In an R4 region, vaccination for any restricted agent may vary from herd to herd within the region. If vaccination is used as the primary control procedure, at least 80 percent of the livestock in 80 percent of the herds must be vaccinated as often as recommended by the manufacturers of the vaccine. In an R4 region, movement of animals and animal products from R3, R4 and RU regions for the restricted agent may not be adequately controlled.

The results of a QRA for an R4 region, if done, would need to show that less than 1 per 100 ( $1 \times 10^{-2}$ ) live animals would be expected to be infected with the restricted agent.

#### Risk Class RU Regions

An additional risk category, Risk Class RU, will be defined as an unclassified or unknown risk. Such a region may not have any surveillance or control program. A region classified as RU may report no known occurrence of a restricted agent, but, because of lack of surveillance, cannot be expected to provide reliable data about the occurrence of the disease in the region. A region classified as RU may have the necessary data to qualify as a classified region, but if the officials in the region have not furnished the data, requested classification of the region, or allowed reasonable access as required in NAFTA, vol. I, part 2, chap. 7, section B, article 716 or GATT-AASPM, article 6, the region shall remain unclassified. The results of a QRA may not be possible from an RU region due to lack of information; or, if information is available, the results may exceed 1 per 100 ( $1 \times 10^{-2}$ ) live animals in the region expected to be infected.

In cases where a QRA is not done, the qualitative criteria for classification of an area, as set forth in proposed § 92.3, "Criteria for risk classification," will be used to classify a region as a Risk Class RN (Negligible Risk), R1 (Slight Risk), R2 (Low Risk), R3 (Moderate Risk), or R4 (High Risk). Any region that does not meet the qualitative requirements of these risk classifications, or does not meet the minimally acceptable risk level expected of a QRA, will be classified as Risk Class RU (Unclassified or Unknown). When the results of a QRA are not available for calculating the risk of introduction of a restricted agent through a specific commodity, then the upper limits of the QRA for the risk class region will be used as the source

or country factor (explained below) in calculating the final risk.

#### Calculating Risk

In determining whether a particular commodity (animal or animal product) should be imported into the United States, the ultimate concern is how much of a risk of disease introduction does that commodity present. For the purposes of this discussion, we refer to the ultimate risk of disease introduction as "final risk." Before a commodity would be allowed to be imported under this proposed rule, the final risk would have to be negligible.

In arriving at final risk, several different types of risk need to be considered. These risks can be identified according to the source (country or region), to the commodity (live animals or animal products), and to the destination (importing country or region). All of these risks contribute to calculating the final risk of disease introduction into the importing country or region. Even commodities from regions with a relatively high source risk can present a negligible final risk if adequate mitigating measures are taken to reduce the commodity risk. Measures can also be taken at the destination (e.g., post-entry quarantine) to reduce the destination risk.

The risk classifications described in § 92.3 of this proposed rule establish the risk only for the source, with no consideration of what kind of product or commodity is being exported. These risk classifications are then used as a starting point from which to determine the necessary mitigating measures for each commodity, as set forth in §§ 93.415 and 93.515 of this proposed rule, for live ruminants and swine respectively, and as set forth in parts 94, 95, 96, and 98 for meat, germplasm, and other animal products.

The "commodity risk" is distinct from the source or destination risk. In calculating the commodity risk, the assumption is that the commodity begins as infected or contaminated. The commodity risk would be the likelihood that the commodity would still be infected after the storage, handling, processing, etc., it must undergo in reaching the final user. The commodity risk would be the same for like commodities, regardless of the source or destination risk. Theoretically, the final risk, i.e., the risk after mitigating measures are applied, would be the source risk times the commodity risk times the destination risk. However, in calculating the "final risk" for importations into the United States, we would multiply only the commodity risk times the source risk, and not factor

in the destination risk. We are using this cautious approach to determine risk based on the premise that any importation of a restricted agent is undesirable.

However, we invite comments on whether "destination risk" should also be factored into "final risk." We recognize that, in some cases, the restricted transportation in the United States and ultimate restricted use of a regulated product can reduce the risk that the product will endanger the livestock of the United States. For instance, § 94.12(b)(4) of the current regulations allows, in specific cases, for the importation of small amounts of pork or pork products whose importation is otherwise restricted due to the existence of swine vesicular disease in the country of origin, provided the pork or product is imported for examination, testing, or analysis, and provided the importation is approved by the Administrator.

We invite comment on whether factors such as destination or use should be generally considered in establishing "final risk" under the revised regulations. We particularly invite comment regarding the mitigating effects of the use of products and the destination of animals. For example, with regard to a vector-borne disease, should restrictions on the importation of an animal take into account whether the vector is not known to exist in the area of the animal's destination, or is not active at the time of year the animal is to be imported?

#### Proposed Risk Model

The formulae for calculating the risk of importing a restricted agent can be illustrated with the following model: Assuming that a commodity with a risk factor calculated to be 1 per million ( $1/1,000,000$ ) is imported from a source region classified as R3 (risk factor 1 per thousand ( $1/1,000$ )) where a specific QRA has not been done, then the final risk per unit of the commodity would be  $1/1,000,000$  times  $1/1,000$  or  $1/1,000,000,000$  (1 per billion or .000,000,001). If 1 million animal units were going to be represented in the total commodity imported per year, then the likelihood of importing one or more infected units of the commodity would be as follows:

Given:  
 $P\{I=0\}$  = Probability of zero infected units in the shipment.  
 $P\{I>0\}$  = Probability of one or more infected units in the shipment.  
 $p$  = Risk probability factor = 1 per billion or .000,000,001.  
 $N$  = Number of animal units represented in the shipment.



Then: From the Binomial distribution function, the following formula is derived.

$$P\{I=0\} = (1-p)^N$$

Therefore:

$$P\{I>0\} = 1 - P\{I=0\} = 1 - (1-p)^N$$

$$= 1 - [1 - (.000,000,001)]_{1,000,000} = .001 \text{ (1 per 1,000)}$$

or, to calculate the frequency that such an event would be expected to occur:  $1 \div .001 = 1,000$

Therefore, we could expect importation of 1 or more infected units of the commodity every 1,000 years, provided the same commodity from 1 million animal units were imported each year into perpetuity.

APHIS requests comments on whether, or to what extent, the binomial model proposed above is appropriate for estimating in the context of animal populations. Comments should suggest and describe alternative statistical models.

#### Listing of Risk Classifications for Individual Regions

Section 92.4 of this proposed rule contains listings of risk classifications for individual regions. This information is presented in two formats. Proposed § 92.4(a) is formatted so that each region listed is followed immediately by the risk classification assigned to that region for each restricted agent. For instance, a listing for all the regions in Africa is followed by the information that those regions are classified as Risk Class RN for Japanese encephalitis virus.

Proposed § 92.4(b) is formatted in such a way that all regions that fall under a particular risk classification for a particular disease are listed together. For instance, the listing for RN regions for Japanese encephalitis virus would include all regions in Africa and all other regions that are classified RN for Japanese encephalitis virus.

In the following paragraphs, we list the proposed classifications of the regions of the world, and set forth the rationale for such classifications. Because this initial proposed listing is based on disease statuses as set forth in the current regulations or, in cases where the disease is not specifically listed in the current regulations, on the published epidemiologic information about the disease distribution, it consists of national entities (countries). However, under this proposed rule, requests may be submitted to APHIS for recognition and classification of regions smaller or larger than individual countries. In all cases where neither regulatory precedent nor adequate published epidemiologic data existed to classify a country as either Risk Class

RN, R1, R2, R3 or R4, we have proposed to classify the country as Risk Class RU for unknown risk or unclassified risk. Where a disease agent has not been reported from a country, and there is no evidence that the disease agent now exists or has ever existed in the country, we have proposed to classify the country as Risk Class RN. (Because this rationale for Risk Class RN classification is the same for most but not all countries, we have used a footnote to refer to this rationale where applicable.) The proposed classifications are based on the epidemiological, geographical, and infrastructure data currently available to us. We welcome information from the public, supported by specific scientific evidence or other data, concurring with or recommending changes to the classifications.

In many cases, the risk classification for a particular disease is the same for all the countries in a geographically or politically linked group of countries. Therefore, to avoid unnecessary repetition of individual countries, for the purposes of these regulations we have combined countries of the world into groupings. The following groupings are set forth in § 92.1, "Definitions," of the proposed regulations.

*Africa:* Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Comoros, Congo, Djibouti, Egypt, Equatorial Guinea, Gabon, Ghana, Guinea, Guinea-Bissau, Ivory Coast, Kenya, Lesotho, Liberia, Libya, Madagascar, Malawi, Mali, Mauritania, Morocco, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Somalia, South Africa, Sudan, Swaziland, Tanzania, The Gambia, Togo, Tunisia, Uganda, Western Sahara, Zaire, Zambia, Zimbabwe.

*Asia:* Afghanistan, Armenia, Azerbaijan, Bangladesh, Bhutan, Burma, Cambodia, China, Georgia, Hong Kong, India, Iran, Japan, Kazakhstan, Kyrgyzstan, Laos, Macau, Malaysia, Mongolia, Nepal, North Korea, Pakistan, Russia, Singapore, South Korea, Sri Lanka, Taiwan, Tajikistan, Thailand, Turkistan, Uzbekistan, Vietnam.

*Atlantic:* Bermuda, Cape Verde, Falkland Islands, South Georgia.

*Australia:* Australia.

*Caribbean:* Anguilla, Aruba, Barbados, British Virgin Islands, Cayman Islands, Cuba, Dominica, Dominican Republic, Grenada, Guadeloupe, Haiti, Jamaica, Martinique, Montserrat, Netherlands Antilles, Puerto Rico, Saint Lucia, Saint Vincent, The Bahamas, Trinidad and Tobago, Turks and Caicos, U.S. Virgin Islands.

*Europe:* Albania, Andorra, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Byelorussia, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Gibraltar, Greece, Greenland, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Moldavia, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, United Kingdom (England, Scotland, Wales, Northern Ireland, Channel Islands, Isle of Man), Vatican City, Yugoslavia.

*Middle America:* Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama.

*Middle East:* Bahrain, Cyprus, Iraq, Israel, Jordan, Kuwait, Lebanon, Malta, North Yemen, Oman, Palestine, Qatar, Saudi Arabia, South Yemen, Syria, Turkey, United Arab Emirates.

*New Zealand:* New Zealand.

*North America:* Canada, Mexico, United States.

*Oceania:* Brunei, Fiji, French Polynesia, Indonesia, Kiribati, Maldives, Mauritius, Nauru, New Caledonia, Papua New Guinea, Philippines, Seychelles, Solomon Islands, Tonga, Vanuatu, Western Samoa.

*South America:* Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, French Guiana, Guyana, Paraguay, Peru, Suriname, Uruguay, Venezuela.

*Note:* We use the term "Middle America" for the area sometimes referred to as "Central America," in order to make clear that Panama is a part of the grouping in question. Historically, in some usages, Panama was not considered to be part of Central America.

#### Risk Classification by Region

*African swine fever virus.*

*Risk Class RN.* All regions of Asia, Atlantic, Australia, Middle America, Middle East, New Zealand, North America, and Oceania.<sup>1</sup>

*Risk Class R1.* All regions of Europe except Italy, Spain and Portugal; all regions of the Caribbean except Cuba and Haiti; and all regions of South America except Brazil.

African swine fever has been reported in parts of Italy, Spain and Portugal. The rest of Europe is tentatively classified as R1 because the regions there are adjacent to affected regions or conduct extensive trade with these regions. African swine fever has been reported in Cuba, Haiti, and Brazil, and the current

<sup>1</sup> The restricted agent in question has not been reported from these countries, nor is there any evidence that it now or has ever existed in these countries.

status of the disease in these countries is uncertain.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Aino virus.*

*Risk Class RN.* All regions of Atlantic, Caribbean, Europe, Middle America, New Zealand, North America, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Akabane virus.*

*Risk Class RN.* All regions of Atlantic, Caribbean, Europe, Middle America, New Zealand, North America, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Bluetongue virus (except serotypes 10, 11, 13 and 17).*

*Risk Class RN.* Canada, New Zealand, Mexico, and all regions of Europe except Greece.

Bluetongue virus has not been reported in Europe, except recently in Greece. Bluetongue type 10 occurred in Spain and Portugal in the 1950's but never became established. New Zealand has never had Bluetongue of any type. Canada and Mexico are known only to be affected with the same types as the United States (10, 11, 13 and 17).

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Besnoitia besnoiti (globidiosis).*

*Risk Class RN.* All regions of Atlantic, Australia, Caribbean, Middle America, New Zealand, North America, and Oceania.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Bovine ephemeral fever virus group (Kotonkan, Obodhiang).*

*Risk Class RN.* All regions of Atlantic, Caribbean, Europe, Middle America,

Middle East, New Zealand, North America, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Bovine spongiform encephalopathy.*

*Risk Class RN.* All regions of Africa, Asia, Atlantic, Australia, Caribbean, Middle America, New Zealand, Oceania, and South America; all regions of North America except Canada.<sup>1</sup>

*Risk Class R1.* All regions of the Middle East except Oman; All regions of Europe except Denmark, France, Great Britain, Northern Ireland, Republic of Ireland, and Switzerland.

Bovine spongiform encephalopathy has never been reported from the Middle East except for Oman. No country of Europe except those listed as exceptions to Risk Class R1 have ever reported the disease. They are listed as Risk Class R1 because of adjacency to affected countries and/or extensive trade with those countries.

*Risk Class R2.* Canada.

Canada had a single case of bovine spongiform encephalopathy in a bovine imported from the United Kingdom. The animal was destroyed and the United States has been kept well informed of the status of all contact animals.

There is no evidence of further cases in Canada.

*Risk Class R3.* None.

*Risk Class R4.* Denmark, France, United Kingdom, Republic of Ireland, Oman, and Switzerland.

These are all countries that have reported one or more cases of bovine spongiform encephalopathy. All of these countries have programs to control the disease. Some of these countries or regions within them may qualify as Risk Class R1, R2 or R3 regions but we do not have sufficient information at present to consider them for a higher class.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Bovine infectious petechial fever.*

*Risk Class RN.* All regions of Asia, Atlantic, Australia, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Brucella abortus.*

*Risk Class RN.* Belize, Bulgaria, Channel Island (U.K), Cyprus, Denmark,

Finland, French Polynesia, Hungary, Israel, Norway, Papua New Guinea, Romania, Sweden, and Switzerland.

All of these regions have reported eradication of *Brucella abortus* from their livestock populations over 15 years ago. (Crawford RP, Huber JD, Adams BS. *Epidemiology and Surveillance. in Animal Brucellosis* edited by Nielsen K, and Duncan JR. CRC Press, Boca Raton, Florida, 33431, 131-151, 1990.)

*Risk Class R1.* Australia, Canada, Czech Republic, Germany, Slovakia, United Kingdom except Channel Islands.

All of these regions have reported eradication of *Brucella abortus* from their livestock population more than 5 years ago. (Crawford RP, Huber JD, Adams BS. *Epidemiology and Surveillance. in Animal Brucellosis* edited by Nielsen K, and Duncan JR. CRC Press, Boca Raton, Florida, 33431, 131-151, 1990.)

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Brucella melitensis.*

*Risk Class RN.* All regions of Oceania, Australia, Canada, Czech Republic, Denmark, Estonia, Finland, Greenland, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, New Zealand, Norway, Poland, Slovakia, Sweden, United Kingdom, and Taiwan.

None of these regions has ever reported *Brucella melitensis* (Alton GG. *Brucella melitensis. in Animal Brucellosis* edited by Nielsen K, and Duncan JR. CRC Press, Boca Raton, Florida, 33431, 393-409, 1990.)

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Brucellosis due to Brucella suis except biovar 4.*

*Risk Class RN.* Canada, Ireland, United Kingdom.

None of these regions has ever reported *Brucella suis* (Alton GG. *Brucella suis. in Animal Brucellosis* edited by Nielsen K, and Duncan JR. CRC Press, Boca Raton, Florida, 33431, 411-422, 1990.)

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Brucellosis due to Brucella suis biovar 4.*

*Risk Class RN.* Africa, Asia except Russia, Atlantic, Australia, Caribbean, Europe, Mexico, Middle America, Middle East, New Zealand, Oceania, South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3, or R4.

*Congo virus (Crimean Hemorrhagic Disease).*

*Risk Class RN.* All regions of Atlantic, Caribbean, Middle America, New Zealand, North America, Oceania, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Contagious agalactia of sheep and goats due to Mycoplasma agalactiae.*

*Risk Class RN.* All regions of Australia, Caribbean, Middle America, New Zealand, North America, South America.<sup>1</sup>

*Risk Class R1.* None

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Contagious bovine pleuropneumonia due to Mycoplasma mycoides var mycoides (CBPP).*

*Risk Class RN.* All regions of Atlantic, Caribbean, Middle America, New Zealand, North America, and South America.

These regions have never reported the presence of this agent, or the agent has been eradicated for more than 15 years. (Brown C. Contagious Bovine Pleuropneumonia, in *Foreign Animal Diseases*, edited by Buisch WW, Hyde JL, Mebus CA. United States Animal Health Association, Richmond VA. 146-151, 1992.)

*Risk Class R1.* Australia, all regions of Europe except Portugal and Spain. Europe has been free of CBPP for over 15 years, except for recent outbreaks in Portugal and Spain. Australia eradicated the disease in 1975, but the status of neighboring areas in Oceania is more uncertain. Therefore, we have proposed to classify Australia and all regions of Europe as Risk Class R1 until further data can be reviewed. (Clay AL, Lloyd LC. The Eradication of Contagious Bovine Pleuropneumonia from Australia. *Bull. Off. Inter. Epiz.*, 81(7/8):533-546, 1975.)

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Contagious caprine pleuropneumonia (Mycoplasma mycoides subsp. capri)*

*Risk Class RN.* All regions of Atlantic, Caribbean, Middle America, New Zealand, North America, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Epizootic hemorrhagic disease virus of deer (Ibaraki) (except serotypes 1 and 2).*

*Risk Class RN.* Canada, Europe, Mexico, New Zealand. Europe and New Zealand have never reported the presence of this agent and there is no evidence that it now exists or has ever existed in these regions. Canada and Mexico have been affected only by serotypes 1 and/or 2, which are endemic in the United States.

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Foot-and-mouth disease virus.*

*Risk Class RN.* Australia; Barbados; Bermuda; all regions of North and Middle America except Panama; all regions of the Caribbean except The Bahamas; Greenland, Iceland, Territory of St. Pierre and Miquelon, Trust territory of the Pacific Islands.

These regions are listed in § 94.1(a)(2) of the current regulations as countries free of both rinderpest and foot-and-mouth disease. They are not listed in current § 94.11(a) as countries that, because of importations of meat from or proximity to rinderpest or FMD-affected countries, are subject to restrictions on importations of meat or meat products into the United States.

*Risk Class R1.* Austria, The Bahamas, Belgium, Chile, Denmark, Fiji, Finland, France, Germany, United Kingdom, Hungary, Japan, New Caledonia, The Netherlands, Norway, Papua New Guinea, Panama, Poland, Portugal, Republic of Ireland, Republic of Korea, Sweden, Spain, Switzerland, and Uruguay.

These regions are listed in § 94.11(a) as countries free of rinderpest and FMD that supplement their meat supply with imports from countries affected with

rinderpest or FMD, or that have a contiguous border with countries affected with rinderpest or FMD. Because the current regulations do not distinguish between countries affected with rinderpest and those affected with FMD, at this time we cannot separate those that import from countries that are infected with rinderpest but not with FMD. We are proposing to include Fiji, New Caledonia and Panama as Risk Class R1 regions because they are adjacent to regions that are considered to be affected with FMD.

*Risk Class R2.* Argentina.

The effect of this classification would be to allow the importation into the United States from Argentina of ruminants and fresh, chilled, and frozen meat of ruminants. However, those importations would be subject to certain restrictions, as set forth in § 93.415 of this proposal. This classification would also relieve certain prohibitions and restrictions on the importation from Argentina of milk and milk products of ruminants.

We believe classifying Argentina as a Risk Class R2 region for FMD is appropriate. The last outbreak of FMD in Argentina occurred in 1994. However, vaccinations for FMD in Argentina still continue. Additionally, Argentina supplements its national meat supply by importing fresh, chilled and frozen meat of ruminants and swine from countries listed in this proposed rule as Risk Class R3, R4 or RU. Argentina also shares land borders with Brazil and Bolivia, which are both designated in this proposed rule as Risk Class RU regions.

In determining the proposed classification for Argentina, APHIS reviewed the documentation submitted by the government of Argentina in support of its request to be considered free of FMD, and a team of APHIS officials traveled to that country in 1994 to conduct an on-site evaluation of the country's animal health program. The evaluation consisted of a review of Argentina's veterinary services, diagnostic procedures, vaccination practices, and administration of laws and regulations intended to prevent the introduction of FMD into Argentina through the importation of animals, meat, or animal products. The APHIS officials conducting the on-site evaluation concluded that Argentina is a low risk region for FMD. (Details concerning the on-site evaluation are available from the person listed under FOR FURTHER INFORMATION CONTACT.)

Based on our proposed risk classification of Argentina, meat and other animal products of ruminants or

swine, as well as the ship's stores, airplane meals, or baggage containing such meat or other animal products originating in Argentina would be subject to the restrictions specified in § 94.11 of these proposed regulations.

*Risk Class R3.* Greece and Italy.

Greece and Italy recently have had localized outbreaks of FMD, which have been controlled. Until more information is available, we are proposing to classify these countries as Risk Class R3 regions. However, it is possible this classification could be limited to smaller areas of these countries when the situation is further reviewed under the procedures provided in § 92.5 of this proposal.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Getah virus.*

*Risk Class RN.* All regions of Africa, Atlantic, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Heartwater due to rickettsia Cowdria ruminantium.*

*Risk Class RN.* All regions of Asia, Atlantic, Australia, Europe, Middle America, Middle East, New Zealand, North America, Oceania, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Hog cholera (classical swine fever).*

*Risk Class RN.* Australia, Canada, Dominican Republic, Fiji, United Kingdom, Iceland, New Zealand, Norway, the Republic of Ireland, Sweden, and Trust Territory of the Pacific Islands.

These regions are listed in §§ 94.9 and 94.10 of the current regulations as countries where hog cholera does not exist, and they neither are adjacent to nor trade extensively with regions where hog cholera is known to exist.

*Risk Class R1.* Denmark, Finland, Spain, and the State of Sonora in Mexico.

Denmark, Finland, and Spain are listed in §§ 94.9 and 94.10 of the current regulations as countries where hog cholera does not exist. However, because they are adjacent to or trade

extensively with regions where hog cholera is known to exist, we propose that these regions be classified as Risk Class R1.

In June, 1994, the Department received a request from the Chief Animal Health Officials in the country of Mexico for recognition of the State of Sonora as a region free of hog cholera under the sanitary and phytosanitary provisions of the North American Free Trade Agreement (NAFTA) and the General Agreement on Tariffs and Trade (GATT).

Under the current regulations, there is no provision for recognition of regions of a country as free of a disease if the entire country is not free of that disease. However, such recognition would be possible under this proposed rule. Therefore, as a result of the request from Mexico, a team of APHIS personnel reviewed the request in accordance with § 92.3 of this proposed rule. A site visit by personnel from APHIS was conducted on October 24–28, 1994, which confirmed the facts of the request from the Mexican government.<sup>2</sup>

Therefore, in this proposed rule, we are proposing that the State of Sonora in the country of Mexico be included as a Risk Class R1 region for hog cholera, because we believe the region meets some of the criteria for a Risk Class RN region for hog cholera, and some of the criteria for an R1 region according to § 92.3 of this proposed rule.

We believe this classification would be warranted due to the following facts:

1. Hog cholera virus has not been diagnosed in Sonora, Mexico for 10 years (since 1985). This would meet the requirements for a Risk Class RN (negligible risk) region for hog cholera according to § 92.3(a)(1) of this proposed rule.

2. Hog cholera virus is currently not known to exist in any of the States of Mexico or the United States that adjoin the State of Sonora, Mexico. This would meet the requirements of a Risk Class RN region for hog cholera according to § 92.3(a)(2) of this proposed rule.

3. Vaccination for hog cholera has been prohibited since 1989. This would meet the requirements for a Risk Class R1 (slight risk) region for hog cholera according to § 92.3(b)(4) of this proposed rule.

4. Adjacent States of Mexico are separated by natural physical barriers or manmade fences. The State of Sonora, Mexico is bordered by the United States

on the north; the State of Baja California Norte, Mexico and the Gulf of California on the west; The State of Chihuahua, Mexico on the east; and the State of Sinaloa, Mexico on the south. The border between Sonora and Chihuahua is separated by the Sierra Madre mountains. There are few mountain passes crossing from Chihuahua to Sonora along this entire border, from the United States to Sinaloa, with only minor road crossings at Puerto San Luis and Maycoba. The southern border of the State of Sonora is separated for most of the eastern part of the border by the same mountains that separate it from Chihuahua. Major highway and rail crossings near Estacion Don are on the coastal plain within a few miles of the Gulf of California. This would meet the requirements for a Risk Class R1 region for hog cholera according to § 92.3(b)(5) of this proposed part.

5. All border access points from adjacent States of Mexico are controlled to prevent movement of swine or swine products into the State of Sonora. The only major ports with other States of Mexico are to Sinaloa on Mexico Federal Highway 15 near Estacion Don, Sonora, Mexico, and a rail crossing near the same town. Estacion Don has washing and disinfection facilities for livestock trucks entering Sonora, cattle corrals and dipping facilities for tick control, and an incinerator for confiscated meats. Swine are not allowed to enter through this port from other areas of Mexico. The disinfection of trucks that have carried swine is funded by the pork producers associations of Sonora. Other road and/or rail crossings are near San Luis, Sonora, Mexico, and Riito, Sonora, Mexico, where bridges cross the Colorado river from Sonora to Baja California Norte, Mexico, and to Puerto San Luis and Maycoba where minor roads cross from the State of Chihuahua, Mexico. Inspection procedures for trucks moving from Chihuahua are similar to those for trucks moving from Sinaloa at Estacion Don. Airports with commercial connections to other areas of Mexico include numerous local airports and 3 international airports located at Obregon, Hermosillo, and Guaymas. The principle seaport is located at Guaymas on the Gulf of California. This would meet the requirements for a Risk Class R1 region for hog cholera according to § 92.3(b)(6) of this proposed rule.

6. Movement of swine and swine products into the State of Sonora from other States of Mexico has been reviewed by the Administrator and appears to meet the same level of biosecurity as required in proposed

<sup>2</sup> Copies of the State of Sonora site visit report may be obtained from USDA, APHIS, National Center for Import and Export, 4700 River Road Unit 39, Riverdale, MD 20837-1231. Requests may be made by telephone to (301) 734-7511 or by FAX to (301) 734-6402.

§ 93.515(e)(1) of this chapter. This would meet the requirements for a Risk Class R1 region for hog cholera according to § 92.3(b)(7) of this proposed part.

7. The State of Sonora maintains a passive surveillance system that includes reporting all suspect cases in back yard herds and commercial herds. The state of Sonora also has active surveillance that consists of periodic surveys of swine on farms and at slaughter plants. In a serological survey, 50 percent of the commercial operations were sampled in 1991, and 25 percent of the commercial operations were sampled in 1993. No evidence of hog cholera was found in these surveys. These surveys did not include small backyard operations. Continuous monitoring of swine at slaughter plants is planned until the State of Sonora achieves recognition as a Risk Class RN region for hog cholera according to § 92.3(a) of this proposed part. Passive and active surveillance in the State of Sonora would meet the requirements for a Risk Class R1 region for hog cholera according to § 92.3(b)(8) of this proposed rule.

8. The laws, regulations, policies, and infrastructure in the State of Sonora and the country of Mexico have been reviewed by the Administrator and are believed to be adequate to maintain surveillance and control and to eradicate hog cholera rapidly in the event of any outbreaks in the State of Sonora, and to curtail and restrict movements of swine or swine products from any other regions of Mexico where hog cholera exists. This would appear to meet the requirements for a Risk Class R1 region for hog cholera according to § 92.3(b)(9) of this proposed rule.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Japanese encephalitis virus.*

*Risk Class RN.* All regions of Africa, Atlantic, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Jembrana (Tabanan) virus.*

*Risk Class RN.* All regions of Africa, Atlantic, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Lumpy skin disease (Neethling virus).*

*Risk Class RN.* All regions of Asia, Atlantic, Australia, Caribbean, Europe, Middle America, New Zealand, North America, Oceania, and South America.

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Malignant catarrhal fever virus (wildebeest form).*

*Risk Class RN.* All regions of Asia, Atlantic, Australia, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Mycobacterium bovis.*

*Risk Class RN.* Bermuda, The Bahamas, Falkland Islands, Luxembourg, Norway, Isle of Jersey (United Kingdom), Cyprus.

These regions have reported complete absence of bovine tuberculosis for over 15 years. (Regional and Country Status Reports, in "Mycobacterium bovis Infection in Animals and Humans," Edited by Thoen, C.D. and Steele, J.H., pp. 169-345, Iowa State University Press, Ames Iowa, 1995).

*Risk Class R1.* None.

*Risk Class R2.* Canada.

All Provinces of Canada are either accredited-free or modified-accredited for bovine tuberculosis. Accredited-free provinces could be classified as Risk Class R1 regions, and modified-accredited as Risk Class R2 if at least 1 year has elapsed without the discovery of any infected herds. Canada follows a tuberculosis eradication program equivalent to that conducted in the United States. Other countries may be equivalent to Canada, but we currently cannot evaluate their status.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Near east encephalomyelitis virus.*

*Risk Class RN.* All regions of Atlantic, Australia, Caribbean, Europe, Middle America, New Zealand, North America, Oceania, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Nairobi sheep disease (Ganjam, Dugbe) virus.*

*Risk Class RN.* All regions of Atlantic, Australia, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Parafilariosis due to Parafilaria bovicola.*

*Risk Class RN.* All regions of North America, Middle America, South America and Caribbean.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Peste des petits ruminants (Kata) virus.*

*Risk Class RN.* All regions of Atlantic, Europe, North America, South America, Australia, and Oceania.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Pseudomonas pseudomallei (melioidosis).*

*Risk Class RN.* All regions of Europe, Canada, and Atlantic.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Pseudorabies (Aujeszky's) virus.*

*Risk Class RN.* None.

*Risk Class R1.* Canada.

Canada eradicated pseudorabies over 15 years ago. However, because it is adjacent to the United States, which is affected with pseudorabies, we are proposing to classify Canada as a Risk Class R1 region for this disease, which would be equivalent in status to pseudorabies-free States in the United States.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Restricted ectoparasites.*

*Risk Class RN.* Canada.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Rift Valley fever virus.*

*Risk Class RN.* All regions of Asia, Atlantic, Australia, Caribbean, Europe, Middle America, New Zealand, North America, Oceania, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Rinderpest virus.*

*Risk Class RN.* Australia; Bermuda; all regions of North America, Middle America, South America except Chile, and the Caribbean except The Bahamas; Greenland; Iceland; New Zealand; Territory of St. Pierre and Miquelon; and Trust Territory of the Pacific Islands.

These regions are currently listed in § 94.1(a)(2) as countries free of both rinderpest and FMD. They are not listed in current § 94.11(a) as countries that, because of importations of meat from or proximity to rinderpest or FMD-affected countries, are subject to restrictions on importations of meat or meat products into the United States. We are proposing to include South America and the Caribbean as Risk Class RN regions for rinderpest because they have never reported rinderpest and there is no reason to believe these regions are now or have ever been infected with rinderpest.

*Risk Class R1.* Austria, The Bahamas, Belgium, Channel Islands, Chile, Denmark, Finland, France, Germany, United Kingdom, Hungary, Japan, The Netherlands, Norway, Papua New Guinea, Poland, Republic of Ireland, Republic of Korea, Spain, Sweden, Fiji, New Caledonia.

These regions are listed in current § 94.11(a) as countries that are free of both rinderpest and FMD, but that supplement their meat supply with imports from areas affected with rinderpest or FMD, or that share borders with countries affected with rinderpest or FMD. Because the current regulations in § 94.11 do not distinguish whether a country's meat supply is being

supplemented from a rinderpest or from an FMD-affected country, we cannot separate those that import from countries infected with foot-and-mouth disease but not rinderpest. Fiji and New Caledonia would be classified as Risk Class R1 for rinderpest because they are adjacent to regions that are considered to be infected with rinderpest.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Scrapie disease agent.*

*Risk Class RN.* All regions of Australia and New Zealand.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* Canada.

Scrapie exists at a low prevalence in Canada, which has a program to eradicate this disease that is equivalent to the scrapie eradication program in the United States.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Sheep pox and/or goat pox virus.*

*Risk Class RN.* All regions of Atlantic, Australia, Caribbean, Middle America, New Zealand, and North America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Swine vesicular disease.*

*Risk Class RN.* Australia, all regions of North America, Middle America, Dominican Republic, Fiji, Finland, Greenland, Haiti, Iceland, New Zealand, Norway, Rumania, Sweden, and Trust Territory of the Pacific Islands.

These regions are listed in § 94.12 of the current regulations as countries where swine vesicular disease does not exist, and are not listed in current § 94.13 as countries that supplement their pork supply from countries affected with swine vesicular disease.

*Risk Class R1.* Austria, The Bahamas, Bosnia-Herzegovania, Bulgaria, Chile, Croatia, Denmark, Finland, Hungary, Luxembourg, Macedonia, Republic of Ireland, Slovenia, Switzerland, United Kingdom, and Yugoslavia.

These regions are listed in § 94.12 as countries free of swine vesicular disease, but are listed in § 94.13 as countries that supplement their national pork supply from countries that are affected with swine vesicular disease.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Taenia (Multiceps) multiceps (dog tapeworm) in livestock handling dogs.*

*Risk Class RN.* All regions of North America, Middle America, and Caribbean.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Teschen disease virus.*

*Risk Class RN.* All regions of Africa, Asia, Atlantic, Australia, Caribbean, Middle America, Middle East, New Zealand, North America, Oceania, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Theileriosis (east coast fever, corridor disease, Mediterranean fever).*

*Risk Class RN.* All regions of Atlantic, Asia, Australia, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Tick-borne encephalitis (louping ill, Central European encephalitis) virus.*

*Risk Class RN.* All regions of Africa, Atlantic, Australia, Caribbean, Middle America, Middle East, New Zealand, North America, Oceania, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Tick-borne fever due to Erlichia (Cytoecetes) phagocytophilia.*

*Risk Class RN.* All regions of Atlantic, Australia, Caribbean, Middle America, Middle East, New Zealand, North America, Oceania, and South America.<sup>1</sup>

*Risk Class R1.* None.

*Risk Class R2.* None.

*Risk Class R3.* None.

*Risk Class R4.* None.

*Risk Class RU.* All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*African (salivarian- or tsetse-transmitted) Trypanosoma spp. (T. brucei, T. congolense, T. evansi, T. suis, T. simiae, T. uniforme, T. vivax).*

**Risk Class RN.** All regions of Asia, Atlantic, Australia, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, and South America.<sup>1</sup>

**Risk Class R1.** None.

**Risk Class R2.** None.

**Risk Class R3.** None.

**Risk Class R4.** None.

**Risk Class RU.** All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Trypanosoma spp. transmitted by vectors other than tsetse flies (NTT-Trypanosomas).*

**Risk Class RN.** All regions of Asia, Atlantic, Australia, Europe, Middle America, Middle East, New Zealand, and North America.<sup>1</sup>

**Risk Class R1.** None.

**Risk Class R2.** None.

**Risk Class R3.** None.

**Risk Class R4.** None.

**Risk Class RU.** All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Vesicular stomatitis virus.*

**Risk Class RN.** All regions of Africa, Asia, Atlantic, Australia, Caribbean, Europe, Middle East, New Zealand, North America except Mexico, and Oceania.<sup>1</sup>

**Risk Class R1.** None.

**Risk Class R2.** None.

**Risk Class R3.** None.

**Risk Class R4.** None.

**Risk Class RU.** All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

*Wesselsbron virus.*

**Risk Class RN.** All regions of Asia, Atlantic, Australia, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, and South America.<sup>1</sup>

**Risk Class R1.** None.

**Risk Class R2.** None.

**Risk Class R3.** None.

**Risk Class R4.** None.

**Risk Class RU.** All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4.

#### Application for Risk Class Recognition

Section 92.5 of this proposed rule contains procedures for applying for recognition of a risk class for a region, procedures that would be followed by APHIS in making a determination of a region's risk class, and provisions for the removal or change of status of a region due to a failure of the region to meet the criteria of its current risk class, or due to the discovery of a restricted agent in a Risk Class RN, R1, or R2 region.

#### Proposed Part 93

Current 9 CFR part 93 contains provisions governing the importation of elephants, hippopotami, rhinoceroses, and tapirs into the United States. As discussed above in this "Supplementary Information" under the heading "Parts 92 and 93," we are proposing to keep these provisions in part 93, and are also proposing to add to part 93 the provisions regarding the importation of birds, poultry, horses, ruminants, swine, dogs, and hedgehogs and possums that are currently set forth in part 92. These provisions would be grouped according to the same subpart designations as in current part 92 (e.g., provisions regarding the importation of birds would continue to be subpart A, provisions for poultry would continue to be subpart B, etc.), and the current part 93 provisions for elephants, hippopotami, rhinoceroses, and tapirs would be designated as subpart H.

The only changes to the provisions for elephants, hippopotami, rhinoceroses, and tapirs would be to correct cross references and to amend the definitions and the introductory text to the definitions section to bring the language in line with that in the other subparts. Aside from being moved to part 93, the regulations regarding birds (subpart A), poultry (subpart B), horses (subpart C), dogs (subpart F), and hedgehogs and possums (subpart G) would be changed only to correct cross references. The only changes to those subparts would be to correct cross references.

However, in this proposal, we are proposing significant substantive changes to the provisions of subpart D (ruminants) and subpart E (swine) in current part 92. These changes would be in accordance with NAFTA and GATT provisions regarding the assessment of the risk of importing animals and animal products from foreign regions.

In subparts D and E of proposed part 93, we would set forth specific criteria for the importation of ruminants and swine from foreign regions, based on the risk classification of a region for a particular restricted agent, and on the type of animal intended for importation. (Unlike current part 92, no criteria for the importation of animal products would be included in proposed part 93. Those provisions that currently appear in part 92 regarding products would be incorporated into part 94, and would be revised as necessary to accommodate our proposed changes to regionalization and risk assessment. These revised criteria for the importation of animal products are discussed in this **SUPPLEMENTARY INFORMATION** in the discussion of changes to part 94.)

In setting forth specific importation criteria in proposed part 93, we would refer to the various risk classification levels set forth in proposed part 92, discussed above under the heading "Criteria for Risk Classification." The discussion that follows in this **SUPPLEMENTARY INFORMATION** explains what would be required to import specific types of animals from each region based on the region's risk classification for the disease in question.

#### Removal of Country-By-Country Exemptions

Subparts D and E of part 92 of the current regulations restrict the importation of ruminants and swine from various countries, due to the existence of certain animal diseases in those countries. For the most part, the regulations are structured so that the restrictions are applied to a list of countries in which the diseases in question exist. However, because of individual circumstances particular to several individual countries, some of the provisions of the regulations refer only to those countries. These include provisions for the importation of ruminants and swine from Canada in current §§ 92.417, 92.418, 92.419, 92.420, 92.421, 92.516, 92.517, 92.518, and 92.519; from the Caribbean countries in §§ 92.422, 92.423, and 92.520; and from Mexico in §§ 92.424, 92.425, 92.426, 92.427, 92.428, 92.429, and 92.521. They also include provisions for the importation of cattle from the Republic of Ireland in § 92.432, and for sheep from New Zealand in §§ 92.433.

In this proposed rule, we do not include special provisions for specific countries, but rather we set forth requirements for importation that would apply to all countries or regions that meet the criteria for a particular risk classification for a specific restricted agent. In some cases, these criteria may, practically speaking, apply to only one or two countries—for instance, countries that import into the United States through land border ports (discussed below under the heading "Exemption from Import Permit Requirements"). However, we believe it is appropriate not to refer to individual countries in this proposal, in light of the requirement in GATT that sanitary and phytosanitary measures must not arbitrarily or unjustifiably discriminate between members where identical or similar conditions prevail (Agreement on the Application of Sanitary and Phytosanitary Measures, GATT, article 2, paragraph 3). In future rulemaking, we would adapt the regulations to recognize regions that do not meet any



of the risk categories we are proposing to establish in this document. In such future rulemaking, we would establish classifications appropriate to that risk posed by those regions. Any other region that meets the criteria established for a new risk classification would be assigned that same classification.

#### General Prohibitions; Inspection; Importation Ports

In the current regulations, §§ 92.401, 92.402, and 92.403 (ruminants), and §§ 92.501, 92.502, and 92.503 (swine) include, respectively, provisions regarding general import prohibitions, the inspection, unloading, and cleaning of means of conveyance; and ports for importation. In this proposal, these sections would be redesignated as being in part 93, but would remain substantively unchanged.

#### Import Permit Requirements

Under the current regulations, with certain exceptions, before ruminants and swine may be imported into the United States, the importer must first apply for and obtain from APHIS an import permit. The requirements for an application for the import permit are set forth in the current regulations in §§ 92.404 and 92.504 for ruminants and swine, respectively. On the application, the importer must include information regarding the type, number, and identification of the animals to be imported, and information on the origin, intended arrival, route, and destination of the animals. These requirements are the same in this proposal.

Under the current regulations, however, an import permit is not required, under certain conditions, for ruminants or swine from certain specified countries or areas of the world (e.g., Canada, Mexico, the West Indies, and Central America). In this proposed rule, we are not setting forth permit exemptions for specifically named countries or regions, because of the need for general applicability of requirements as discussed above. However, we continue to believe that certain importations from countries with land border ports to the United States can be carried out without the need for import permits, for the reasons discussed below.

In §§ 93.404 and 93.504 of this proposal, we are setting forth provisions that would exempt certain ruminants or swine presented at a land border port from the import permit requirements. To be eligible for this exemption, the animals would have to originate in regions that are not known to be affected with foot-and-mouth disease and rinderpest, and for swine, hog cholera,

African swine fever, or swine vesicular disease. These provisions would apply only to animals being imported by land from either Canada or Mexico. We believe these exemptions are warranted, because, if the animals are found upon inspection at the port of entry to be affected with any communicable disease, the animals are not accepted into the United States, whereas animals transported to the United States by air or ship are difficult and costly to return to their origin, and holding them at the quarantine facility may create a space problem.

Import permits are used primarily as reservations for space in the quarantine stations. The need for permits for importation at facilities other than land border ports is to assure that the port facilities have sufficient space to handle animals as they are imported. At land border ports there may be a limited amount of space, but the animals can be unloaded on the Canadian or Mexican side of the border until space becomes available. It is not possible to hold animals for any length of time on planes or ships at other ports.

In the current regulations, § 92.404(a)(2) includes the statement that "An application for permit to import will be denied for domestic ruminants from any country where it has been declared, under section 306 of the Act of June 17, 1930, that foot-and-mouth disease (FMD) or rinderpest has been determined to exist, except as provided in § 92.430." Section 92.504(a)(2) includes a like statement for swine. In §§ 93.404 and 93.504 of this proposal, we are not including this statement. While it is true that ruminants and swine may not be imported, without stringent restrictions, from countries at high risk for such animals being affected with FMD or rinderpest, we believe it is misleading to imply that such importations are prohibited except in rare cases. Under §§ 93.415 and 93.515 of this proposed rule, ruminants and swine imported from regions classified as R3, R4, or RU for FMD and rinderpest would be required to be quarantined at the Harry S Truman Animal Import Center (HSTAIC), just as is required under the current regulations for ruminants and swine from countries where FMD or rinderpest exists.

#### Certificate Requirements

In the current regulations, §§ 92.405 (ruminants) and 92.505 (swine) require that, with certain exceptions based on whether the animals come from specifically named countries of origin, ruminants and swine imported into the United States be accompanied by a

certificate issued in the country of origin. This document must certify that the ruminants and swine have been in the country of origin for at least 60 days immediately preceding the date of intended exportation from that country, and must also certify that the country or district of origin has been free of certain specified diseases during that 60-day period. In addition, the certificate for sheep and goats must contain certain statements related to scrapie.

In this proposed rule, in §§ 93.405 (ruminants) and 93.505 (swine), we would require that all ruminants and swine imported, except for ruminants and swine imported for immediate slaughter from regions classified as RN for all restricted disease agents of ruminants and swine, respectively, must be accompanied by a certificate of export. This certificate of export, which would have to be issued and signed by an authorized veterinarian and endorsed by an official of the National Veterinary Services of the country of export, would need to certify that the ruminants or swine originate from premises that are not known to have been affected with any communicable disease or restricted ectoparasites of the type of animal in question for the previous 60 days. The certificate would also need to state that during transportation to the port of embarkation, there was no direct or indirect exposure to potential carrier animals from any region affected with restricted disease agents; that while en route to the port of entry, the animals were not trailed or driven through any Risk Class R3, R4, or RU region for (i.e., region affected by) any tick-borne restricted diseases; and that while en route to the port of entry, the animals were not trailed, driven, transported, or otherwise moved through any Risk Class R3, R4, or RU region for any restricted insect-transmitted diseases during a time of year when insect vectors are active. Finally, the certificate would need to certify that the animals either were inspected on the day of embarkation and were found to be free of restricted ectoparasites, or were treated for ectoparasites within 10 to 14 days of embarkation.

As noted above, only ruminants or swine that are from Risk Class RN (negligible risk) regions for all restricted disease agents of ruminants or swine, respectively, and that are imported for immediate slaughter would be exempted from the requirements for a certificate of export. Most ruminants or swine would still be required to have a certificate of export even though they may not be required to have an import permit under proposed §§ 92.404 and 92.504.

The value of the required certification would be dependent on the integrity and quality of inspections in the exporting country. The animal health infrastructure of a country is a factor in assigning a risk classification to a region. For regions with higher risk, quarantine or testing requirements validate the export certification.

*Current §§ 92.407/92.506*

In the current regulations, §§ 92.407 (ruminants) and 92.506 (swine) set forth provisions regarding the presentation of certificates, declarations, and affidavits required by the regulations. These provisions are set forth in §§ 93.406 and 93.506 of this proposal, and except for the addition of clarification as to which documents are being referred to, would remain unchanged.

*Current §§ 92.408/92.507*

The current regulations in §§ 92.408 (ruminants) and 92.507 (swine) contain requirements for the inspection, at the port of entry, of imported ruminants and swine. These requirements are set forth in §§ 93.407 and 93.507 of this proposed rule, and would be amended in one respect. The inspection requirements in current §§ 92.408 and 92.507 refer to certain exceptions for animals from specific countries—i.e., Canada, Mexico, and the British Virgin Islands when importing into the United States Virgin Islands. In accordance with GATT, these exceptions for specific countries would be removed.

*Current §§ 92.409/92.508 and 92.410/92.509*

The current regulations in §§ 92.409 (ruminants)/92.508 (swine) and §§ 92.410/92.509 set forth requirements regarding articles accompanying imported animals and regarding movement from conveyances to quarantine stations. These provisions are set forth in §§ 93.408 and 93.509 (ruminants) and §§ 93.508 and 93.509 of this proposal, and would remain unchanged.

*Current §§ 92.411/92.510*

The current regulations in §§ 92.411 (ruminants) and 92.410 (swine) include quarantine requirements for ruminants and swine, respectively, imported into the United States. The length of required quarantine for swine as set forth in current § 92.410 is the same (15 days) no matter what the origin of the swine. However, the length of required quarantine for ruminants varies according to which country the ruminants originated in.

Under this proposed rule, these provisions would be removed. Because

§§ 93.415 and 93.515 of this proposed rule include quarantine requirements specific to the risk class of the region of origin and the disease in question, it would no longer be adequate or appropriate to have a uniform length of quarantine, as currently is the case with swine, or, alternatively, to refer to specific countries, as currently is the case with ruminants. The quarantine requirements for animals from any particular country or region would be governed by the risk class of the region of origin.

*Current §§ 92.412/92.511 and 92.413/92.512*

Under the current regulations, §§ 92.412 and 92.413 (ruminants) and §§ 92.511 and 92.512 (swine) include requirements regarding importation quarantine facilities. These provisions are set forth in §§ 93.411 and 93.412 (ruminants) and §§ 93.511 and 93.512 (swine) of this proposed rule and would remain unchanged.

*Current §§ 92.414/92.513 and 92.415/92.514*

Under the current regulations, §§ 92.414 and 92.415 (ruminants) and §§ 92.513 and 92.514 (swine) set forth, respectively, provisions regarding milk and manure from quarantined animals. These provisions are set forth in §§ 93.413 and 92.414 (ruminants) and §§ 92.513 and 92.514 (swine) of this proposed rule and would remain unchanged.

*Appearance of Disease Among Ruminants in Quarantine*

In the current regulations, §§ 92.416 (ruminants) and 92.515 (swine) provide that if any contagious disease appears among the animals in quarantine, special precautions must be taken to prevent the spread of the infection to other animals in the quarantine station or those outside the grounds. Under this provision, the Administrator may take action to deal with outbreaks of clinical disease while the animals are in quarantine. These provisions are in proposed §§ 93.414 (ruminants) and 93.514 (swine).

Additionally, the proposed rule would provide that, if there are test-positive animals during quarantine (in the absence of clinical signs of disease), the Administrator may require additional testing of both the test-positive and the test-negative animal(s). We believe that this provision is necessary because many diseases are not immediately manifested in a clinical form and depend upon serological or other tests for diagnosis in live animals.

*Requirements for Importation Based on Disease Risk*

As discussed above in this “Supplementary Information” under the heading “Parts 92 and 93,” the current regulations in part 92 include restrictions on the importation of certain ruminants and swine due to their risk of transmitting diseases to animals in the United States. Current part 92, in general, bases restrictions on importation on whether a disease in question is considered to exist or not exist in a particular country.

In this proposed rule, we are proposing to move from a country-by-country approach to one based on individual regions, and are also proposing to substitute a gradation of risk levels for an “exist/does not exist” consideration of disease risk.

Restrictions on the importation of ruminants and swine from regions, based on risk level, are set forth in this proposed rule in §§ 93.415 (ruminants) and 93.515 (swine). The requirements for a particular importation would depend on three factors: (1) The type of animal to be imported; (2) the disease in question; and (3) the risk classification level of the region from which the animals are to be imported. As the risk increases that unrestricted importations from a region will result in disease transmission, the need for greater import restrictions also increases. To mitigate disease risk, several broad risk management options, applied individually or in combination, are available. These options can be applied to either animals or their products. The risk management options available are:

1. Certification of origin of animals and animal products.
2. Tests and inspection of imported animals or products.
3. Tests and inspection of herds or premises of origin.
4. Treatment of animals or products.
5. Quarantine of imported animals.
6. Restricted use or movement of imported animals or products to reduce costs of failure.

In this proposed rule each of these management options is used for various disease agents. Not all of the options are appropriate for every disease agent, so different strategies will be necessary for different agents. Some of the variabilities of the disease agents include:

1. Incubation period.
2. Duration of carrier status in animals.
3. Number of potential host species that may be affected.
4. Survivability of agent outside the host animal.

5. Effectiveness of available test procedures to detect the disease agent.
6. Effectiveness of available treatment procedures to eliminate the disease agent.
7. Availability of technology to eradicate agent if it were introduced.
8. If agent were introduced, potential cost to eradicate, or potential costs into perpetuity if agent cannot be eradicated.

#### Rationale for Import Requirements for Ruminants and Swine from Differing Risk Class Levels

Although the import requirements in this proposal differ for different animals and diseases, a broad model of requirements based on risk class levels can be drawn, and we believe that certain generalizations can be made about the type of mitigation measures necessary for each risk class level. In general, the measures established for each level of risk are built upon the protections proposed for levels of lesser risk. For example, the requirements for importation from a region classified as R4 for foot-and-mouth disease would incorporate and add to the requirements for an R3 region. The requirements for an R3 region would incorporate and add to the requirements for an R2 region, and so on. The rationale for the broad requirements for each Risk Class level are as follows (specific requirements for specific diseases are discussed later in this Supplementary Information under the heading "Risk Level Classifications other than Risk Level RN"):

**Risk Class R1 Regions:** From a Risk Class R1 region, there should be no concern about possible residual infection in the region. The principal concern is the possible deliberate introduction of animals into this region from regions with higher risk classifications in order to qualify them as animals from a Risk Class R1 region. Requiring a negative serological test for any animals imported from R1 regions would ensure that animals offered for importation are not vaccinated, and that animals from regions of higher risk are not being presented as being from the Risk Class R1 region. Requiring such tests would also provide some additional active surveillance for the exporting region.

**Risk Class R2 Regions:** There could possibly be residual infection in Risk Class R2 regions. Requiring a pre-embarkation quarantine for animals from such regions for importation into the United States would ensure that any imported animals are not incubating the disease when they are presented for export. As for Risk Class R1 regions, a negative serological test during the quarantine period for any animals from

such regions would ensure that the animals intended for export are not vaccinated, and would ensure that animals from other higher risk regions are not presented as being from the Risk Class R2 regions. Again, such testing would provide some additional active surveillance for the exporting region.

Requiring a serological test at the U.S. post-importation quarantine facility would ensure that animals have not been exposed to a restricted disease agent during pre-embarkation quarantine, and that any incubating animals during the pre-embarkation quarantine period have had ample opportunity to develop antibodies to the disease.

**Risk Class R3 Regions:** Risk Class R3 regions would be low prevalence regions with a good history of disease surveillance and control. Herds would be identified that are free of the contagious disease of concern. Although the risk of importing a restricted disease agent from an established herd is small, the risk of disease exposure to such a herd while in transit or while being assembled is much higher. Due to the incubation period for many of the diseases of concern, the proposed requirements for Risk Class R3 regions would generally require a 30- to 60-day pre-embarkation quarantine period for animals assembled. We believe this would be necessary to detect any incubating animals, depending upon the disease. Although vaccination is often an important method of control of some contagious diseases, we would be concerned that vaccinated animals may mask a low prevalence of disease in the herd. Therefore, we would expect that animals being prepared for export would not be vaccinated and would serve as sentinels for possible residual infection in the source herd. Unvaccinated animals would therefore be more likely to develop disease during the pre-embarkation quarantine, but this would also serve to monitor the presence of any agent that may be introduced into the quarantine center. If there are any incubating animals in the group of animals intended for export, the exposed susceptible animals should develop clinical illness either during the pre-embarkation or, when required, during the post-importation quarantine. For this reason we do not believe that additional sentinel animals are necessary for the importation of animals from this Risk Class level where sentinel animals are generally specified.

**Risk Class R4 and RU Regions:** Risk Class R4 or RU regions would be higher prevalence regions, or regions that may have less than adequate control and surveillance programs. The health status

of animals in source herds would be considered to be more uncertain, and more difficult for the veterinarians in the region of origin to certify. The likelihood of incubating animals, innately resistant animals, or animals that have been vaccinated and not identified as such would be greater than for Risk Class R3 regions. The pre-embarkation quarantine and testing would be generally the same as for R3 regions, but the post-importation quarantine may require using U.S.-source sentinel animals that would be highly susceptible to any foot-and-mouth disease, hog cholera, African swine fever, or swine vesicular disease virus that may be shed by infected animals in the shipment. A 30- to 60-day pre-embarkation and post-importation quarantine period would be necessary to detect these agents.

#### Solicitation of Information

The following proposed import requirements have been formulated based on current import requirements and the most recent epidemiological data available to us. We welcome information from the public, supported by scientific evidence or other data, regarding the proposed requirements.

#### Requirements for Importation From Risk Class RN Regions

Although, for the most part, the importation restrictions in proposed §§ 93.415 and 93.515 vary according to the restricted agent in question, the requirement for one risk class level, that of RN for negligible risk, would be the same for all diseases. This requirement, set forth in §§ 93.415(a) (ruminants) and 93.515(a) (swine), would be a certification that the animal in question have only been on premises in RN regions. A region that is classified as RN for all restricted disease agents would be able to import animals into the United States without any quarantine or testing requirements. Such animals would still need to be inspected at the U.S. port of entry for the general freedom from communicable diseases and, if found to be affected with a disease agent, would be quarantined either until they recovered from the disease, were destroyed, reexported or were returned to the region of origin. Animals imported through land border ports could be returned directly to the region of origin. At this time, based on the information available to us, there are no countries in the world that would qualify as Risk Class RN for all restricted disease agents of ruminants or swine, although individual regions in some countries may be able to meet such requirements.

At this time, there are many countries that may be classified as Risk Class RN for certain restricted disease agents. Therefore, specific testing and quarantine would not be required for those disease agents, even though testing or quarantine would be required for other agents. For example, Canada and Mexico would both be considered as Risk Class RN for foot-and-mouth disease virus and rinderpest virus in ruminants and swine. Canada would also be considered as Risk Class RN for hog cholera in swine, but because hog cholera does exist in parts of Mexico, those Mexican regions would be required to meet specific test and quarantine requirements to import swine into the United States. However, we would not have any greater requirements for Mexico for foot-and-mouth disease or rinderpest virus than we would have for Canada.

The criteria for a Risk Class RN region include the requirement that all susceptible animals present in the region were not living when the region was last infected. Arriving at an estimate for the specific time interval this requires will vary with the species involved. In the case of cattle, although the lifespan of a few cattle can exceed 20 years, for practical purposes most cattle in a domestic herd would be culled before 15 years. In swine, occasionally a sow or boar may live 15 years, but in practice, nearly all sows and boars in domestic farm operations are culled before 5 years of age, although there may be some marginal farm operations that keep a boar for up to 10 years. In determining the birthdates of ruminants and swine in a region for the purpose of classifying the region RN, we would use 15 years as the estimated life expectancy for cattle and 10 years for swine. These time spans reflect the pragmatic management of domestic livestock. Although other susceptible ruminants such as elk, camels, llamas, or bison may theoretically be kept longer than the 15 years we are considering as the maximum life span, we do not believe that in these species survival after 15 years would occur at a high frequency.

**Risk Level Classifications Other Than Risk Class RN**

Except for Risk Class RN, the requirements for the importation of animals from regions of each risk class level would be dependent on the

disease in question, as well as the animal. As discussed above in this **SUPPLEMENTARY INFORMATION** under the heading "Proposed Part 92," there are certain restricted diseases that are not specifically mentioned in the current regulations, because, practically speaking, animals that may have been affected with these diseases were prohibited or restricted importation due to the existence of other diseases in the country of origin. With the proposed establishment of risk class levels for regions, however, a region may be of low risk for a disease that is addressed in the current regulations, but of high risk for a disease not specifically addressed in the current regulation. Therefore, we believe it is necessary to establish distinct restrictions regarding all disease agents of concern, even those not addressed in the current regulations.

One broad category of diseases not addressed consistently in the current importation regulations is that of disease agents that are present in the United States, but that are subject to control or eradication programs. The requirements that do exist are specific to particular importing countries. For example, current § 92.418 includes testing requirements for tuberculosis and brucellosis for cattle from Canada. Current § 92.419 includes requirements for scrapie certification for sheep and goats from Canada. Current § 92.427 includes requirements for fever ticks, tuberculosis, and brucellosis for cattle from Mexico. Each of these requirements is particular to the country specified. In this proposal, we are setting forth requirements regarding the importation of ruminants and swine from countries affected with restricted disease agents subject to control or eradication programs in the United States, and we apply these requirements according to the Risk Class levels of foreign regions, rather than to specifically named countries.

**Restricted Diseases That are Present in the United States But Are Subject to Control or Eradication Programs.**

*Mycobacterium Bovis*

Proposed §§ 93.415(b) and 93.515(g) include requirements for the importation of ruminants and swine, respectively, from Risk Classes R1 through R4 with regard to *Mycobacterium bovis* (*M. bovis*), the causative agent of bovine tuberculosis.

*M. bovis* can affect a wide variety of animals, including most species of ruminants, swine and rodents. The United States has been working since 1917 to eradicate this disease agent. At present, there are a few cases of bovine tuberculosis in some States of the United States.

Bovine tuberculosis has a long incubation period, often measured in months or years. Affected animals may not show any external clinical evidence of the disease until the final terminal stages, but most will remain carriers for life. There is no cost effective treatment for bovine tuberculosis, even though treatments with various antibacterial chemicals are routinely done for humans affected with tuberculosis. The use of similar treatments in animals is not desirable because of the risk of developing resistant strains of the organism, and the prohibitive cost.

The only effective method of detecting infected carrier animals is by use of various tests. Intradermal tests have generally been applied. These tests require injection of tuberculin into the skin of the animal, and then observation of the reaction at a later time, usually 72 hours. Animals generally cannot be retested again for at least 60 days, because the test usually results in desensitization of the skin at the test site. The skin test is relatively insensitive and may miss many infected animals. It is generally more sensitive in detecting infected herds when applied to the entire herd of origin. Quarantine beyond the period of time necessary to conduct an intradermal test is not effective for bovine tuberculosis, except to prevent the quarantined animals from contacting infected animals.

The domestic regulations for bovine tuberculosis are set forth in 9 CFR part 77. Essentially, the program in the United States is based on domestic "regionalization," through the classification of States based on their risk status. Each of the States in the United States qualifies as either *Accredited free* or *Modified accredited*, as defined in § 77.1. In order for a State to become accredited free, 5 years must pass without any known infection in the State.

If each State classified under the domestic bovine tuberculosis program were a foreign region, the State classifications would fall into regional risk classifications as follows:

Domestic classification	Conditions	Comparable risk class
"Modified Accredited" .....	Infected herds in State; more than 0.1% of herds infected. No States in the United States currently in this category.	R4

Domestic classification	Conditions	Comparable risk class
"Modified Accredited" .....	Infected herds in State; fewer than 0.1% of herds infected .....	R3
"Modified Accredited" .....	No known infected herds in State for at least 1 year .....	R2
"Accredited Free" .....	No known infected herds in State for at least 5 years .....	R1
"Accredited Free" .....	No known infected herds in State for at least 15 years "Accredited Free" at least 10 years.	RN

Currently, there are no States in the United States that are not at least "Modified Accredited." If there were such areas, they would be equivalent to proposed Risk Class R4 if testing were being done to achieve a "Modified Accredited" status or as proposed Risk Class RU if such testing were not being done.

As indicated above, the risk classes we are proposing for foreign regions with regard to *M. bovis* are comparable to the domestic classifications of accredited free and modified accredited. The proposed requirements for importations from Risk Class R1 regions would be similar to interstate movement requirements in the United States from "Accredited Free" States. A certification of origin would be required for importation from both Risk Class RN and R1 regions to prevent presentation of ruminants or swine from higher risk regions as originating from Risk Class RN or R1 regions. Because of the prolonged incubation period for bovine tuberculosis, this requirement would be applicable during the lifetime of any ruminant or swine intended for importation from these regions. If animals that originated in a Risk Class R2, R3, R4 or RU region were presented for export from Risk Class RN or R1 regions, they would be required to meet the requirements for importation from the region of greater risk.

The proposed requirements for importation of ruminants or swine from regions classified as R2 and R3 for bovine tuberculosis would be similar to the requirements for interstate movement requirements in the United States from modified accredited States. Although the Federal regulations do not require a test for breeding cattle or swine moving interstate from modified accredited States, most States do have such a requirement for cattle and other ruminants entering their State from modified accredited States.

In the case of ruminants or swine intended for importation from regions

classified as Risk Class R2 for *M. bovis*, only non-neutered ruminants or swine would be required to be tested, 60 to 90 days prior to export, with a retest at the port of entry. We believe these tests would be necessary, because these are the animals most likely to move into established breeding herds in the United States. Because neutered animals usually remain separate from other animals, and are slaughtered soon after reaching the United States, combined with the low risk of the source region and the low risk of transmission once in the United States, we believe neutered animals do not need to be tested.

For importation from a region classified as Risk Class R3 for *M. bovis*, the ruminants and swine must either originate from a herd that meets the criteria for "accredited-free" as defined in § 77.1, or the herd of origin must have had a negative test for bovine tuberculosis 4 to 12 months prior to export to the United States. We believe the minimum 4-month requirement is necessary to allow at least 60 days before the individual exported animals must be retested, because the intradermal tests for *M. bovis* must be at least 60 days apart.

For importation from a Risk Class R3 region, the certificate of export for swine must certify that the swine have never been on any premises while animals affected with *M. bovis* have been present on those premises. Both neutered and non-neutered ruminants and swine would need to be tested 60 to 90 days before export, and non-neutered animals would be required to be tested again at the port of entry. Because of the increased risk that neutered animals from Risk Class R3 regions might be infected, such animals would need to be identified with a permanent mark on the left hip, consisting of the letter "M" for males and "Mx" for neutered females. Traditionally most animals imported into the United States that would fit into this class have been from Mexico, so, currently, such an "M" has been

interpreted to mean "Mexican origin," but we propose the "M" be used to indicate high risk for "Mycobacterium" from any origin.

The proposed requirements for the importation of ruminants and swine from regions classified as R4 and RU regions for *M. bovis* would be similar to those for R3 regions. However, because the equivalent of accredited herds are not recognized in R4 or RU regions, all ruminants or swine would be required to originate from a herd that has had a negative test for bovine tuberculosis 4 to 12 months prior to export. The animals to be exported would be required to be quarantined for at least 60 days prior to export to prevent exposure to infection to other untested animals before export.

*Brucella Abortus, B. Suis, and B. Melitensis*

In § 93.415(c) of this proposal, we set forth the requirements for the importation of ruminants imported from Risk Class R1 through Risk Class RU for *Brucella abortus*, *B. suis biovar 4*, and *B. melitensis*. The United States currently has an eradication program for *B. abortus*, which exists at a low prevalence in a few States. *Brucella suis biovar 4* does not occur in the United States except in caribou in the State of Alaska. *Brucella melitensis* has been eradicated from the United States.

The bovine brucellosis eradication program in the United States in effect regionalizes the United States according to the prevalence of brucellosis infected herds in the individual States. The regulations regarding brucellosis in the United States are set forth in 9 CFR part 78. In § 78.1, definitions for the disease risk status of individual States are set forth for *Class Free*, *Class A*, *Class B*, or *Class C* for bovine brucellosis.

It is possible to gauge where each of these classes would fall if the States to which they apply were foreign regions classified by Risk Class level. The following comparison could be made:

Domestic classification	Conditions	Comparable risk class
Class Free .....	Class Free for more than 15 years and vaccination not permitted except for export	RN
Class Free .....	Class Free for more than 4 years and vaccination not permitted except for export	R1
Class Free .....	No known infected herds for more than 1 year and/or vaccination permitted	R2

Domestic classification	Conditions	Comparable risk class
Class A .....	Less than 0.1% herd incidence rate .....	R3
Class A .....	More than 0.1% herd incidence rate .....	R4
Class B		
Class C		
Quarantined area .....	Does not meet minimum standards of eradication program .....	RU

Currently, all States in the United States are either Class Free or Class A. If the individual States were in a foreign country, all of the Class A States would be classified as Risk Class R3, because the herd infection rate is less than 0.1% (1 per 1000). Class A status allows for herd infection rates up to 0.25% (2.5 per 1000) so in theory it would be possible for a Class A State to be Risk Class R4. All of the Class Free States in the United States would be Risk Class R2 because they all permit, and some even encourage, calfhood vaccination. Some of these States could easily qualify as Risk Class RN or R1 if they were to prohibit calfhood vaccination except for animals that were to be exported to other States.

Because the only clinical evidence of brucellosis in animals is abortion, inspection of animals is not a reliable indicator of infection. *Brucella* affects only breeding animals, so there is no need to test neutered animals for brucellosis. The approved testing procedures for brucellosis are very sensitive, and most infected animals that have had a sufficient incubation period will be positive to the test. The incubation period for brucella infections can be quite variable, depending primarily on the stage of pregnancy in the infected animal. For this reason, under the restrictions for importation from Risk Class R3, R4, and RU regions, we would not allow animals to be imported from infected herds, even if the individual animals test negative.

There is no cost-effective treatment for brucella infections in animals. Since most animals will show some serological signs of brucellosis after 30 days, quarantines of 30 to 60 days are an effective method of preventing introduction of exposed animals.

To qualify for importation from a region classified as either Risk Class RN or R1 for brucellosis, non-neutered ruminants over 6 months of age would need to be accompanied to the United States with a certification of origin and certification that the ruminants were not vaccinated with any live brucella vaccine. However, if ruminants to be imported originate from a Risk Class R1 region and had been vaccinated with *Brucella abortus* Strain 19 vaccine before the region became a Risk Class R1

region, they would be subject to the requirements for importation from Risk Class R2 regions.

To qualify for importation from a region classified as either Risk Class R2 or (if a certified brucellosis-free herd) as Risk Class R3, these proposed rules would require a certification of origin for the ruminants to be imported from either a Class RN, R1, R2, or (if a certified brucellosis-free herd) R3 region, negative results to a brucellosis test of the animals to be imported conducted 30 to 60 days before being presented for export, and a retest with negative results at the port of entry. The ruminants may have been vaccinated only with *B. abortus* Strain 19 in accordance with the procedures in 9 CFR part 78.

For non-neutered ruminants from herds not certified as brucellosis-free in Risk Class R3 regions, or for non-neutered ruminants from Risk Class R4 and Risk Class RU regions, the herd of origin must have been tested and found negative for brucellosis within 6 to 12 months prior to export of the ruminants. If any test-positive animals were found during the test, they must have been removed from the herd and all remaining animals must be retested with negative results not less than 6 months after any test-positive animals were removed. Additionally, individual ruminants to be imported must have undergone a minimum of 30 days pre-embarkation quarantine prior to export, must have had a negative result to an approved test for *B. abortus*, *B. suis* biovar 4, and/or *B. melitensis* within the 30 days prior to export, must be quarantined for at least 15 days at a post-importation quarantine designated and approved by the Administrator, and must have a negative result to approved tests for *B. abortus*, *B. suis* biovar 4, and/or *B. melitensis* during the post-importation quarantine period.

**Brucella Suis**

Proposed § 93.515(b) specifies requirements for swine intended for export from regions classified from Risk Class R1 through RU for *Brucella suis*. Just as comparisons can be made between domestic State Risk Class status and foreign Risk Class status for bovine brucellosis, similar comparisons

can be made with regard to swine brucellosis, as follows:

Swine brucellosis classification	Conditions	Comparable risk class
Validated Brucellosis-Free.	Validated Free for more than 10 years. No adjacent States risk class R3, R4 or RU.	RN
Validated Brucellosis-Free Stage II.	No known infected domesticated herds for more than 5 years, Validated Free for more than 3 years.	R1
Validated Brucellosis-Free Stage III.	No known infected domestic herds for more than 1 year and/or infected feral swine in region. May include some Stage II areas qualifying for Stage III.	R2
Non-validated Stage II.	Less than 0.1% herd incidence rate.	R3
Non-validated Stage I.	More than 0.1% herd incidence rate.	R4
Non-validated	Does not meet minimum standards of eradication program.	RU

Currently all States in the United States are either validated brucellosis-free or, if non-validated, have less than 0.1% herd incidence rates. If the States in this country were foreign regions, all of the validated brucellosis-free States would be Risk Class RN, R1, or R2, and the non-validated States would be Risk Class R3.

Vaccination is not permitted or recommended in swine herds. Some States have known infection in feral swine located in the State. These States, if foreign regions, would fall into the Risk Class R2 classification, provided there has been no transmission of *B. suis* to domesticated swine herds within the previous year. States in which transmission to domestic swine herds has occurred would, if foreign regions, be Risk Class R3.

Under proposed § 93.515(b) regarding *B. suis*, swine from any regions classified as Risk Class R1 or R2 for the disease, or from an R3 region if from a validated brucellosis-free herd, would be allowed to move for slaughter to any approved slaughter plant in the United States, provided they move in vehicles closed with official seals of the United States government applied and removed by an APHIS representative, or an individual authorized for this purpose by an APHIS representative.

For swine to be otherwise imported from regions classified as Risk Class R1, these proposed rules would require that the swine be accompanied by a certification that they originated in a Risk Class RN or R1 region, and that the animals were not vaccinated with any live brucella vaccine.

For swine to be imported from regions classified as Risk Class R2, or for swine from validated brucellosis-free herds in Risk Class R3 regions, a certification of origin in a Risk Class RN, R1, or R2 region, or from a validated brucellosis-free herd would be required, along with a negative test of the imported animals for *B. suis* 30 to 60 days before being presented for export. A negative retest at the port of entry would also be required.

For the importation of non-neutered swine over 6 months of age from herds not validated brucellosis-free in Risk Class R3 regions, and for non-neutered swine over 6 months of age from Risk Class R4 or RU regions, all swine over 6 months of age in the herd of origin would need to have had negative results to a test for *B. suis* within 6 months prior to the date the swine to be

imported are removed from the herd. If any swine were found to be positive on a herd test, the herd would need to have undergone a herd cleanup plan equivalent to the plan required in 9 CFR part 78. The complete herd test, and clean-up of each infected herd, would essentially qualify the herd as a validated brucellosis-free herd. Therefore, individual swine subsequently intended for importation from R3 regions would be subject to the same requirements as swine from R3 regions intended for importation from validated brucellosis-free herds.

No swine from any risk category would be eligible for importation if they have been vaccinated with a live *Brucella* vaccine. Vaccination of swine for brucellosis has not been found to be efficacious in the United States. Some areas of the world use a live attenuated *B. suis* biovar 2 vaccine. *Brucella suis* biovar 2 is not known to exist in the United States, so this vaccine, even though attenuated, would be considered an exotic disease agent in the United States.

*Pseudorabies*

In this proposed rule, § 93.515(c) sets forth import requirements for swine intended for importation from regions classified from Risk Class R1 through RU for pseudorabies virus (PRV). Pseudorabies affects all classes of swine and can occasionally affect other animals, such as sheep or cattle, which are dead-end hosts. The primary reservoir is in swine. On breeding swine farms, reproductive disorders and nervous disorders in baby pigs are the most frequently seen clinical signs of PRV. The incubation period of PRV in susceptible swine is usually variable, ranging from 36 to 48 hours in newborn pigs, and 3 to 5 days in older swine.

Most infected swine excrete virus only for 14 to 28 days following infection, but some do become persistent carriers of the virus for long periods of time. Recrudescence with virus excretion can occur following stress or other stimuli, such as

parturition. Any seropositive animal should be considered a potential virus carrier. Carrier swine would not be expected to have any clinical signs of the infection.

Current tests for PRV are very sensitive, and infected swine will be expected to have detectable antibody as early as 6–7 days after exposure, with peak antibody titers about 5 weeks after exposure. Antibodies in recovered or carrier swine may persist for years. Vaccinated swine may be protected from clinical disease, but the virulent virus may still replicate and become established in a carrier state.

Pseudorabies virus is relatively stable at mild acidic or alkaline conditions, although strong acids and strong alkalis readily kill the virus. The virus can survive for long periods in the environment if the pH and humidity remain within an optimal range of pH 6–8, and the temperature remains between –8° C to 25° C. The virus generally dies out rapidly when frozen at –13° C to –20° C. However, although freezing in most cases rapidly kills the virus, it can be preserved for years frozen at –90° C. Direct sunlight rapidly destroys the virus. Although the virus can survive for relatively long periods of time in meat, usually little virus is found in the muscle of naturally infected swine. The virus exists primarily in the lymphoid and nerve tissue. There are no known treatment procedures that will clear infected carrier swine of the infection.

Currently, a cooperative Federal/State eradication program for PRV is conducted in all States of the United States. The PRV eradication program in the United States in effect regionalizes the country by State, according to the prevalence of PRV infected herds and the progress in the eradication program in each State. The State classifications are Stage I (Preparation), Stage II (Control), Stage III (Mandatory herd cleanup), Stage IV (Surveillance), and Stage V (Free). If the States of the United States were foreign regions, they would be classified according to Risk Class as follows:

Pseudorabies classification	Conditions	Comparable risk class
Stage V (Free) .....	Stage V for more than 10 years and vaccination not permitted except for export .....	RN
Stage V (Free) .....	Stage V (Free) for more than 3 years and vaccination not permitted except for export .....	R1
Stage V (Free) .....	Stage V (Free) after 2 years. No known infected herds for more than 2 years .....	R2
Stage IV (Surveillance) .....	Stage IV (Surveillance) for at least 1 year. No known infected herds for at least 1 year. Vaccination permitted.	R2
Stage IV (Surveillance) .....	Stage IV for less than 1 year .....	R3
Stage III .....	Less than 0.1% herd incidence rate .....	R4
Stage III .....	More than 0.1% herd incidence rate .....	
Stage II		
Stage I .....	Does not meet minimum standards of eradication program .....	RU



Currently all States in the United States are in stages II through V of the PRV program. Under proposed § 93.515(c), swine from any region with regard to pseudorabies would be allowed movement to slaughter under the same conditions as those described above for direct movement to slaughter with regard to *B. suis*. There is no known evidence that PRV is transmitted to swine from meat or infected meat scraps fed in garbage.

Under this proposal, to be imported from a Risk Class R1 region, swine would need to be accompanied only with certification that the swine originated in a Risk Class RN or R1 region, and that the animals were not vaccinated with any PRV vaccine.

To be imported from either a Risk Class R2 region or from a qualified pseudorabies-negative (QPN) herd in a Risk Class R3 region, swine would need to be accompanied by certification that they originated in a Risk Class RN, R1 or R2 region, or in an R3 region if from a qualified pseudorabies-negative herd that has been qualified according to procedures equivalent to those set forth in part 85 of this chapter, and by certification that the swine tested negative for PRV within 30 days before being presented for export. The purpose of the test is to prevent importation of any residual infection that may occur in the region. We believe the testing is necessary to detect animals that may be vaccinated but not recorded as vaccinated animals.

For swine to be imported from herds not QPN in Risk Class R3 regions, and from Risk Class R4 and Risk Class RU regions, the swine intended for export must have had a negative test within 30 days prior to export and must have been quarantined separate from all swine not in the shipment, for 30 days prior to export. The imported swine would be subjected to a post-importation quarantine for at least 15 days, during which time they must have a negative test for PRV. Certain vaccines are permitted in the United States under part 85 of this chapter. Because tests are available that will distinguish between the vaccine strains and virulent PRV, the vaccinated swine should create no problem in the testing procedure. We believe the 30 day pre-embarkation quarantine would be adequate to detect any swine that were incubating PRV infection when they entered the farm. The additional 15 days post-importation quarantine would be to assure that there was no transmission from possible silent carrier swine or from environmental contamination while in pre-embarkation quarantine.

### Scrapie

In this proposed rule, § 93.415(h) sets forth requirements for sheep and goats imported from regions classified as Risk Class R1 through Risk Class RU for scrapie. Scrapie disease of sheep and goats exists in the United States at a low prevalence. The United States has attempted to eradicate scrapie disease since the 1950's, when it was first imported in sheep. The nature of the causative agent for scrapie is somewhat controversial, as it is not a true virus, although there are many attributes of the infection that resemble a virus infection. Sheep and goats are usually infected at a young age, but the disease does not appear until several years later as an encephalopathy. The incubation period for scrapie can last up to 5 years. Currently, the only certain method of diagnosing scrapie is by microscopic examination of the brain tissue of infected animals. Reliable serologic tests are generally not available. The only practical method of certifying sheep or goats for movement is by flock or herd history of the flock of origin, or regional history of scrapie.

Only a few countries of the world are considered to be free of scrapie. Others have eradication programs similar to the United States, but are low prevalence infected areas. According to the risk class criteria proposed in § 92.2 of this proposal, the United States, if a foreign region, would be classified as a Risk Class R3 region.

Under this proposal, for sheep and goats to be imported from regions classified as risk class RN, R1 or R2 for scrapie, the sheep and goats would need to be accompanied by certification that they have been only in one of those regions during their entire life, and have only been on premises where no cases of scrapie have been diagnosed during the 5 years immediately preceding the date of intended exportation.

The requirements for the importation of sheep and goats from regions classified as risk class R3 for scrapie would be similar to the current scrapie importation requirements for sheep and goats from Canada, set forth in § 92.419 of the current regulations. The proposed regulation equivalent to requirement "(5)" below, regarding the Canadian scrapie eradication program, would be the requirement that the region in question conduct a scrapie eradication program equivalent to that conducted in the United States. The provisions in current § 92.419 require a certificate stating:

(1) That the sheep and goats have been inspected on the premises of origin

and found free of evidence of scrapie, and of any other communicable disease;

(2) That, as far as it has been possible to determine, such animals have not been exposed to any such disease during the preceding 60 days;

(3) That, as far as can be determined, scrapie has not existed on any premises on which such sheep or goats were located during the 42 months immediately prior to shipment to the United States;

(4) That each of such animals is not the progeny of a sire or dam that has been affected with scrapie; and

(5) That, as far as it has been possible to determine, each of such animals is not a sheep or goat that would have been slaughtered under the current Canadian scrapie eradication program had that program been in effect since April 1957.

Sheep and goats would be prohibited importation from regions classified as Risk Class R4 and RU for scrapie, because we believe that the requirements for Risk Class R3 regions are necessary to guard against the importation of scrapie-affected animals, and we do not believe that the certifications of Risk Class R3 regions can be made in Risk Class R4 or RU regions.

### Contagious Diseases Exotic to the United States

In this proposal, § 93.415(d) sets forth requirements for ruminants imported from regions classified as Risk Class R1 through RU for foot-and-mouth disease (FMD) virus in ruminants, and § 93.515(e) sets forth requirements for swine moving from regions classified as Risk Class R1 through RU for FMD, rinderpest (RP), African swine fever (ASF), hog cholera (HC), and swine vesicular disease (SVD). The requirements governing these diseases are set forth in the same paragraph of this proposal, because the importation requirements for each of the diseases are similar for each of the risk classes. These diseases are grouped also because the epidemiology is similar and all of these diseases can be transmitted to new animals in meat and other animal products.

The incubation periods for FMD, RP, ASF, HC, and SVD are all relatively short, and all of these diseases are highly contagious, with spread by contact, aerosol, and feed or water being the most common methods of spread. Vector transmission of ASF by *Ornithodoros* ticks has been shown to occur and mechanical vector transmission of HC has also been demonstrated. Mechanical transmission

of each of these disease agents by ticks and insects is possible.

#### *Foot-and-Mouth Disease*

Foot-and-mouth disease affects all members of the family Artiodactyla, as well as some rodents such as the hedgehog. Cattle are readily infected and may be carriers of the virus for long periods of time through localization of the virus in the pharyngeal lymphoid (tonsil) tissue. Vaccinated cattle may become infected and either not show any clinical signs or have a mild atypical disease. Carrier cattle do not readily transmit the virus to other animals, but are a constant threat to do so. Swine produce and disseminate large quantities of virus when infected, but do not remain carriers for long periods of time. Foot-and-mouth disease virus is relatively resistant outside the host animal, provided the pH remains near neutral. Acidic or alkaline conditions readily kill the virus.

#### *African Swine Fever, Hog Cholera, and Swine Vesicular Disease*

Only swine are affected with ASF, HC and SVD viruses. These viruses are primarily transmitted directly between swine, but ASF particularly can be transmitted by *Ornithodoros* ticks. Infected swine that recover may remain carriers of these agents for long periods of time. The viruses of ASF and SVD are quite resistant to heat, putrefaction, and acidic and alkaline conditions. Wild swine such as the wart hog, bush pig and giant forest pig in Africa are the primary reservoir of ASF. Infected pork and pork products can readily carry HC, ASF and SVD. Sheep and calves can be infected with SVD but do not develop a clinical illness and are not likely to spread the virus unless meat from affected animals is fed to swine. Only swine are susceptible to HC virus, in which acute, subacute and chronic disease occurs. Congenital infection of pigs helps maintain the disease in a herd, but movement of carrier swine or feeding of meat scraps to swine is the primary method of transmission between herds. Acidic and alkaline conditions readily destroy HC virus but the virus is very stable in refrigerated and frozen meat.

Viral infections with FMD, ASF, HC, and SVD are readily detected with modern serological tests. Testing the herd of origin as well as any exported pigs from areas known to be affected will significantly reduce the risk of introducing any of these viruses. Quarantines are necessary to detect any animals that may be incubating the virus or be inapparent carriers upon entry into the quarantine. There are no

effective treatments for any of these viruses, and any recovered animals would be likely to be carriers. Therefore, if there is evidence of infection in a quarantine facility, none of the exposed animals would be allowed to enter the United States.

#### *FMD Requirements for Ruminants and Swine, and RP, ASF, HC, and SVD Requirements for Swine*

Under this proposal, we would prohibit the importation of any ruminants and swine that have been vaccinated for FMD, RP, ASF, HC, or SVD. Ruminants and swine to be imported from regions classified as R1 for FMD, RP, ASF, HC, or SVD would be required to be accompanied by a certification that the ruminants or swine were born and resided only in regions classified as Risk Class RN or R1 for the disease in question, and have had a negative test for the disease in question within 30 days prior to the date of export.

The only ruminants and swine from R1 regions excepted from the testing requirements, and also from the quarantine requirements for R2 regions discussed below, would be ruminants and swine imported for immediate slaughter that were born and raised in regions classified as Risk Class R1 or R2 for the diseases in question. Such animals would be required to be consigned from the port of entry to a recognized slaughtering establishment, and there slaughtered within 2 weeks of the date of entry. The ruminants would need to be moved from the port of entry in conveyances closed with official seals of the United States government applied and removed by an APHIS representative, or by an individual authorized for this purpose by an APHIS representative.

For ruminants and swine to be imported from regions classified as Risk Class R2 for FMD, and for swine to be imported from regions classified as Risk Class R2 for RP, ASF, HC, or SVD, the animals would need to be accompanied by a certificate that certifies that they were born and resided only in regions classified as Risk Class RN, R1, or R2 for the diseases in question. The ruminants and swine would also be required to meet the testing requirements required for animals from R1 regions, and, additionally, would need to undergo a 30-day pre-embarkation quarantine (for swine from regions classified as Risk Class R2 for ASF, the pre-embarkation quarantine must be conducted in a vector-proof facility approved by the Administrator), and a 15-day post-importation quarantine. During the post-importation quarantine, the ruminants

and swine would need to test negative to an approved serological test for FMD, RP, ASF, HC, and/or SVD.

For ruminants and swine to be imported from regions classified as Risk Class R3 for FMD, and for swine to be imported from regions classified as Risk Class R3 for RP, ASF, HC, or SVD, the animals would need to be accompanied by certification that they (1) were born and resided only in regions listed as Risk Class RN, R1, R2, or R3 for FMD; (2) have not been on any premises affected with FMD virus during the 12 months prior to export; (3) have not been on any premises located within 25 miles (40 km) of any premises affected with FMD virus in the 90 days prior to export; (4) have undergone pre-embarkation quarantine for at least 60 days prior to export, under USDA supervision in a facility approved by the Administrator; and (5) have had, during the pre-embarkation quarantine, negative results to two tests conducted for FMD, using an approved serological test. If indicated, oesophageal-pharyngeal fluid samples would be taken for further testing. Additionally, the ruminants and swine would have to be quarantined for at least 60 days without sentinel animals at the Harry S Truman Animal Import Center, during which time they would be tested for the disease in question at least once.

The requirements for ruminants and swine to be imported from regions classified as R4 or RU for FMD, and for swine to be imported from regions classified as R4 or RU for RP, ASF, HC, or SVD, would be the same as those for ruminants and swine imported from R3 regions, except for the certification of residency, and except that ruminants and swine from R4 regions would need to be quarantined at HSTAIC for at least 90 days with sentinel animals from the United States.

#### *Rinderpest and Peste de Petits Ruminants*

In § 93.415(e) of this proposal, we set forth requirements for ruminants to be imported from regions classified as Risk Class R1 through RU for rinderpest and *peste de petits ruminants* (PPR). Rinderpest virus primarily affects cattle and buffalo but a wide variety of cloven hoofed animals are susceptible. European swine do become infected, but the disease is primarily inapparent. The incubation period ranges from 3 to 15 days, and affected animals have a high mortality rate. Recovered animals do not remain carriers. Subacute infections may occur in regions where the disease is endemic or in breeds of animals or species that have an innate resistance. Rinderpest virus is not very stable

outside the host, and is readily destroyed by acidic or alkaline conditions, and by direct sunlight. The virus of PPR is closely related to rinderpest virus but primarily affects sheep and goats.

Viral infections with rinderpest and PPR are readily detected with modern serological tests. Testing the herd of origin, as well as any exported animals from areas known to be affected, will significantly reduce the risk of introducing any of these viruses. Quarantines are necessary to detect any animals that may be incubating the virus or be inapparent carriers upon entry into the quarantine. There are no known effective treatments for these viruses. Although any recovered animals do not remain as carriers, as a matter of precaution, animals with a known history of infection or exposure, including those exposed to infection in a quarantine center, should be prohibited entry into the United States. As with rinderpest, any animal vaccinated for PPR would be prohibited importation into the United States.

Ruminants intended for importation from regions classified as R1 or R2 for RP and PPR would be required to meet the same requirements as ruminants from regions classified as R1 and R2 for FMD. The requirements for ruminants from R3 regions for RP and PPR would be the same as for R3 for FMD, except that, in the case of RP and PPR, the ruminants would be required to undergo pre-embarkation quarantine for at least 30 days, would have to test negative to two tests conducted not less than 15 days apart (if indicated, nasal swabs or other tissues or samples would be taken for further testing), and would be required to be quarantined at HSTAIC for at least 30 days without sentinel animals. The requirements for ruminants from regions classified as R4 or RU for RP and PPR would be the same as those for R3 regions, except that, for animals from R4 regions, the quarantine at HSTAIC would have to be conducted with sentinel animals.

#### *Bovine Spongiform Encephalopathy*

Section 93.415(g) of this proposal specifies requirements for the importation of cattle from regions classified as Risk Class R1 through RU for bovine spongiform encephalopathy (BSE). BSE is a scrapie-like disease of cattle that has appeared in the past decade in Europe, particularly in Britain. It is thought to have been introduced into cattle from scrapie-infected sheep brains that were included in rendered protein meal added to cattle feed. The disease has an incubation period of from 5 to 7 years.

Although BSE is not known to affect humans, the fear of the disease generated in the United Kingdom has caused severe economic hardship to the cattle industry in the British Isles. Because of the long incubation period and the lack of a suitable diagnostic test, the only way of preventing introduction of the disease is by certification of herd and regional history of the disease, along with the presence of a strong regional animal health infrastructure capable of recognizing and diagnosing the disease if it should occur.

Under this proposal, cattle imported from regions classified as Risk Class R1 or R2 for BSE would need to be accompanied by certification that the cattle were born and resided only in R1 or R2 regions, and that the cattle have only been on premises where no cases of BSE have been diagnosed during the 10 years immediately preceding the date of exportation.

Cattle from regions classified as Risk Class R3, R4, or RU for BSE would be prohibited importation into the United States.

#### *Contagious Agalactia due to Mycoplasma agalactia, Sheep Pox Virus, Goat Pox Virus, and Contagious Caprine Pleuropneumonia due to Mycoplasma Mycoides Subsp. Capri*

Section 93.415(i) of this proposal sets forth requirements for sheep and goats intended for importation from regions classified as R1 through RU for Contagious agalactia due to *Mycoplasma agalactiae* (CA), Sheep pox (SP), goat pox (GP), and contagious caprine pleuropneumonia (CCPP due to *Mycoplasma mycoides* subsp. *capri*). These diseases are grouped together because they affect only sheep and goats and the epidemiology is similar. Both CA and CCPP are chronic diseases with long incubation periods. Antibodies generally are found in infected animals long before the appearance of clinical signs. Both SP and GP are acute viral diseases in which the virus can remain in the recovered host or host materials for long periods after recovery. Serological tests for these disease agents are adequate to detect either recovered carriers in the case of SP or GP, or prodromal carriers in the case of CA or CCPP. Although each of these diseases could probably be easily eradicated if detected in the United States, they could become widespread before they were detected and therefore would be costly to eradicate.

All sheep or goats that have been vaccinated for CA, SP, GP, or CCPP would be prohibited importation into the United States. To be imported from regions classified as Risk Class R1 for

CA, SP, GP, or CCPP, sheep and goats would need to be accompanied by certification that they were born and resided only in regions classified as Risk Class RN or R1, and that they have had a negative test for the disease in question within 30 days prior to export.

Sheep and goats to be imported from regions classified as Risk Class R2 for CA, SP, GP, or CCPP would be required to be accompanied by certification that they were born and resided only in regions classified as Risk Class RN, R1, or R2, and that they have had a negative result to an approved serological test for the disease in question 30 to 60 days prior to exportation to the United States. Additionally, the sheep and goats would have to be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator, and would have to test negative to an approved serological test for the disease in question during the post-importation quarantine.

In addition to residency certification, sheep and goats to be imported from regions classified as Risk Class R3 for CA, SP, GP, or CCPP would have to meet one of the following requirements: Either (1) test negative to an approved serological test for the disease in question 30–60 days prior to exportation to the United States; or (2) originate from a herd or flock in which all sheep and goats over 6 months of age have had a negative result to an approved serological test within 12 months prior to the time of export. Additionally, the sheep and goats would have to be quarantined and isolated for at least 30 days prior to export from all animals not part of the shipment, in facilities approved by the Administrator. The sheep and goats would also have to undergo at least a 15-day post-importation quarantine, and have a negative result to an approved serological test during that quarantine.

To be imported from regions classified as R4 or RU for CA, SP, GP, or CCP, sheep and goats would have to be certified as having undergone at least a 60-day pre-embarkation quarantine, and as testing negative to two approved tests for the disease in question, at least 30 days apart, with the second test during the pre-embarkation period and not more than 30 days before export. Additionally, the sheep and goats would have to be quarantined for at least 30 days post-importation, and be tested negative there to an approved serological test for the disease in question.

#### *Malignant Catarrhal Fever*

In this proposal, § 93.415(j) sets forth requirements for the importation of

ruminants from regions classified as Risk Class R1 through RU for malignant catarrhal fever—African or wildebeest Type (MCF-A). This disease is transmitted from infected wildebeest and other wild reservoirs in Africa to cattle. There is little evidence of transmission from cattle to cattle. The causative agent for this disease has been identified as a herpesvirus. The causative agent for the sheep-associated type of malignant catarrhal fever (MCF-S) has not been positively identified, although several candidate viruses have been recovered. MCF-S is transmitted from sheep to cattle and is found worldwide, including in the United States. Therefore, it would not be considered a restricted type of the disease agent in this proposed rule.

(Although we refer simply to "MCF" when discussing malignant catarrhal fever in § 93.415(j) of the proposed rule, because the MCF-A type would be the only type considered a restricted disease agent, in this Supplementary Information we specify "MCF-A" when referring to the African or wildebeest type, to differentiate it from the MCF-S type.)

The principal concern with the importation of MCF-A would be the importation of infected wildebeest or other African wildlife that may carry the virus, rather than introduction in domestic livestock. However, although the research done indicates that MCF-A is not transmitted from cattle to cattle, we believe there is sufficient doubt to warrant requiring that any ruminant at least test serologically negative before importation. MCF-A virus has been isolated from antelope and deer in two zoos and a wild animal park in the United States. Serologic tests for MCF-A are sufficiently sensitive to detect possible carrier animals from affected regions. Because, as with most herpesvirus infections, an infected animal probably remains infected for life, any animal with a serologic titer should be excluded from importation.

Any ruminant that has been vaccinated for MCF-A would be prohibited importation into the United States. Ruminants intended for importation from regions classified as Risk Class R1 for MCF-A would be required to be accompanied by certification that they were born and resided only in regions classified as Risk Class RN or R1 for MCF-A, and that they have had a negative result to an approved serological test for MCF-A within 30 days prior to the date of export.

Ruminants intended for importation from regions classified as Risk Class R2 for MCF-A would be required to be

accompanied by certification that they were born and resided only in regions classified as Risk Class RN, R1, or R2 for MCF-A, and have had a negative result to an approved serological test for MCF 30–60 days prior to the date of export. The ruminants would also be required to be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator, and would need to have a negative result to an approved serological test for MCF-A during the post-importation period.

Ruminants intended for importation from regions classified as Risk Class R3 for MCF-A would be required to be accompanied by certification that they were born and resided only in regions classified as Risk Class RN, R1, R2, or R3 for MCF-A, that they have been in a pre-embarkation quarantine facility, approved by the Administrator, for a minimum of 30 days prior to export, and that they either (1) have had a negative result to an approved serological test for MCF-A 30 to 60 days prior to the date of export, or (2) originate from a herd in which all ruminants in the herd over 6 months of age have had a negative result to an approved test for MCF-A within the previous 12 months. Additionally, the ruminants would need to be quarantined for at least 15 days at a post-importation facility designated and approved by the Administrator, and would need to have a negative result to an approved serological test for MCF-A during the post-importation quarantine period.

Ruminants intended for importation from regions classified as R4 or RU for MCF-A would be required to be accompanied by certification that they originate from herds that have not been affected with MCF-A during the previous 12 months, that they have undergone a minimum of 60 days pre-embarkation quarantine, and that, during the pre-embarkation quarantine, they have had negative results to two tests conducted not less than 15 days apart with an approved serological test for MCF-A. Additionally, the ruminants would be required to undergo post-importation quarantine for at least 15 days at a facility designated and approved by the Administrator, and would need to test negative to an approved serological test for MCF-A during the post-importation quarantine period.

#### *Contagious Bovine Pleuropneumonia*

In this proposal, § 93.415(k) sets forth requirements for the importation of ruminants from regions classified as Risk Class R1 through RU for contagious

bovine pleuropneumonia (CBPP) in cattle due to *Mycoplasma mycoides* subsp. *mycoides*. This disease was eradicated from the United States in the 19th century. The disease has a long incubation, and infected cattle may not demonstrate clinical signs until the late stages of infection. Serologic tests have sufficient sensitivity to detect incubating animals long before any other clinical evidence is apparent. Any serologically positive animal would be excluded from import.

Any ruminant vaccinated for CBPP would be prohibited importation into the United States. Cattle intended for importation from regions classified as Risk Class R1 for CBPP would be required to be accompanied by certification that the cattle were born and resided only in regions classified as Risk Class RN or R1 for CBPP, that they have undergone a minimum 30-day pre-embarkation quarantine, and that they have had a negative result to an approved serological test for CBPP within 30 days prior to export.

Cattle intended for importation from regions classified as Risk Class R2 for CBPP would be required to be accompanied by certification that they were born and resided only in regions classified as Risk Class RN, R1, or R2 for CBPP and that they have had a negative result to an approved serological test for CBPP 30 to 60 days prior to the date of export. The cattle would also be required to be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator, and would need to test negative to an approved serological test for CBPP during the post-importation quarantine period.

The requirements for importation from regions classified as Risk Class R3 for CBPP would be similar to those for importation from regions classified as Risk Class R3 for MCF-A, discussed above.

The requirements for importation from regions classified as Risk Class R4 and RU for CBPP would be similar to those for importation from regions classified as Risk Class R4 or RU for MCF-A, discussed above, except that the interval between pre-embarkation negative tests would have to be at least 30 days for CBPP, as compared to 15 days for MCF-A, and the post-importation quarantine for CBPP would be at least 30 days for CBPP, rather than 15 days as for MCF-A.

#### *Teschen Disease Virus*

In this proposal, § 93.515(h) sets forth requirements for the importation of swine from regions classified as Risk Class R1 through RU for Teschen

disease (TDV, also known as poliоencephalomyelitis). TDV causes an encephalomyelitis in swine, due to an enterovirus similar to poliovirus in humans. Teschen disease virus is due to porcine enterovirus type 1. Other porcine enterovirus types are found throughout the world, including in the United States. Except for TDV, the porcine enteroviruses generally produce a mild inapparent infection in swine. Enteroviruses are very resistant to inactivation and may remain in the environment for long periods. Recovered swine usually do not shed the virus for long periods after appearance of antibody. Animals with stabilized or declining antibody levels would not be expected to be carriers, but generally any animal with antibody to TDV antigen would be avoided if from a TDV-affected region. Cross reactions with other enterovirus types may produce some confusion if swine from areas not affected with TDV are tested.

Any swine that has been vaccinated with any live TDV is prohibited importation into the United States. Swine intended for importation from regions classified as Risk Class R1 or R2 for TDV would be required to be accompanied by certification that the swine were born and resided only in regions classified as Risk Class RN, R1, or R2 for TDV, and that the swine have had a negative result to an approved test for Teschen disease within 30 days of the date of exportation.

Swine intended for importation from regions classified as Risk Class R3 for TDV would be required to be accompanied by certification that the swine were born and resided only in regions classified as Risk Class RN, R1, R2, or R3 for TDV, that the swine meet one of the following requirements: Either (1) they have had a negative result to an approved test for TDV 30 to 60 days before exportation; or (2) they originate from herds in which the entire herd over 6 months of age has had negative results to an approved test for TDV within 12 months prior to the date of exportation. Unless swine meet the latter of the above two options, they would also be required to be quarantined for at least 30 days prior to export. Additionally, the swine would be required to be quarantined for at least 15 days at a post-importation quarantine station approved by the Administrator, and would need to test negative to an approved serological test for TDV during that quarantine period.

Swine intended for importation from regions classified as R4 and RU for TDV would be required to be accompanied by certification that the swine originate

from herds in which the entire herd over 6 months of age has had a negative result to an approved test for Teschen disease within 60 to 180 days prior to the date of exportation; that the swine were quarantined for at least 60 days prior to export, and that during the pre-embarkation quarantine period, the swine have had negative results to an approved test for TDV 30 to 60 days prior to the date of export. Additionally, the swine would be required to be quarantined at a post-importation quarantine facility for at least 30 days, and, during this quarantine period, have two negative results, not less than 30 days apart, to an approved test for Teschen disease.

#### *Ectoparasites*

In this proposal, §§ 93.415(f) and 93.515(d) set forth requirements for ruminants and swine intended for importation from regions classified as Risk Class R1 through RU for restricted ectoparasites. Based on the information currently available to us, every region of the world except Canada has one or more restricted ectoparasites. Therefore, except for Canada, there are currently no regions that would qualify as Risk class RN, R1 or R2. Although such regions may exist, at the present time we do not have information that would allow us to make such classifications.

Control of ectoparasites is important, not only because of the damage that can be done by the ectoparasite itself, but also because certain restricted diseases are known to be transmitted or carried only by certain ectoparasites. By preventing or intercepting the ectoparasite, we effectively prevent transmission of the restricted agent, even if it were to be brought into the United States in infected animals. An example of this situation is bovine piroplasmiasis due to *Babesia bigemina*, which is transmitted solely by the ticks *Boophilus annulatus* or *B. microplus*. This disease has been eliminated from the United States by eliminating the tick, rather than addressing the infection status of the animals.

Under this proposal, for ruminants and swine to be imported from regions classified as Risk Class R1 or R2 regions for ectoparasites, the animals would be required to be inspected for restricted ectoparasites at the port of entry. If restricted ectoparasites are found, the animals may not enter until they have been treated again in 10 to 14 days. This time period is necessary because the treatment will not kill the eggs of the parasites, and if any eggs have hatched they must be destroyed by a second dipping.

For ruminants and swine to be imported from regions classified as Risk Class R3, R4 and RU for ectoparasites, the animals offered for export would be required to be treated 10 to 14 days before export, and to be inspected prior to export to be certain they have been cleared of any ectoparasites. Except for animals imported for immediate slaughter, ruminants and swine would also have to be inspected at the port of entry and retreated for ectoparasites. If animals are found to be infested with ectoparasites at the port of entry, they would be returned to the country of origin after treatment if offered for entry at a land border port, or would be quarantined for at least 15 days if at other ports.

The purpose of port of entry inspection is to discover any ectoparasites that may have survived the previous treatment in the region of origin. Any ectoparasites found would indicate that the animals had not been adequately treated or had become reinfected after treatment in the region of origin. At least 10 days must pass after treatment to allow the treatment to have full effect because some treatments do not immediately kill the ectoparasites.

#### Vector-Borne Diseases That Are Exotic to the United States

##### *Aino and Akabane Virus*

In this proposal, § 93.415(l) sets forth requirements for ruminants offered for importation from regions classified as Risk Class R1 through RU for Aino and Akabane virus. The incubation periods for Aino and Akabane virus are short, and mature ruminants do not remain carriers of the virus for more than 7 to 14 days, or for 4 to 6 days after appearance of antibody. Both these viruses cause fetal deformities, and the carrier status of affected fetuses is more uncertain. Serologically positive pregnant cattle would not be imported. After a 30-day period with no evidence of increasing serological titer, even serologically positive animals are of negligible risk for introducing infection. The disease is seasonal and, even from high risk regions, there is no need to have insect-secure quarantine facilities during times of the year when insect vectors are not active. During seasons when insect vectors are active or from areas where insect vectors are always active, insect-secure quarantine facilities would be required to be provided to prevent infection of the animals to be exported during the pre-embarkation quarantine period. Non-pregnant animals with stabilized or declining serological titers are a

negligible risk source of infection in the United States.

Any ruminant that has been vaccinated for aino or akabane virus would be prohibited importation into the United States. Ruminants offered for importation from regions classified as Risk Class R1 or R2 for aino or akabane virus would be required to be accompanied by certification that, for at least 60 days preceding importation, the ruminants have been only on premises in regions classified as Risk Class RN, R1, or R2. The certification would also need to state that the ruminants have had a negative result to an approved serological test for aino and/or akabane virus within 30 days prior to the date of export. If, upon being tested, any of the ruminants in the shipment had a positive result to the test, for any of the remaining ruminants to be imported, all positive pregnant female ruminants would need to be removed from the shipment, and all remaining ruminants (both positive and negative) would need to be retested with either negative, decreasing, or stabilized test results at least 30 days following the first test.

For ruminants to be imported from regions classified as Risk Class R3, R4, or RU for aino or akabane, the ruminants would be required to be accompanied by certification that they did not originate from a herd that has been known to be infected with aino and/or akabane within 12 months of the date of export. Additionally, if the ruminants are offered for export during a time of the year when vectors are active, the certification would need to state that the ruminants were quarantined for at least 60 days prior to export in a vector-proof facility approved by the Administrator and by the national veterinary services in the country of origin. If the ruminants are offered for export during a time of the year when insect vectors are not active, the certification would need to state that at least 60 days has passed since the first killing frost of the season. The certification would also need to state that the ruminants were tested twice with negative results to approved serological tests for aino and/or akabane virus, at least 30 days apart, with the second test conducted within 30 days prior to export. If any of the ruminants in the shipment tested positive, then the same procedure as for R1 and R2 regions regarding retesting after removal of pregnant positives would be followed. The ruminants would need to be quarantined for at least 15 days at a post-importation quarantine facility, during which time the ruminants must have negative, decreasing, or stabilized

test results to an approved serological test for aino and/or akabane virus.

*Bluetongue, Epizootic Hemorrhagic Disease, Bovine Ephemeral Fever, Rift Valley Fever, and Wesselsbron*

In this proposal, § 93.415(m) sets forth importation requirements for ruminants from regions classified as Risk Class R1 through RU for Bluetongue virus (BTV), other than serotypes 10, 11, 13, and 17 which are already endemic in parts of the United States; Epizootic hemorrhagic disease virus (EHDV), except serotypes 1 and 2 which are already endemic in parts of the United States; bovine ephemeral fever (BEF, also known as Kotankan or Obodhiang) virus; Rift valley fever (RVF) virus, and Wesselsbron (WB) virus.

There are at least 20 serotypes of BTV and 6 serotypes of EHDV that have been identified in the world that are not known to be present in the United States. Each of these could possibly become established, and would be as difficult to eliminate as the types already present in the United States. Bovine ephemeral fever, RVF and WB are viruses that could also find ready vectors in the United States because they are transmitted by Culicoides or mosquitoes. The incubation periods for these viruses is much longer than for Akabane and Aino. In each case, the virus either produces prolonged viremias even after the appearance of antibody, or there is insufficient history about the duration of the viremia. Any animal with specific antibody with any of these agents from affected regions would be avoided, because they present a moderate, high or unknown risk of introducing virus into the United States. Serologically positive animals with stable titers may be introduced safely if they are negative to virus isolation tests.

To be imported from regions classified as Risk Class R1 or R2 for BT, EHD, BEF, RVF, and WB, ruminants would be required to be accompanied by certification that they have resided for at least 60 days prior to export only on premises located in regions classified as Risk Class RN, R1, or R2, and also that they have had a negative result to an approved serological test for BT, EHD, BEF, RVF, and/or WB virus. If any of the ruminants in the group test positive, then the remaining ruminants could be imported only if they qualify as being from a Risk Class R3, R4, or RU region.

To be imported from regions classified as Risk Class R3, R4, or RU for BT, EHD, BEF, RVF, and WB, ruminants that are offered for export during a season of the year when insect vectors are active, or less than 60 days after the

first killing frost in the fall of the year, would be required to be accompanied by certification that they were quarantined and isolated from all animals not part of the shipment for at least 60 days prior to embarkation in a vector-proof facility approved by the Administrator. If the ruminants are offered for export during a season of the year when insect vectors are not active, the certification must state that the ruminants have remained on premises in areas where the first killing frost in the fall occurred at least 60 days prior to the date of embarkation.

In either case, the certification would also need to state that the ruminants have had negative results to an approved serological test 30 to 60 days prior to the embarkation. If any of the ruminants tested positive to this test, for the remaining ruminants to be imported, the positive animals would need to be removed from the shipment, and the remaining ruminants would have to test negative to an approved serological test. If any of the ruminants has a positive test result to this second test, and it is a season of the year in the exported region when insect vectors are active, then the remaining animals may not be imported during the insect vector season. If it is a season of the year when insect vectors are not active, then the ruminants testing positive may be removed and the remaining animals may be imported if they all test negative to a retest at least 30 days following the previous test.

The imported ruminants would need to be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator if imported during a season of the year in the United States when insect vectors are not active, and must be quarantined for 60 days if imported during a season of the year when insect vectors are active in the United States. During this quarantine period, the ruminants would need to test negative to an approved serological test for BT, EHD, BEF, RVF, and or WB virus.

*Nairobi Sheep Disease*

In this proposal, § 93.415(n) sets forth requirements for the importation of ruminants from regions classified as Risk Class R1 through RU for Nairobi sheep disease (NSD, also known as Dugbe or Ganjam) virus. This is a tick-borne virus disease that has a relatively long incubation period and convalescent carrier status. Animals without antibody titers from affected regions would be difficult to find in the population, because the infection rate in affected regions is often quite high.

Serologically positive animals with stabilized titers may be safely imported if they are negative upon virus isolation.

Any ruminant vaccinated for NSD virus would be prohibited importation into the United States. Ruminants intended for importation from regions classified as Risk Class R1 or R2 for NSD would be required to be accompanied by certification that the ruminants have resided for at least 60 days in RN, R1, or R2 regions, and that the ruminants have tested negative to an approved serological test for NSD virus within 30 days prior to export to the United States. If any of the ruminants test positive, then the remainder of the animals would have to meet the requirements for ruminants from Risk Class R3, R4, or RU regions.

Ruminants intended for importation from regions classified as Risk Class R3, R4, or RU for NSD would have to be accompanied by certification that the ruminants were quarantined, for at least 60 days prior to export, in a vector-proof facility approved by the Administrator and by the national veterinary services of the country of origin, and that, during this quarantine period, the ruminants tested negative twice, within 60 days prior to export and at least 30 days apart, using an approved serological test for NSD virus. If any ruminants in the shipment tested positive to the first serological test, then all ruminants (positive and negative) would need to be retested at least 30 days following the previous test, with negative, decreasing, or stabilized test results. Only those animals that were negative to both tests, or that were negative on virus isolation procedures could be imported into the United States.

Additionally, the ruminants from the R3, R4, and RU regions would need to be quarantined for at least 15 days at a post-importation quarantine facility approved by the Administrator, and would need to test negative to an approved serological test during that quarantine.

#### *Cowdria ruminantium*, Tick-Borne Encephalitis, and Louping Ill

In this proposal, § 93.416(o) sets forth importation requirements for ruminants intended for importation from regions classified as Risk Class R1 through RU for heartwater due to *Cowdria ruminantium*, tick-borne encephalitis, and Louping Ill, which is a form of tick-borne encephalitis. These diseases are tick-borne infections that have long carrier periods and that may be able to be transmitted by ticks already present in the United States.

Any ruminant that has been vaccinated for *Cowdria ruminantium*,

tick-borne encephalitis, or Louping Ill is prohibited importation into the United States. Ruminants intended for importation from regions classified as Risk Class R1 or R2 for *Cowdria ruminantium*, tick-borne encephalitis, or Louping Ill would be required to be accompanied by certification that the ruminants have resided on premises located in RN, R1, or R2 regions for at least 60 days immediately prior to export and have had a negative result to an approved serological test for *Cowdria ruminantium*, tick-borne encephalitis, and/or Louping Ill within 30 days prior to export.

Ruminants intended for importation from regions classified as Risk Class R3, R4, or RU for *Cowdria ruminantium*, tick-borne encephalitis, or Louping Ill would be required to be accompanied by certification that the ruminants were quarantined for at least 60 days immediately prior to export in a vector-proof facility approved by the Administrator and the National Veterinary Services in the country of export, and that during the quarantine period the ruminants were tested negative twice, within 60 days prior to export and at least 30 days apart, using an approved serological test for *Cowdria ruminantium*, tick-borne encephalitis, and/or Louping Ill. Additionally, the ruminants must be quarantined for at least 30 days at a post-importation quarantine facility designated and approved by the Administrator, during which time the ruminants must be tested negative at least once using an approved serological test.

#### *Theileria*

In this proposal, § 93.415(p) sets forth requirements for the importation of ruminants from regions classified as Risk Class R1 through RU for *Theileria* spp. Of particular concern for cattle are *T. parva*, the cause of east coast fever; *T. lawrencei*, the cause of Corridor disease; and *T. annulata*, the cause of Mediterranean fever; and, for sheep and goats, *T. hirci*, the cause of malignant bovine or caprine theileriosis. *Theileria* are transmitted by ticks, and are rather host specific both for the primary hosts and for the vector. The specific *Theileria* species are usually not found outside the range of their secondary host tick. The primary control mechanism is to keep the transmitting tick out of the United States, but there is also some concern with *Theileria*-infected animals, because there may be native ticks in the United States that could transmit one or more of these agents. *T. mutans* is a species that is found throughout the world, and although apparently not associated with any

disease, does find a number of vectors. Once an animal becomes infected with these agents it probably remains infected for life.

Any ruminant that has been vaccinated for *Theileria* is prohibited importation into the United States. Ruminants intended for importation from regions classified as Risk Class R1 or R2 for *Theileria* would be required to be accompanied by certification that the ruminants, for at least 1 year immediately prior to export, have resided only on premises located in RN, R1, or R2 regions, and have had a negative result to an approved serological test for *Theileria* within 30 days prior to export.

Ruminants intended for importation from regions classified as Risk Class R3, R4, or RU for *Theileria* would be required to be quarantined for at least 60 days prior to export in a vector-proof facility approved by the Administrator and the National Veterinary Services of the country of export, and that, during this quarantine period, the ruminants tested negative twice, at least 30 days apart, to an approved serological test for *Theileria*. Additionally, the ruminants would need to be quarantined for at least 30 days at a post-importation quarantine facility designated and approved by the Administrator, and, during this period, would need to test negative at least once using an approved serological test for *Theileria*.

#### *Besnoitia besnoiti*, Vesicular Stomatitis, Lumpy Skin Disease, and *Parafilaria bovicola*

In this proposal, § 93.415(r) sets forth requirements for the importation of ruminants from regions classified as Risk Class R1 through RU for globidiosis due to *Besnoitia besnoiti*, lumpy skin disease (LSD) virus, and parafilariosis caused by *Parafilaria bovicola* in ruminants.

Any animal that has been vaccinated for *Besnoitia besnoiti*, LSD, or *Parafilaria bovicola* is prohibited importation into the United States. Ruminants offered for importation from regions classified as R1 or R2 for *Besnoitia besnoiti*, LSD, or *Parafilaria bovicola*, would be required to be accompanied by certification that, for at least 60 days prior to export, the animals have resided only on premises located in Risk Class RN, R1, or R2 regions, and have had a negative result to an approved serological test for the disease in question within 30 days prior to export to the United States.

Ruminants offered for importation from regions classified as R3, R4, or RU for *Besnoitia besnoiti*, LSD, or *Parafilaria bovicola*, must be



accompanied by certification that the animals were quarantined and isolated, for at least 60 days prior to export, from all animals not part of the shipment, in a vector-proof facility approved by the Administrator. During this quarantine, the animals would need to be tested negative twice, at least 30 days apart, using an approved serological test for *Besnoitia besnoiti*, LSD, and/or *Parafilaria bovicola*. Additionally, the animals would need to be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator, and, during this quarantine, would need to be tested negative at least once using approved serological tests.

#### *Trypanosomes Transmitted by Tsetse Flies*

In this proposal, §§ 93.415(q) and 93.515(i) specify importation requirements for ruminants and swine, respectively, from regions classified as Risk Class R1 through RU for tsetse fly transmitted *Trypanosoma* spp. including *T. brucei*, *T. congolense*, *T. evansi*, *T. simiae*, *T. suis*, *T. uniforme*, and *T. vivax*. The tsetse fly does not occur outside of Africa, but some of the trypanosomes that are found to be transmitted by the tsetse fly have been able to be transmitted by Tabanids and other biting flies, which allows them to become established outside the areas of tsetse fly presence. *Trypanosoma vivax* has become established throughout South and Central America, where it is transmitted by species other than the tsetse fly, and *T. evansi* is primarily transmitted by biting flies other than the tsetse fly. It is possible that some native North American biting flies could become adapted to transmit one or more of the Trypanosomes, so care must be taken to assure that animals infected with the parasites are not imported. Once an animal is infected, it probably remains infected for life.

Any ruminant or swine that has been vaccinated for trypanosomes may not be imported into the United States. Ruminants and swine to be imported from regions classified as R1 or R2 for African trypanosomes and tsetse flies would be required to be accompanied by certification that the ruminants have resided only on premises located in Risk Class RN, R1, or R2 regions for trypanosomes and tsetse flies for their entire life, and have had a negative result to an approved serological test for African trypanosomes within 30 days prior to export to the United States.

Ruminants and swine to be imported from regions classified as Risk Class R3, R4, and RU for African trypanosomes and tsetse flies would be required to be

accompanied by certification that the animals originated from premises that have not had trypanosomiasis diagnosed during the previous 24 months, that they were quarantined and isolated for at least 60 days prior to export in a vector-proof facility approved by the Administrator, and that during the pre-embarkation quarantine period, they had negative results to an approved serological test for trypanosomes. Additionally, the ruminants and swine would need to be quarantined for at least 30 days at a post-importation quarantine facility designated and approved by the Administrator, and, during this quarantine period, would need to be tested negative at least once for trypanosomes using an approved serological test.

#### *Trypanosomes Transmitted Other Than by Tsetse Flies*

In this proposal, § 93.415(s) sets forth importation requirements for ruminants from regions classified as Risk Class R1 through RU for *Trypanosoma* spp. that affect ruminants and that are transmitted by species other than tsetse flies (*Glossina* spp.) (NTT-Trypanosomas), tick-borne fever due to *Ehrlichia* (*Cytoecetes*) phagocytophilia, or bovine petechial fever due to *Ehrlichia* (*Cytoecetes*) *ondiri*. The NTT-Trypanosomas include *T. brucei*, *T. evansi*, and *T. vivax*, which may also be transmitted by biting flies other than tsetse. *Trypanosoma evansi* causes a disease called surra that affects primarily equines, camels, goats, and carnivores, but cattle may be asymptomatic carriers of the parasite.

Any ruminant that has been vaccinated for NTT-Trypanosomes, TBF, or BPF is prohibited importation into the United States. Ruminants offered for importation from regions classified as Risk Class R1 or R2 for NTT-Trypanosomes, TBF, and/or BPF would be required to be accompanied by certification that the ruminants have resided for their entire life only on premises located in regions classified as Risk Class RN, R1, or R2, and have had a negative result to an approved serological test for NTT-Trypanosomes, TBF, and/or BPF within 30 days prior to export.

Ruminants offered for importation from regions classified as Risk Class R3, R4, or RU for NTT-Trypanosomes, TBF, or BPF would be required to be accompanied by certification that the ruminants were quarantined for at least 60 days prior to export, in a vector-proof facility approved by the Administrator and the National Veterinary Services of the country of origin, and that, during the quarantine, the ruminants tested

negative twice, at least 30 days apart, to an approved serological test for NTT-Trypanosomes, TBF, and/or BPF.

If the ruminants are imported during a season of the year when vectors are not active in the United States, they would be required to be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator. The post-importation quarantine period would need to be at least 60 days if the ruminants are imported during a season of the year when vectors are active in the United States. In either case, during the post-importation quarantine period, the ruminants would need to test negative to an approved serological test for NTT-Trypanosomes, TBF, and/or BPF.

#### *Vesicular Stomatitis Virus*

In this proposal §§ 93.415(t) and 93.515(j) set forth importation requirements for ruminants and swine, respectively, from regions classified as Risk Class R1 through RU for vesicular stomatitis virus (VSV).

Ruminants and swine intended for importation from regions that are classified as Risk Class R1 for VSV would be required to be accompanied by certification that the ruminants and swine have resided for at least 60 days prior to export only on premises located in Risk Class RN or R1 regions for VSV, and have not been vaccinated for VSV.

Ruminants and swine intended for importation from regions that are classified as Risk Class R2 for VSV would be required to be accompanied by certification that the ruminants and swine have resided for a minimum period of time (60 days for ruminants; 30 days for swine) prior to export only on premises located in Risk Class RN, R1 or R2 regions for VSV, that the animals have not been vaccinated with any live attenuated vaccines for VSV, and that the animals have not been vaccinated with inactivated vaccines for VSV within 60 days prior to export.

Ruminants and swine intended for importation from regions that are classified as Risk Class R3, R4, or RU for VSV would be required to be accompanied by certification that the ruminants and swine have not been vaccinated with any live attenuated vaccines for VSV, have not been vaccinated with inactivated vaccines for VSV within 60 days prior to export, and have not been located on any premise where VSV has occurred within 60 days prior to export. Additionally, if the animals are exported during a season of the year when insect vectors were active, the certification must state that the animals were quarantined and

isolated from all other animals not part of the shipment for at least 30 days prior to export in a vector-proof facility approved by the Administrator, and, during the pre-embarkation quarantine period, had negative results to an approved serological test for VSV within 14 days prior to export. If the ruminants and swine are imported during a season of the year when insect vectors are active within the United States, the animals must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator, and, during the post-importation quarantine period, the animals must have negative results to an approved serological test for VSV.

#### *Japanese Encephalitis and Getah*

In this proposal, § 93.515(f) sets forth importation requirements for swine from regions classified as Risk Class R1 through RU for Japanese encephalitis virus (JEV) and Getah virus in swine.

Japanese encephalitis virus (JEV) is a flavivirus transmitted by various species primarily of the genus *Culex* found throughout eastern Asia. The disease primarily affects horses and humans, but swine and birds are the primary reservoir and amplifying host for the virus. The disease is primarily inapparent in swine, except in pregnant sows, in which stillborn and weak pigs may be born. The disease can also cause infertility in breeding boars.

The viremia in swine may persist throughout the vector season and provide a constant source of virus for mosquitoes. Although the introduction of this virus into North America is a constant threat, it is not known whether the virus could be established if introduced. Infected swine would be the most likely means of introducing the infection, as infected horses and humans usually have a very short, low-level, viremia that cannot infect mosquitoes.

Getah virus is an alphavirus with roughly the same distribution and vectors as JEV. It causes similar problems in swine as does JEV virus. Swine and horses are the primary amplifying hosts for this virus, and affected horses may develop a febrile illness characterized by skin lesions and edema. Pregnant sows may have reproductive failure due to Getah virus infection.

Swine intended for importation from regions classified as Risk Class R1 for JEV or Getah Virus would be required to be accompanied by certification that the swine have resided for at least 60 days immediately prior to export only on premises located in regions classified as Risk Class RN or R1 for JEV or Getah

Virus, and have had a negative result to an approved serological test for JEV and/or Getah within 30 days prior to export.

Swine intended for importation from regions classified as Risk Class R2 for JEV or Getah Virus would be required to be accompanied by certification that the swine have resided for at least 60 days only on premises located in Risk Class RN, R1, or R2 regions. The certification would also need to state that the swine have undergone a 30-day pre-embarkation quarantine, which, if conducted during a time of year when insect vectors are active, would need to be in a vector-proof facility approved by the Administrator. Additionally, the certification would need to state that the swine have tested negative to an approved serological test for JEV and/or Getah within 30 days prior to export. The swine would also need to undergo a post-importation quarantine of at least 15 days at a facility designated and approved by the Administrator.

Swine intended for importation from regions classified as Risk Class R3, R4, or RU for JEV or Getah Virus would be required to be accompanied by certification that they have undergone pre-embarkation quarantine for at least 60 days immediately prior to export. If the quarantine is conducted during a time of the year when insect vectors are active, it would have to be carried out in a vector-proof facility approved by the Administrator.

While in pre-embarkation quarantine, the swine would also need to test negative twice, within 60 days prior to export and at least 30 days apart, to an approved serological test for Japanese encephalitis and/or Getah.

If the swine are imported during a time of the year when vectors are active in the United States, the swine would need to be quarantined for at least 60 days at a post-importation quarantine facility designated and approved by the Administrator. Otherwise, the post-importation quarantine would need to be at least 15 days. In either case, during the post-importation quarantine, the swine would need to test negative to JEV and/or Getah virus, using approved serological tests.

#### *Definitions*

In §§ 93.400 (ruminants) and 93.500 (swine) of this proposed rule, we have added definitions to those already included in current §§ 92.400 and 92.500. The definitions that would be added in both §§ 93.400 and 93.500 are: *Adjacent regions, affected animals, affected premises or regions, approved brucellosis test, approved tests for restricted diseases or agents, authorized*

*veterinarian, case, contagious disease, driven, ectoparasites, equivalent test, exposed, identification, import (imported, importation) into the United States, livestock, official seal, operator, permitted treatment, post-importation quarantine, pre-embarkation quarantine, quarantine, region, restricted agents, risk class regions, susceptible animals, trail, transported, vector-borne disease, and Veterinarian in Charge.* Additionally, in proposed § 93.400 we would add a definition of approved bovine tuberculosis test, and in proposed § 93.500 we would add a definition of *approved pseudorabies test*.

#### *Part 94*

The regulations in current 9 CFR part 94 govern the importation into the United States of specified animals and animal products, in order to prevent the introduction into the United States of various animal diseases, including rinderpest, foot-and-mouth disease, bovine spongiform encephalopathy, African swine fever, hog cholera, and swine vesicular disease. These are dangerous and destructive communicable diseases of ruminants and swine. Part 94 also restricts the movement of certain garbage, and the importation of carcasses, products, and eggs of poultry, game birds, and other birds.

Under the regulations in current part 94, countries are identified in which rinderpest, foot-and-mouth disease, African swine fever, hog cholera, swine vesicular disease, and/or bovine spongiform encephalopathy are considered to exist. Also under part 94, swine and/or ruminants from these countries are prohibited or restricted importation into the United States. Certain of the conditions governing restricted importation are set forth in current part 94. The remainder of the conditions are set forth in current part 92, in either subpart D (ruminants) or subpart E (swine).

In this proposed rule, we are proposing to remove from part 94 all provisions regarding the existence of diseases affecting ruminants or swine in specific countries, and all provisions regarding the importation of live animals.

The provisions in current part 94 that list countries in which specific diseases affecting ruminants and swine are considered to exist would not be necessary, because they would be replaced by the criteria for risk class levels we are proposing to set forth in revised part 92, discussed above. (However, until there is future rulemaking on the provisions in current

§ 94.6 regarding the importation of eggs, carcasses, and other products from poultry or birds, those provisions would remain the same and continue to be based on specified countries where exotic Newcastle disease or *S. enteritidis* is considered to exist.)

All requirements for the importation of live animals would be incorporated into the importation requirements in proposed part 93, discussed above. So that, as revised, part 94 would include only restrictions and requirements for the importation of meat and other animal products, and for the movement of regulated garbage into the United States.

Section 94.1(a) of the current regulations sets forth a list of countries considered to be free of both rinderpest and foot-and-mouth disease. All countries not on this list are considered to be those in which rinderpest or foot-and-mouth disease exists. A similar list for countries considered free of hog cholera is set forth in § 94.9. Section 94.8 of the current regulations sets forth a list of countries in which African swine fever is considered to exist, and §§ 94.12(a) and 94.18(a) set forth such lists for swine vesicular disease and bovine spongiform encephalopathy, respectively. As noted above, these lists would not be necessary under the regionalized approach to risk class levels set forth in this proposed rule. Therefore, we are proposing to remove them from the regulations. Additionally, current § 94.1a, which sets forth criteria for determining the separate status of a territory or possession as to rinderpest and foot-and-mouth disease, would be removed.

In the current regulations, each of the paragraphs listing those countries in which specified disease exists, except for those in § 94.1 for rinderpest and foot-and-mouth disease, are followed by provisions for the restricted importation of meat and meat products from those countries. Similar provisions for meat from rinderpest and foot-and-mouth disease-affected countries are set forth in current § 94.4.

Additionally, current § 94.11 includes requirements for the importation of meat and other animal products from countries that are free of rinderpest and foot-and-mouth disease, but that present some disease risk due to their importation policies or their proximity to a country in which the diseases exist. Similar provisions regarding swine vesicular disease are set forth in current § 94.13.

In all of the sections described in the above two paragraphs, the requirements for the importation of meat and meat products from countries affected with

the disease in question require, among other requirements, cooking or curing of the meat or meat products. In this proposed rule, except as discussed in this "Supplementary Information" under the heading "Proposed § 94.5," we are proposing essentially to retain the cooking and curing requirements in the current regulations for meat and meat products intended for importation from countries where rinderpest, foot-and-mouth disease, bovine spongiform encephalopathy, African swine fever, hog cholera, or swine vesicular disease exists. The requirements for all cooked or cured meat products, other than those that are dry-cured, would be set forth in new § 94.5. The requirements for dry-cured products that are set forth in § 94.17 of the current regulations are set forth in § 94.11 of this proposal.

The current regulations in part 94, in most cases, do not set forth requirements for the importation of fresh, chilled, or frozen meat from foreign countries. This is because, under the current regulations, in most cases, either a country is considered to be one in which a particular disease exists, or it is considered free of the disease. If the disease exists in the country, meat from that country must be cooked or cured before importation. If the country is considered free of the diseases, meat and meat products may be imported from that country with relatively few restrictions. The only exceptions to this "free/not free" approach in part 94 are the provisions in §§ 94.11 and 94.13, which list countries in which rinderpest/foot-and-mouth disease or swine vesicular disease, respectively, are not considered to exist, but that are considered to present some risk of disease introduction due to their importation policies or proximity to countries in which the disease exists. Meat to be imported from countries listed in §§ 94.11 or 94.13 must either be cooked (in the case of swine vesicular disease) or must be accompanied to the United States with certification that the facility where the animals were slaughtered follows preparation and processing practices to ensure it does not handle contaminated meat, and also that the animals to be slaughtered have never been in a country affected with the disease in question.

Under the risk class levels that would be established by this proposal, the number of disease-risk categories a country could fall into would be expanded from "free," "not free," or "free with some risk," to any one of six different risk classes.

Regions classified as RN for a particular disease would, under the current regulations, be considered to be

a country free of a particular disease, and meat and meat products could be imported from those countries with little restriction.

Under this proposal, regions classified as Risk Class R1 would be similar to those countries listed in current §§ 94.11 and 94.13, that are considered to be free of a disease, but that present some increased risk due to importation practices or proximity to countries affected with a disease. Meat and meat products from Risk Class R1 countries could be imported only if certain specified requirements, discussed below are met.

Proposed Risk Class R2 would be a risk class that essentially straddles our current designations of "free" and "not-free." As defined in this proposal, a Risk Class R2 region would be one in which a particular disease is not known to exist, but in which vaccination of animals for the disease is carried out or the disease has recently been known to exist. Under our current policy, such a country would not be considered free of a disease, for reasons discussed above in this **SUPPLEMENTARY INFORMATION**, under the heading "Risk Class R3 Regions." Under this proposal, however, an R2 region would be one that does not present as much risk as a region in which the disease exists (R3, R4, RU), but that presents a greater risk than a region in which vaccination is not carried out (RN, R1).

Regions in the proposed Risk Class R3, R4, and RU levels would, under the current regulations, be considered countries in which a particular disease is considered to exist. Under this proposal, meat and meat products from these regions, with the exceptions discussed below, would be prohibited importation, just as they are under the current regulations. The requirements for importation of meat and meat products from the different risk class levels are discussed below.

#### Prohibitions

The importation of fresh, chilled or frozen meat from swine in regions classified as Risk Class R3, R4, or RU for hog cholera, African swine fever, or swine vesicular disease would be prohibited (proposed § 94.1(b)). The destruction of virus in fresh meat by methods generally employed to process fresh meat are not sufficient to remove hog cholera, African swine fever, or swine vesicular disease from swine meat, or bovine spongiform encephalopathy from bovine meat.

This proposal would, in § 94.1(a), prohibit the importation of fresh, chilled, or frozen meat of ruminants or swine from regions classified as Risk

Class R4 or RU for rinderpest or foot-and-mouth disease, and, in § 94.1(c), would prohibit the importation of fresh, chilled, or frozen meat of ruminants from Risk Class R4 or RU levels for bovine spongiform encephalopathy.

We believe that fresh, chilled, or frozen meat can be imported from regions classified as R3 for rinderpest or foot-and-mouth disease, because an R3 region is by definition regarded as a region of low disease prevalence. The GATT sanitary and phytosanitary provisions allow imports from low prevalence regions for FMD and rinderpest, and the virus in FMD and rinderpest carrier animals is largely eliminated by deboning and standard curing of the meat, by which the meat is hung for 36 hours to increase its tenderness. Quantitative risk assessments done for meat estimate that meat from fewer than 7 per billion FMD-infected animals would still be infective after the standard curing and deboning process.

#### Importation Requirements for Fresh, Chilled, or Frozen Meat of Ruminants and Swine

Under § 94.1(d) of this proposed rule, fresh, chilled, or frozen meat from ruminants and swine raised and slaughtered in regions classified as Risk Class RN or R1 for foot-and-mouth disease, rinderpest, bovine spongiform encephalopathy, African swine fever, hog cholera, and/or swine vesicular disease could be imported into the United States provided the authorized official of the exporting country certifies on the required foreign meat inspection certificate that the shipment originated in regions that are classified as Risk Class RN or R1 for the disease in question, and that the meat has not been in contact with meat from regions that are classified as Risk Class R2, R3, R4, or RU regions for the disease in question.

Under proposed § 94.1(e), fresh, chilled, or frozen meat from ruminants or swine raised and slaughtered in regions that are classified as Risk Class R2 for foot-and-mouth disease or rinderpest could be imported into the United States provided that the authorized official of the exporting country certifies the following: (1) The shipment originated in a region classified as Risk Class RN, R1, or R2 for foot-and-mouth disease or rinderpest in ruminants or swine; (2) the meat has not been in contact with meat from Risk Class R3, R4 or RU regions; (3) the meat originated from premises where foot-and-mouth disease or rinderpest has not been present during the lifetime of any ruminants or swine slaughtered for

export; (4) the meat originated from premises located in regions where foot-and-mouth disease or rinderpest has not been diagnosed within the previous 12 months; (5) the meat originated from premises on which ruminants and swine have not been vaccinated with modified or attenuated live viruses for foot-and-mouth disease at any time during the lifetime of any of the ruminants or swine slaughtered for export; (6) the meat originated from ruminants or swine that have not been vaccinated for rinderpest, African swine fever, hog cholera or swine vesicular disease at any time during the lifetime of any of the ruminants or swine slaughtered for export; (7) all bone, blood clots, and lymphoid tissue have been removed from the meat; and (8) the meat comes from carcasses that have been allowed to maturate at 40° to 50°F (4° to 10°C) for a minimum of 36 hours after slaughter and have reached a maximum pH of 6.0 in the loin muscle at the end of the maturation period. As proposed, any carcass in which the pH does not reach a maximum of 6.0 may be allowed to maturate an additional 24 hours and be retested, and, if the carcass still does not reach a maximum pH of 6.0 after 60 hours, the meat from the carcass may not be imported into the United States.

The rationale for proposed requirements "(5)" through "(8)," above, is as follows: Vaccination with modified or attenuated live viruses for foot-and-mouth disease could create the risk of the live virus being present in meat imported into the United States. Because any vaccine that currently exists for rinderpest, African swine fever, hog cholera, or swine vesicular disease contains a live virus, all vaccination for those diseases would be prohibited. The proposed requirement that certain parts of the animal product be removed is necessary because those locations on the carcass can be reservoirs of the disease agent. The requirement that a maximum pH of 6.0 be reached would be necessary to ensure any foot-and-mouth disease agent has been destroyed.

Under § 94.1(f) of this proposal, fresh, chilled, or frozen meat from swine raised and slaughtered in regions that are classified as Risk Class R2 for African swine fever, hog cholera, and/or swine vesicular disease could be imported into the United States provided that the authorized official of the exporting country certifies the following: (1) The shipment originated from regions that are classified as Risk Class RN, R1, or R2 for African swine fever, hog cholera, and/or swine vesicular disease in swine; (2) the meat

has not been in contact with meat from regions that are classified as Risk Class R3, R4 or RU for African swine fever, hog cholera, and/or swine vesicular disease; (3) the meat originated from premises where African swine fever, hog cholera, and/or swine vesicular disease has not been present during the lifetime of swine slaughtered for export; (4) the meat originated from premises located in regions where African swine fever, hog cholera, and/or swine vesicular disease has not been diagnosed within the previous 12 months; (5) the meat originated from premises on which ruminants and swine have not been vaccinated with modified or attenuated live viruses for foot-and-mouth disease at any time during the lifetime of any of the swine slaughtered for export; (6) the meat originated from swine that have not been vaccinated for rinderpest, African swine fever, hog cholera or swine vesicular disease at any time during the lifetime of any of the swine slaughtered for export; and (7) all bone, blood clots, and lymphoid tissue have been removed from the meat.

Our primary concern regarding meat from regions classified as Risk Class R2 for African swine fever, hog cholera, and/or SVD would be possible residual virus infection on previously infected premises in the region, and also some risk of recent introductions from adjacent affected areas. The certification of the premises of origin as being free of the disease would be the principal method of risk mitigation in these regions. We believe this would create little hardship in these areas, because fewer than 0.1% of the farms would be expected to have a recent history of one of these diseases. Because the only proven method of eliminating the diseases is complete herd depopulation of the affected premises and restocking with fresh swine after a suitable fallow period, such a restocked herd would qualify for export, since none of the restocked swine would have been present when the restricted disease agent was present.

Under § 94.1(g) of this proposal, fresh, chilled, or frozen meat from ruminants or swine raised and slaughtered in regions that are classified as Risk Class R3 for foot-and-mouth disease and/or rinderpest could be imported into the United States, provided the authorized official of the exporting country certifies the following: (1) The shipment originated from a region that is classified as Risk Class RN, R1, R2 or R3 for foot-and-mouth disease and/or rinderpest; (2) the meat has not been in contact with meat from regions that are classified as Risk Class R4 or RU for

foot-and-mouth disease and/or rinderpest; (3) the meat originated from premises where foot-and-mouth disease and rinderpest have not been present during the lifetime of any ruminants or swine slaughtered for export; (4) the meat originated from premises where foot-and-mouth disease and/or rinderpest has not been diagnosed within 15 statute miles (25 kilometers) within the previous 12 months; (5) the meat originated from premises on which ruminants and swine have not been vaccinated with modified or attenuated live viruses for foot-and-mouth disease at any time during the lifetime of any of the ruminants or swine slaughtered for export; (6) the meat originated from ruminants or swine that have not been vaccinated for rinderpest, African swine fever, hog cholera or swine vesicular disease at any time during the lifetime of any of the ruminants or swine slaughtered for export; (7) the meat has all bone, blood clots, and lymphoid tissue removed; (8) the meat comes from carcasses that have been allowed to mature at 40° to 50°F (4° to 10°C) for a minimum of 36 hours after slaughter and that have reached a maximum pH of 6.0 in the loin muscle at the end of the maturation period (any carcasses in which the pH did not reach a maximum of 6.0 may be allowed to mature an additional 24 hours and be retested, and if the carcass still does not reach a maximum pH of 6.0 after 60 hours, the meat from the carcass may not be exported to the United States); and (9) the meat was held at no more than 40°F (4°C) for a minimum of 14 days before export, during which time the premises of origin of all animals in the shipment remained free of foot-and-mouth disease, rinderpest, African swine fever, hog cholera, and swine vesicular disease. This 14-day period would be sufficient to ensure that the incubation period for the disease agent in question has elapsed.

Under § 94.1(h) of this proposal, fresh, chilled, or frozen meat from cattle from regions that are classified as Risk Class R2 or R3 for bovine spongiform encephalopathy could be imported into the United States provided the authorized official of the exporting country certifies the following: (1) The shipment originated from a region that is classified as Risk Class RN, R1, R2, or R3 for bovine spongiform encephalopathy; (2) the meat has not been in contact with meat from regions that are classified as Risk Class R4 or RU for bovine spongiform encephalopathy; (3) the meat originated from premises where, for at least 10 years, bovine spongiform encephalopathy has not

been known to be present; (4) the meat originated from premises where protein of ruminant origin has not been fed to ruminants during the lifetime of any animals currently living on the premises; (5) the meat is from cattle that have not been in any region classified as Risk Class R3, R4 or RU for bovine spongiform encephalopathy during any period when the region permitted the use of ruminant protein in ruminant feed; and (6) the cattle were examined prior to slaughter by a veterinarian employed by the national government of the country in which the ruminants were slaughtered, and were found not to display any signs indicative of a neurological disorder. We believe requirements "(4)" and "(5)," above, regarding ruminant feed, are necessary because the bovine spongiform encephalopathy agent can exist in, and be transmitted by, feed processed from ruminants infected with the disease. Because the symptoms of bovine spongiform encephalopathy include neurological disorder, cattle exhibiting such a disorder must be presumed to be affected with the disease.

Under § 94.1(i) of this proposal, fresh, chilled or frozen meat derived from animals in the family Cervidae from regions that are classified as Risk Class R2, R3, or R4 for bovine spongiform encephalopathy could be imported into the United States, provided the authorized official of the exporting country certifies the following: (1) The meat was derived either from wild cervidae, or from farm-raised cervidae that have never been fed ruminant protein; (2) all bones and visually identifiable lymphatic tissue and nerve tissue have been removed from the meat; (3) the meat is from cervidae that have not been in any region classified as Risk Class R3, R4, or RU for bovine encephalopathy during a period of time when the region permitted the use of ruminant protein in ruminant feed; and (4) the cervidae were examined prior to slaughter by a veterinarian employed by the national government of the country in which the ruminants were slaughtered, and were found not to display any signs indicative of a neurological disorder.

We believe it is warranted to provide different requirements for the importation of cervidae from Risk Class R3 regions for BSE than for cattle, because, as a general practice, cervidae feed by grazing and are less likely than cattle to have been fed ruminant protein and to have been in contact with ruminants infected with the disease. Except in zoos, there have been no reports of BSE in cervidae.

### *Proposed § 94.3*

Section 94.2(a) of the current regulations prohibits the importation of fresh, chilled, or frozen products (other than meat, and milk and milk products) derived from ruminants or swine originating in, shipped from, or transiting any country designated as one in which rinderpest or foot-and-mouth disease exists. An exception to this prohibition is made in current § 94.3 for organs, glands, extracts, or secretions of ruminants and swine that are imported for pharmaceutical or biological purposes, and in current parts 95 and 96 for other specified animal products, such as casings, glue stock, etc., processed under certain conditions.

In this proposed rule, we would redesignate § 94.2(a) as § 94.3(a) and apply its prohibitions to regions classified as Risk Class R3, R4, or RU for rinderpest, foot-and-mouth disease. Under this proposal, regions classified as Risk Class R3, R4, or RU are considered those in which the disease in question exists.

Current § 94.2(b) prohibits the importation of milk and milk products from countries in which FMD or rinderpest exists. This paragraph would be redesignated as § 94.3(b). In addition to prohibitions because of FMD and rinderpest, we are proposing to also prohibit the importation of milk and milk products of ruminants and swine originating in, shipped from, or transiting any region that is classified as Risk Class R3, R4, or RU for *Brucella melitensis*. Under this proposal, such regions are those in which the disease is considered to exist. We are proposing to add *Brucella melitensis* to this list because it is exotic to the United States and is a hazard to both animals and humans that may be exposed to fresh milk from infected animals. The primary concern with milk is the possible feeding of raw milk or milk products to young ruminants or swine.

### *Proposed § 94.5*

As stated above, the cooking and processing requirements for meat imported from countries in which diseases of concern exist, that are set forth in current §§ 94.4, 94.8, 94.9, 94.11, 94.12, 94.13, and 94.18, would be consolidated in proposed § 94.5. Also, as noted above, the references to countries in which a disease is considered to exist would be replaced by references to regions classified as Risk Class R3, R4, or RU. All of the current regulations for such cooking and processing would be included in this proposed rule.

Current § 94.5 includes provisions restricting the movement and handling of certain international garbage. These provisions would remain unchanged by this proposal, but would be redesignated as § 94.6.

Current § 94.6 includes provisions regarding the importation of carcasses, or parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds from countries where exotic Newcastle disease or *S. enteritidis* is considered to exist. These provisions would remain unchanged by this proposal, but would be redesignated as § 94.7.

Current § 94.7 includes provisions for the disposal of animals, meats, and other articles ineligible for importation under the regulations regarding rinderpest and foot-and-mouth disease in current § 94.1. In this proposal, we would redesignate current § 94.7 as § 94.8 and amend it by removing all references to animals and by expanding the regulations so that they refer to African swine fever, hog cholera, swine vesicular disease, and bovine spongiform encephalopathy, as well as to rinderpest and foot-and-mouth disease. Provisions regarding the disposal of animals are set forth in §§ 93.407 and 93.507 of this proposed rule, for ruminants and swine, respectively.

Current § 94.15(a) includes requirements for products that would be eligible for entry into the United States and that transit the United States for export. These provisions would be set forth in § 94.9(a) of this proposed rule, but would not otherwise be changed.

Current § 94.15(b) includes provisions that allow pork and pork products from Chihuahua and Sonora, Mexico that are not otherwise eligible for entry into the United States to transit the United States for immediate export under specified conditions. These conditions include the obtaining of an APHIS permit, movement from the region of origin in a leakproof container with serially-numbered seals approved by APHIS, submission of information to APHIS concerning the route and seal numbers of the shipment, and exportation from the United States within a time limit specified on the permit. We do not believe that it is necessary to limit the opportunity for transiting to pork and pork products from Chihuahua and Sonora, and believe that the provisions currently in place for pork and pork products from Chihuahua and Sonora would be adequate to guard against disease risk from any meat or meat product imported through a land border port for transiting and immediate export.

Therefore, we are proposing to extend the provisions accordingly, and include them in proposed § 94.9(b).

Sections 94.11 and 94.13 of the current regulations set forth requirements for the importation of meat and meat products from countries in which rinderpest, foot-and-mouth disease, and swine vesicular disease are not known to exist, but that pose an increased disease risk due to importation policies or proximity to affected countries. One of the requirements for such importation is that the meat or meat product be prepared in inspected establishments that are eligible to have their products imported into the United States under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) Current § 94.15(c) allows meat and other animal products from countries listed in §§ 94.11 or 94.13, that were not prepared in eligible establishments, to be imported for transit through the United States for immediate export. Under this proposal, countries that are listed under §§ 94.11 and 94.13 would be classified as Risk Class R1 or R2 regions. We are proposing to provide in § 94.9(c) of this proposal that meat and other animal products from R1 or R2 regions that are not otherwise eligible for importation may transit the United States for immediate export, provided the requirements of § 94.8(a) regarding notification and movement in a sealed leakproof container are met.

In § 94.9(d) of this proposal, we are also proposing to add provisions to the regulations that would allow the limited transiting in the United States of meat and other animal products not otherwise eligible for entry into the United States. This transiting would be limited to movement at the port of arrival. Under the current regulations, if a ship or aircraft that arrives in the United States is carrying meat or other animal products that are prohibited entry into the United States, the containers in which the meat or other animal products are contained may not be offloaded from the means of conveyance to another means of conveyance, even if the second means of conveyance is scheduled for immediate departure from the United States. When such offloading does occur, it is a violation of the regulations and the carrier is fined. This restriction has reduced the number of transport routes available to producers and shippers of meat and meat products.

We believe that the current regulations are unnecessarily restrictive. As long as meat and other animal products are securely contained aboard the carrier while in the port or while

being offloaded, and as long as their overland movement in the United States is confined to the port of arrival, we do not believe that such meat or other animal products pose a risk to livestock in this country. Therefore, we are proposing in proposed § 94.9(d) to allow such movement. To qualify for such transiting, notification of the transiting would have to be made by the importer to the Plant Protection and Quarantine Officer at the port of arrival prior to the transiting. The animal products and materials would have to be contained in a sealed, leakproof carrier or container or other means of conveyance, or, if the container or carrier in which the animal product or material is transported were offloaded in the United States for reshipment, it would have to remain sealed at all times. The animal product or material could be held or stored for no more than 24 hours at the port of arrival.

Current § 94.16 includes importation requirements for specified milk and milk products. In this proposal, these provisions are set forth in § 94.9. The references in current § 94.16 to countries in which rinderpest or foot-and-mouth disease exists have been changed to references to regions classified as Risk Class R3, R4, or RU for rinderpest or foot-and-mouth disease. References to countries free of rinderpest and foot-and-mouth disease have been changed to references to regions classified as RN, R1, or R2 for the restricted diseases. Except for these and one other change, the provisions in current § 94.16 would remain unchanged. In proposed § 94.10(b)(2), we are proposing to remove the requirement in current § 94.16(b)(2) that dry milk products intended for importation must be processed for human food. We believe that as long as they are processed in a manner determined by the Administrator to be adequate to prevent the introduction of livestock diseases into the United States, their use does not need to be restricted to human food.

We are also proposing to add a new § 94.10(f) that would provide that milk or milk products from regions that are classified as Risk Class R3, R4, or RU for *Brucella melitensis* may enter the United States only under the following conditions: (1) The milk is pasteurized according to Food and Drug Administration (FDA) requirements; (2) milk and milk products, including cheese, meet FDA requirements for imported milk; (3) milk products, including cheese, are prepared from milk treated according to current requirements for milk from rinderpest and foot-and-mouth disease countries,

in facilities that process only milk and milk products according to FDA requirements.

In this proposal, we are also proposing to add provisions at new § 94.13 that meat or meat products consigned from the port of arrival to an approved establishment must be moved under Customs or APHIS seal, and must be otherwise handled as the Administrator may direct in order to guard against the introduction and dissemination of contagious diseases of livestock. The required seals would not be permitted to be broken except by persons authorized by the Administrator to do so.

Section 94.15 of this proposal includes provisions for the cancellation of compliance agreements, and provisions for the appeal of such a cancellation.

We are also proposing to amend current § 94.0, "Definitions," to include definitions currently set forth in § 94.4(h), and are proposing to add to part 94, in § 94.0, definitions of *cervid*, *contact*, *pink juice test*, *region*, *restricted agents*, *risk class regions*, *ruminants*, and *veterinarian in charge*.

The proposed definitions of *region*, *restricted agents*, and *risk class regions* are the same as those in §§ 93.400 and 93.500 of this proposed rule. The proposed definition of *veterinarian in charge* is the same as that used elsewhere (e.g., § 78.1) in the current regulations. A definition of *cervid* would be included to make clear that the term applies to all species of deer, elk, and moose.

The proposed definition of *contact* reads as follows: "Known or potential commingling of products of animals during processing or storage, or while being transported from any point to any other point. Contact includes simultaneous processing in the same facility, or storage or shipment in the same room, locker, or container, but not necessarily the same storage facility or conveyance, as long as security measures provided are determined to be adequate by an authorized APHIS representative." The purpose of this definition is to set forth the various ways disease agents can be transmitted among animal products.

In § 94.0 of the current regulations, the definition of *Indicator piece* refers to meat to be used for the "pink juice test." This test is a visual method of determining whether meat has been sufficiently heated to destroy the foot-and-mouth disease virus. However, the current regulations do not define "pink juice test." Therefore, to clarify the meaning of this term, we are proposing to add a definition of *pink juice test* to

mean "determination of whether meat has been thoroughly cooked by observation of whether the flesh and juices have lost all red and pink color."

#### 9 CFR Part 95

The regulations in 9 CFR part 95 contain restrictions on the importation of certain animal products and hay and straw in order to prevent the introduction of certain animal diseases.

In this proposal, we are proposing to make three types of substantive changes to part 95. First, in each section where the current regulations refer to "country" of origin, we would replace the word "country" with the word "region." Second, in each case where reference is made to a country in which a particular disease is not considered to exist, we would refer instead to a region classified as Risk Class RN, R1, or R2 for the disease in question. Third, in each case where reference is made to a country in which a particular disease is considered to exist, we would refer instead to a region classified as Risk Class R3, R4, or RU for the disease in question.

The sections in part 95 in which we would make the changes described above are §§ 95.2, 95.4, 95.5, 95.7, 95.9, 95.14, 95.15, 95.17, 95.21, and 95.23. Additionally, in § 95.28, which deals with hay, straw, grass, and similar material, we would replace the reference to "tick-infested pastures, ranges, and premises" with a reference to "regions classified as R3, R4, or RU for restricted ticks."

Additionally, we would add definitions of *region* and *risk class regions* to the definitions in § 95.1, and would make several non-substantive wording changes in part 95 for clarity and to clarify internal APHIS management procedures.

#### 9 CFR Part 96

The regulations in 9 CFR part 96 govern the importation of animal casings into the United States to prevent the introduction of contagious livestock diseases.

We are proposing to replace references to "country" in §§ 96.2 and 96.3 with references to "region," are proposing to replace the reference in § 96.3 to countries free of African swine fever to regions classified as Risk Class RN, R1, or R2 for African swine fever, and are proposing to replace the references to countries in which specified diseases exist with references to regions classified as Risk Class R3, R4, or RU for those diseases.

Additionally, in § 96.10, we would remove the references to specific cities in which casings that arrive in the

United States without certification may be disinfected, and would state instead that such casings may be forwarded to a USDA-approved facility for disinfection. We are proposing to make this change because the facilities in the cities specified are no longer in operation, and such disinfection, if it were necessary, could be done at any facility approved by APHIS.

Finally, we are proposing to remove § 96.15, "Common carriers; marking papers," and § 96.16, "Form for reporting release," because they specify administrative procedures that have been discontinued for a number of years.

#### 9 CFR Part 98

The regulations in 9 CFR part 98 govern the importation of animal germ plasm so as to prevent the introduction of contagious diseases of livestock or poultry into the United States.

In this proposal, we are proposing to replace references to "country" with references to "region" in the headings for subparts A and B, and in §§ 98.3, 98.4, 98.7, 98.12, 98.13, 98.14, 98.15, 98.16, 98.17, and 98.34. Also, we would replace references to countries free of rinderpest and foot-and-mouth disease with references to regions classified as Risk Class RN, R1, or R2 in the heading for subpart A and in § 98.3, and would replace references to countries in which rinderpest or foot-and-mouth disease exists with references to regions classified as Risk Class R3, R4, or RU in the heading to subpart B, and in §§ 98.12, 98.13, 98.14, 98.15, 98.16, and 98.34.

#### Pending Proposed Rules

On May 11, 1995 (60 FR 25151-25162, Docket No. 94-085-2), APHIS published in the Federal Register a proposed rule regarding the importation of sheep and goats and sheep and goat germ plasm. That document proposed to amend provisions concerning who may issue health certificates for ruminants offered for importation into the United States, and proposed to significantly revise the conditions for importing sheep and goats and sheep and goat germ plasm. The proposal also contained provisions concerning privately operated quarantine facilities for goats. Because no final rule has been issued, those provisions are not reflected in this proposed rule. However, the provisions of Docket No. 94-085-2 that are made final, and any future rulemaking affecting this proposal (Docket No. 94-106-1), will be reflected in the final rule to this proposal (Docket No. 94-106-1).



### National Performance Review

This regulatory action is being taken as part of the National Performance Review program to eliminate unnecessary regulations and improve those that remain in force.

### Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be economically significant and was reviewed by the Office of Management and Budget.

This proposed rule has been determined not to be major as provided by Public Law 103-354, the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994. This law requires that certain economically significant USDA rules published in the Federal Register include an analysis of the risks, costs, and benefits of the action, and that this analysis be reviewed by the USDA Office of Risk Assessment and Cost Benefit Analysis. However, P.L. 103-54 applies this requirement only to rules the primary purpose of which is to regulate issues of human health, human safety, or the environment. This proposed rule does not fall under these criteria, and consequently has not been reviewed by the Office of Risk Assessment and Cost Benefit Analysis.

In accordance with 5 U.S.C. 603, we have performed an Initial Regulatory Flexibility Analysis regarding the impact of this proposed rule on small entities. This proposed action may have a significant economic impact on a substantial number of small entities. Therefore, we are inviting comments concerning potential impacts. In particular, we are interested in determining the number and kind of products, countries, and small entities that may incur benefits or costs from implementation of this proposed rule.

In accordance with 21 U.S.C. 111, the Secretary of Agriculture is authorized to promulgate regulations to prevent the introduction or dissemination of any contagious, infectious, or communicable disease of animals from a foreign country into the United States. This proposed rule would establish criteria for foreign "regions" based on risk class levels. In this proposed rule, we define the term *region* to mean "any defined geographic land region identifiable by geological, political, or surveyed boundaries." Under this definition, a region may be a national entity, part of a national entity, combined parts of several national entities, or a group of several national entities combined into a single trading block. The criteria for

classified regions would be used to establish importation requirements for particular animals and animal products from those regions. We are also proposing to allow, under certain conditions, the unloading and reloading at the port of arrival of meat and other animal products otherwise prohibited entry into the United States.

This proposed rule, if adopted, would revise the process for establishing United States importation policies regarding live ruminants and swine, and the meat and products of such animals. Under this proposal, the United States would in some cases look at the disease risk in defined production regions, rather than entire countries, and would assess the risk of specific disease introduction according to risk class levels, rather than only by determination of whether a region is or is not free of a particular disease.

This proposed rule is a departure from the current regulations in that a region would not be classified simply as one in which a specific disease is or is not known to exist. Rather, a region in which we have determined that a certain disease does not exist would be classified as one of three different risk class levels, depending on the length of time the region has been free of the disease, and the risk that the disease might be introduced into the region. Likewise, under this approach, two separate risk classifications for regions in which a disease is known to exist would be established, as well as one additional risk class category for countries or regions that do not yet have specific classification as another risk class level. Therefore, under this proposed rule, regions would fall into one of six risk class levels or categories.

Under this proposal, biosecurity measures for the importation of animals and animal products become more stringent as the risk class number increases, in order to protect domestic agriculture from exotic animal diseases. The six risk categories in the proposed rule are described qualitatively and quantitatively in terms of the expected range of results from quantitative risk assessments using scientifically accepted methods. Decisions whether an animal or animal product may be imported depend on the risk classification of the source region and whether there exist biosecurity measures to mitigate the risk to a negligible level. Thus, within the proposed rule, the standard for imported animals and products after mitigation is one of negligible risk. Economic theory would call for this standard to be discovered by an explicit comparison of marginal benefits and

marginal costs at different risk levels. However, data limitations, analytical complexity, and the inherent imprecision in calculating biological risks and quantitative economic effects make such comparisons impractical.

The changes being proposed in this regulation are intended to comply with U.S. obligations under provisions concerning sanitary and phytosanitary (SPS) regulation in both the North American Free Trade Agreement (NAFTA) and the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures under the General Agreement on Tariffs and Trade (GATT) Uruguay Round agreements.

Although the two agreements differ in a few respects, both NAFTA-SPS and WTO-SPS provide that:

A member Country shall recognize the concepts of regions of low pest or disease prevalence, and shall ensure that its sanitary and phytosanitary measures are adapted to take into account the characteristics of regions from which products originate and to which products are destined. In doing so, the Member should take into account relevant geography, ecology, methods of surveillance and effectiveness of control systems. [NAFTA-SPS, Article 716; WTO-SPS, Articles 6.1-6.2]

At the same time, the agreements explicitly recognize the right of governments to take measures to protect human, animal, and plant health, as long as these are based on science, are necessary for the protection of health, and do not unjustifiably discriminate among foreign sources of supply. In considering this proposed rulemaking, APHIS identified and considered four options, keeping in mind the two goals of compliance with the international agreements and protection of domestic animal health.

The first option was to retain the current regulatory system that bases animal and animal product import requirements on whether a disease is considered to exist or not exist anywhere in a country. APHIS believes this alternative would not be in compliance with NAFTA-SPS or WTO-SPS, cited in the preceding paragraph. This alternative would likely lead to a negative economic impact on the United States, as U.S. policies would be challenged under NAFTA and GATT, with reciprocal measures likely being taken by foreign countries.

Further, we believe that the current regulatory policy unnecessarily prohibits or restricts the importation of animals and animal products in many situations where such importation can be carried out with insignificant risk of

introducing disease agents into the United States. For example, under the current regulations, a country in which cattle are vaccinated for FMD is not considered to be a country in which FMD does not exist, even if there have been no recently reported cases of the disease in the country. This situation exists because vaccinated cattle could potentially become infected with the FMD virus and not show any clinical signs. However, animals from countries in which the disease has not been reported, but in which vaccination is carried out, do not present the same risk as animals from countries in which the disease is considered to exist. We believe that the risk from countries which carry out vaccination can be reduced to a negligible level through mitigating measures. Under the current regulations, however, the two types of countries are subject to the same prohibitions.

A second alternative considered by APHIS was to establish levels of risk, with accompanying mitigating measures, but to establish a fewer number of such levels than the six set forth in this proposed rule. While this option would be less restrictive than the "free/not-free" approach, we believe that it would unnecessarily group countries and regions that have distinct levels of risk. For example, if the regulations were to establish the risk categories of "low risk," "moderate risk," and "high risk" for FMD, both Canada and Uruguay would be categorized as low risk, because the disease does not exist in either country. This would make both countries subject to the same requirements for the importation of ruminants and swine and their products into the United States. However, we believe that these countries present different levels of risk. A longer period of time has elapsed since the last reported case of FMD in Canada than in Uruguay. Vaccination for FMD was conducted in Uruguay until relatively recently, whereas vaccination has not been carried out in Canada because the last reported outbreak there was in the 1950s. Additionally, Uruguay shares borders, albeit protected ones, with countries where FMD exists, whereas Canada does not. Under this proposal, therefore, Canada is considered a region of negligible risk for FMD and Uruguay is considered a region of slight risk.

Another alternative APHIS considered was to establish more than six risk class levels. However, the distinctions among an increased number of risk classes would be extremely difficult to identify consistently based on current research,

and would be unwieldy on a working level to administer.

By making distinctions that can be practically made between different risk class levels, we believe that it is appropriate to establish more than three risk categories. APHIS believes that six risk class levels are scientifically defensible for imports from other countries. Also, similar categorizations could in the future justifiably be considered by other countries regarding exports from the United States.

In this proposed rule, we propose classifications of "regions" of the world which consist almost exclusively of national entities (countries), to develop a baseline similar to the disease statuses as set forth in the current regulations. In cases where a disease is not specifically listed in the current regulations, the baseline is based on the published epidemiologic information about the disease distribution. In all cases where neither regulatory precedent nor adequate published epidemiologic data existed to classify a country as either Risk Class RN (negligible risk), R1, R2, R3, or R4, we have proposed to classify the country as Risk Class RU for unknown or unclassified risk. Where a disease agent has not been reported from a country, and there is no evidence that the disease agent now exists or has ever existed in the country, we have proposed to classify the country as Risk Class RN. It is important to note, however, that the classifications set forth in this proposed rule are subject to change based on information supplied to APHIS by members of the public, or by countries or other regions, that indicates that the region size or risk class should be changed.

This proposed rule sets forth procedures for requesting recognition of an area as a region and for establishment of risk class designations that differ from those set forth in this proposal. These procedures are set forth in § 92.5 of this proposed rule. In general, they provide that the official of the national government of any country, who has the authority in that country to request such a change, may request at any time that all or part of the country be classified or reclassified as a Risk Class RN, R1, R2, R3, or R4 region, or be included within an adjacent previously classified region. After receiving a formal questionnaire from APHIS, the Chief Veterinary Officer of the region must return the completed questionnaire to APHIS, along with a copy of the region's applicable agricultural laws and regulations. This information will be evaluated by a committee formed by the Administrator of APHIS, which will either deny the request or indicate

further information is needed, or will recommend to the Administrator that the request be approved. If the recommendation is to approve the request, a notice of proposed rulemaking will be published in the Federal Register, proposing the status of the region for the restricted agent in question, evaluating the relative risks, and analyzing the impacts of the classification. Public comment will be solicited on the proposed risk class designation. If, after reviewing public comment, APHIS continues to believe the proposed risk class should be made final, a final rule will be published, along with an updated evaluation of the risks and an updated impact analysis.

The long-range impact of this rule will depend on trade decisions made by foreign importers and foreign governments, and on market considerations. This concept is perhaps the most significant policy and regulatory issue facing APHIS and our trade partners. It is expected to create new opportunities for the United States, as well as for other countries, to export not only from areas that are demonstrated to be free of particular diseases, but also from areas of low disease or pest prevalence under mitigated circumstances.

As discussed above, the risk class designations in this proposed rule are largely based on the country classifications set forth in the current regulations. However, based on epidemiological evidence and other data available to us, and site (country) visits to review animal health programs, we are proposing to use the proposed process to implement risk classification for two countries differently than would be the case solely based on the current regulations. The rationale for these designations is set forth in the supplementary information of this document under the heading "Listing of Risk Classifications for Individual Regions." We are proposing that Argentina be designated Risk Class R2 (low risk) for FMD, and the State of Sonora in Mexico be designated as Risk Class R1 for hog cholera. In the current regulations, Argentina is listed as a country in which FMD is considered to exist, and Mexico is listed as a country in which hog cholera is considered to exist. As such, the current regulations prohibit or restrict certain animal and product imports from these countries.

At this time, we have conducted an analysis for two countries, Argentina and Mexico, that could be affected in the short term by the regulation change. Although Argentina and Mexico would initially be the most likely countries to be affected by this rule as proposed, we

are moving in the direction of multilateral regionalization with much broader effects than implied by this partial analysis. A more complete analysis is not possible now, but over time the United States will have additional export opportunities as well as import competition.

#### Imports From Argentina

Argentina is currently considered a country in which foot-and-mouth disease (FMD) exists. With such a designation, the importation of fresh meat and meat products of ruminants and swine from Argentina is prohibited. Under this rule, however, fresh meat from ruminants and swine could be imported from Argentina, because it would be classified as Risk Class R2 (low risk) for FMD, because it has a maximum herd incidence of a restricted disease at less than 0.1 percent and has effective border control between other countries. If this rule is adopted, we expect Argentina to export up to 20,000 metric tons of fresh meat to the United States.

The changes in the regulations would be expected to mainly affect bovine meat and meat products (beef). Other livestock sectors that would be expected to be marginally affected are: swine, dairy, and the mutton/lamb/goat complex.

#### Analysis

**Beef:** The proposed regulation changes would relax the FMD- and rinderpest-related restrictions imposed on the importation of live cattle, bovine meat and prepared products from Argentina. This rule change would be expected to substantially alter beef imports from Argentina, since the United States has had restrictions on uncooked beef imports from Argentina since the 1930 Tariff Act. However, this analysis assumes that Argentine uncooked beef exports to the U.S. would not exceed their 20,000 MT tariff-rate quota limit. Future economic impact on U.S. beef producers would depend on demand-side factors, such as consumer acceptance of Argentine product, but also on whether the uncooked beef imports consist mainly of grass-fed beef as expected, and whether Argentina reaches or exceeds 20,000 MT's of uncooked beef shipments to the U.S. Recent speculation is that Argentina would most likely start with grass-fed beef product and attempt, over time, to produce product that would be suitable for the U.S. grain-fed beef market.

Argentine beef production is made up of mostly grass fed product. These animals take longer to reach slaughter weights and are lighter at slaughter than

cattle fed on grain. Most of the grass-fed meat production is suitable for low-quality uses in the United States. Selected cuts from grass-fed cattle could possibly classify as grain-fed beef.

With large present and potential beef production, Argentina is likely to increase its beef exports. With comparable or higher returns from chilled product (as compared with prepared product), trade sources suggest that sufficient economic incentive and product exists to encourage Argentina to fill (and possibly exceed) its 20,000 MT tariff-rate uncooked beef quota with the U.S. through increased production and/or diversion of current exports.

**Impact on U.S. Consumers:** Assuming Argentina fills its 20,000 MT beef tariff-rate quota limit in the U.S.'s uncooked beef market with grass-fed beef, consumer welfare gains of \$90 million annually are possible. Grass-fed beef is used mainly in "non-table-cut" beef applications, such as in hamburger meat patties, sausages, and other prepared meals and foods. This analysis assumes that 22 percent of U.S. beef consumption goes into such non-table-cut applications while 78 percent goes into consumer applications, such as table cut use at home and away-from-home eating that utilizes beef made from grain-fed beef. Grain-fed beef production dominates U.S. domestic beef production (87 percent). Thus, imports consisting of grass-fed beef affect consumer prices more than domestic producer prices because of grass-fed beef's higher quantity weight in consumption compared to production. When imports are assumed to consist mainly of grass-fed beef, consumers stand to gain almost \$90 million as average retail beef prices drop by \$8.27 per MT carcass weight equivalent (CWE).

**Impact on U.S. Livestock Sector:** Primary producers of livestock and beef products would be detrimentally affected by increased beef imports. The magnitude and the type of beef imported would determine the size and distribution of domestic producer welfare loss across the farm and secondary production levels. When imports are assumed to consist mainly of grass-fed beef, domestic producer welfare throughout the system is lowered by an estimated \$41 million (\$3.84/MT CWE).

Imports of Argentine, uncooked, grass-fed beef would be expected to dampen demand for low-quality beef (made from both culled beef and dairy cows), and force some of the domestic producer losses to be shared by both the U.S. dairy and beef sectors.

Although the aggregate domestic producer welfare losses would appear to be significant, total industry sales and the large number of operations make the per farm producer losses relatively small. Beef and dairy farms with annual sales of less than \$0.5 million are considered small according to Small Business Administration (SBA) size criteria. Recent Census data show that about 99.8 percent of operations with beef cows have herds with fewer than 1,000 head.<sup>3</sup> On average, these 801,940 operations had sales of under \$0.5 million while maintaining 92.9 percent of beef cow inventories. Farms with less than \$0.5 million of cattle and calves sales averaged sales of \$20,976 in 1992, as opposed to average sales of \$1.3 million on larger farms. Similarly for dairy operations, most producers fall in the "small" business category. Recent USDA data show that 95.6 percent of operations with milk cows have fewer than 200 head in their herds. Census data is available on farms with dairy product sales, but not by herd size. These data show that 95.2 percent of these farms have sales of less than \$0.5 million. Assuming that both data are tracking roughly the same dairy operations, we can deduce that 68.2 percent of milk cow inventories are on the 152,500 operations with sales of less than \$0.5 million and average dairy product sales of less than \$93,800 per farm in 1992. Besides the sale of dairy products, the sale of cull dairy cattle and young stock (not selected to be retained for milking or breeding purposes) contribute to farm income. USDA budget data for 1992 indicated that, on an average U.S. dairy operation, the sale of culled cattle contributed \$1.27 (around 8 percent) for every \$15.85 of receipts. Census data indicate that cattle sales contribute about \$8,000 toward gross farm sales on a small dairy farm (total sales average about \$102,000), also about 8 percent of total gross farm income.

Maximum per farm drops in producer gross sales would be expected to range from \$15 to \$35 for cow-calf beef operators. In either case, gross farm income would drop less than one-sixth of one percent. Expected maximum per farm percentage drops in dairy producer gross sales would be even lower than those for cow-calf beef operators.

**Impact on Feedlot Operators:** No quantity effect would be registered if imports consist of grass-fed beef. With increased imports of grass-fed beef, the increased market beef supplies would be expected to displace low-quality

<sup>3</sup> Source: 1992 US Census, Beef Cow Herd Size by Inventory and Sales: 1992, Table 28, pg. 30.

beef, mainly affecting dairy and beef cow-calf operations and indirectly affecting feedlots by reducing the number of cattle available to be placed on feed. This increased culling of dairy and beef cows would reduce the supply of beef calves and raise the prices for both yearlings and grain-fed cattle. Gains from output price increases (on grain-fed cattle) would be offset by losses incurred by price increases on purchased calves.<sup>4</sup> The net per head loss would be \$0.24. Such small losses would not be expected to substantially change production. The potential aggregate domestic feedlot operators' producer welfare loss is estimated at \$5.4 million with increased imports of grass-fed beef. This aggregate loss is expected to translate into less than a \$30 per year drop in gross sales on an average "small" feedlot (about a 0.03 percent drop).

*Impact on Live Cattle Dealers/Transporters:* Close estimation of the impact on this sub-sector is not possible given the available data. Because census data on transporters is in a general category with other agricultural product shipments, it is unclear how important cattle transportation is to a particular "small" firm's business. Additional data are also needed on average miles traveled and net returns per trip. However, it appears that there would be a negligible reduction in transporter trips needed due to this proposed rule—ranging from negligible if potential imports are assumed to be grass-fed beef, to less than 1,500 if potential imports are assumed to be grain-fed beef. A negligible increase in transport of imported meat and meat products from ports of arrival would be expected.

*Impact on Cattle Slaughterers/Primary Processors:* As in the case with cattle dealers/transporters, the reduction in cattle marketings would be expected to be very small in relation to current marketings. With increased beef imports consisting of grass-fed beef, slaughterers would receive virtually the same number of marketings, but enjoy lower priced culled beef and dairy cows while facing lower wholesale prices for their output. On average, the losses from lower retail grass-fed beef prices would be expected to almost equal the gains from price drops on purchased culled cows.

*Swine:* No significant impacts because of Argentine swine production and trade would be expected as a result of this proposed rule. Argentine swine production has declined considerably since the early 1990s. Pork imports into

Argentina during this period rose from 1,363 MT to 25,392 MT, while exports declined from 2,755 MT to 67 MT.

*Dairy:* With regards to the sale of dairy products, we do not anticipate a major increase in exports of milk and milk products from Argentina into the United States as a result of this proposed rule. Only about 5 percent of Argentina's cow herd is made up of dairy cows, and it is expected that the increase in beef cattle returns will not significantly alter this situation. In addition, all dairy products imported into the United States are restricted by quotas except for casein, caseinate, and other casein derivatives (hereafter referred to as casein), which are dry milk products. The United States does not produce casein. Argentina has not exported casein to the United States in recent years, and this proposed rule would be expected to have minimal if any effect on the amount of casein imported into the United States.

*Miscellaneous:* The United States has not imported any mutton, lamb, or goat meat from Argentina in the past 2 years. This situation would not be expected to change as a result of this proposed rule. Miscellaneous animal products from Argentina, including embryos, semen, breeding animals, and other products, are already allowed importation into the United States under certain restrictions. This proposed rule would lessen the restrictions on the importation of these products. We welcome information from the public regarding any potential impact this lessening of restrictions might have.

#### Imports From Mexico

It appears that the State of Sonora, Mexico would meet all the criteria in proposed § 92.3 to be classified as a Risk Class R1 region for hog cholera. The changes in the regulations would be expected to primarily affect feeder pigs, slaughter hogs, and pork products. No other livestock sectors are expected to be affected by the proposed classification of Sonora.

#### Analysis

The regulation changes would relax the hog cholera-related restrictions imposed on the importation of live swine and prepared pork products from Sonora, Mexico. This rule change could significantly alter current swine imports from Mexico. Based on various assumptions, some combination of Mexican live swine and/pork exports to the U.S. would be expected to take place.

Important assumptions are:

1. The production of live hogs in Sonora would be maintained at the current 1.5 million head level;

2. Twenty percent of total production would continue to be shipped out of the region live for slaughter and processing (currently most of these shipments go to Mexico City, some 1,500 miles away). The Los Angeles, California area is only 500 miles away and is currently receiving live slaughter hogs from other parts of the U.S., including the U.S. Midwest, making it a potentially attractive demand site for live slaughter hog shipments from Sonora;

3. The remaining 80 percent of production would be processed in Sonora with about 15 percent going as specialized pork cuts to Japan; the remaining 85 percent would be available for use in Mexico or shipment to the U.S.;

4. Current hog feeders in Mexico would be able to hedge on currency and commodity markets, so as to minimize short-run financial risk of exchange rate and feed price fluctuations. These instruments are not capable of shielding long-lasting currency devaluations, such as what has recently occurred in Mexico. Operations which require large amounts of imported feeds, such as hog feeding operations that rely on U.S. feedstuffs—bought with Mexican currency—are probably experiencing considerable financial difficulties. Such pressure, in the short term, may lead to cutbacks in Mexican production and/or trade from Mexico to the U.S. However, such devaluations would assist in the export of finished products from Mexico, such as live swine and processed pork products. Also, in the longer run, some appreciation of the Mexican peso is expected. Uncertainty as to when and what extent such appreciation will occur leads to the following assumption: The influence on Mexican production and trade due to exchange rate fluctuation is assumed to be neutral in this analysis;

5. 1994 US marketings of 95.697 million head of slaughter hogs at the average price of \$40.03 per CWT liveweight are used as the U.S. base year;

6. A low-impact scenario is constructed consisting of 75,000 live hogs and 18.6 million pounds carcass weight equivalent (CWE) of pork products. This assumes that one-quarter of current live slaughter hog shipments out of Sonora is diverted to the Southwest (mostly to Los Angeles), as well as about 10 percent of the processed pork production of Sonora. Imported swine and pork are assumed to substitute perfectly for U.S. product and displace it;

<sup>4</sup> Yearling prices go up more per head (\$0.64 per head) than for fed cattle (\$0.40 per head).

7. A high-impact scenario is constructed consisting of 300,000 live hogs and 92.9 million pounds carcass weight equivalent (CWE) of pork products. This assumes that all of current live hog shipments out of Sonora is diverted to the Southwest as well as about 50 percent of the processed pork production of Sonora. Again, imported swine and pork are assumed to perfectly substitute for U.S. product and displace it.

Future economic impact on U.S. swine producers will depend on demand-side factors, such as consumer acceptance of Mexican product, but probably most heavily on two supply-side factors—increases in total Mexican production and the composition of product shipped from Mexico. This supply effect will be heavily affected by the long-term exchange rate between the U.S. and Mexico. Composition of product will affect producer and consumer effects as follows:

1. If the weight of increased imports are in the form of feeder pigs, adverse economic impacts would be localized on feeder pig producers, not feed grain producers or slaughters/processors. Increased feed pig shipments could be particularly important in times of high feed costs in Mexico, such as occurs at times in the U.S. Southeast.

2. Live slaughter hog imports would be expected to directly displace U.S. produced hogs. For every four hogs or hog equivalents imported, one U.S. hog would be expected to be displaced and its economic contribution to slaughter and processing lost. Feed grain producers would experience some loss if Mexican producers do not rely on U.S. grain. However, it is possible that a greater amount of U.S. feed would be used if some amount of Mexican pork/swine is imported, given that Mexican hog producers use U.S. feedgrains. Activity at the slaughter/processor level would be increased with Mexican live hog slaughter imports.

3. The impact of pork product imports is difficult to forecast because of the uncertainty as to how they would substitute for foreign and/or domestic product. For example, certain Mexican pork imports might not affect U.S. producers at all. These imports might not substitute for a U.S.-produced pork product, or they might completely substitute for and displace a similar pork product currently imported from another country. In those cases where Mexican pork products would displace U.S. product, U.S. prices would decrease, U.S. production would decrease, and activity at the slaughter/processor level would drop.

*Impact on U.S. Consumers:* Assuming Mexico swine producers find it in their interest to ship swine and/or pork products to the U.S., consumer welfare gains of \$28 million (low-impact scenario) to \$150 million (high-impact scenario) annually would be possible depending on the volume and composition of imports from Mexico.

*Impact on U.S. Livestock Sector:* Primary producers of livestock and swine products would be detrimentally affected whether live slaughter hogs or pork product imports increase. When imports are assumed to be in the low-impact range, producer welfare throughout the system would be lowered by an estimated \$28 million (\$0.13/CWT CWE) as opposed to \$149 million (\$0.66/CWT CWE) when imports are assumed to be in the high-impact scenario. A further break-down of the potential impact on the U.S. livestock sector follows:

*Impact on Farrow-to-Finish Swine Operators:* Imports in the low-impact scenario are assumed to represent about 178,200 hogs per year in a combination of live slaughter hogs and pork product imports. Barrow and gilt slaughter hog prices would decrease by about 15 cents per CWT. This lower price would elicit a cut in total U.S. hog production of about 45,000 hogs per year. The lower production level at a slightly lower price would reduce producer receipts by about \$28 million per year.

When imports are assumed to fall in the high impact scenario, increased imports would be expected to represent up to 816,000 hogs per year in a combination of live slaughter hog and pork product imports. Barrow and gilt slaughter hog prices would be expected to decrease by about 66 cents per CWT. This lower price would elicit a cut in total US hog production of about 200,000 hogs per year. This lower production level, along with a lower price, would reduce producer receipts by about \$149 million per year.

Although the aggregate potential producer welfare losses appear significant, total industry sales and the large number of operations would make the per-farm producer losses relatively small. In 1992, there were about 191,347 hog and pig farms in the United States, of which it is estimated that about 96.4 percent would be considered "small" entities (annual sales of less than \$0.5 million, according to Small Business Administration (SBA) size criteria). Total value of hog inventories on December 1992 exceeded \$4,146.6 million, producing \$9.9 billion in sales. The small hog and pig entities maintain over 70 percent of these hog and pig inventories. Historical U.S. data show

declining farm numbers (but almost stable production) and persistent competitive pressure on producers to adopt least-cost production methods to the extent available. Dividing the adjusted aggregate economic impact generated under the two scenarios listed above (low- and high-impact scenarios) by the number of small swine operations results in a potential loss in net annual farm income of almost \$154 and \$808, respectively.

*Impact on Live Hog Dealers/Transporters:* Reductions in the number of hogs produced in the United States as a result of imports under either the low- or high-impact scenario would be expected to be minimal—225 and 1,035 less trips, respectively. The impact of the worst case scenario represents less than .2 percent of total hauls of US hog shipments in 1994.

Most firms in this industry are considered "small" according to SBA guidelines (i.e., sales of less than \$12.5 million and fewer than 500 employees). Firms in this industry are assumed to be classified in the general Census category, motor freight transportation and warehousing (SIC 4212 and SIC 4213) with over 10,600 firms in 1992. SIC 4212 pt. (other local trucking, without storage, of agricultural products) contained 6,203 establishments with \$2.197 billion in revenue in 1992 and employed 26,897 employees. The average firm revenue was \$354,183, with employment of 4 to 5 workers. Thus, the average firm in the industry would fall under the SBA category of "small" with sales of less than \$12.5 million and less than 500 employees. SIC 4213 pt. (trucking, except local, of agricultural products) contained 4,483 establishments with \$3.3 billion in revenue in 1992 and employed 30,518 employees. The average firm revenue was \$736,114, with employment of 6 to 7 workers. Thus, the average firm in the industry would fall under the SBA category of "small," with sales of less than \$12.5 million and less than 500 employees. More detailed data on the actual distribution of firms by size are not available at this time.

Estimation of the potential impact on this sub-sector is not possible given the available data. Census data on transporters is in a general category with other agricultural product shipments, thus it is unclear how important livestock transportation is to a particular "small" firm's business. Additional data are also needed concerning average miles traveled and net returns per trip. The relatively small reductions in trips needed suggest that the economic impact on this sub-sector would

probably be very small. Further, if we assume that these reductions would be expected to fall evenly across all firms, this reduced level of economic activity is not expected to drive any small livestock dealers/transporters out of business. Some increase in transport of swine or pork products from ports of arrival would be expected.

*Impact on Swine Slaughterers/Primary Processors:* As was the case with livestock dealers/transporters, the reduction in swine marketings would be very small in relation to current marketings. However, it should be kept in mind that hog slaughterers and processors would benefit if imports consist of higher proportions of live hogs relative to processed pork. Under the two scenarios considered, increased slaughter (brought about by increased slaughter hog imports) would more than offset production losses from processed pork product imports. In the low-impact scenario, processors would realize a net increase of 30,000 slaughter hogs. Under the high-impact scenario, an increase of 93,000 slaughter hogs appears possible.

The size distribution of firms in this sub-sector makes it difficult to allocate the small benefits estimated above across large and small firms. In the past, the desire to reduce transportation costs of cattle and product, to gain economies of scale in plant operations, and to shift to newer plants (without existing labor contracts) has led to increased industry concentration in this U.S. sub-sector. The exit of many older, smaller plants and companies have also contributed to increased market concentration. Most firms have multi-million dollar operations made up of new, large, state-of-the-art slaughter and packing plants. In 1992, there were 1,385 meat packing establishments in the U.S. down from 1,434 such establishments in 1987.<sup>5</sup> The 1987 data indicate that 88 pork-slaughter companies had more than 20 employees. These companies had a total of 34,300 employees, with a payroll of \$713.8 million and shipments of pork valued at \$11.6 billion.

#### Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

<sup>5</sup>Source: 1992 Census of Manufacturers, MC92-SUM-1(P), Preliminary Report, Summary Series, pg. 9.

#### Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 94-106-1. Please send a copy of your comments to: (1) Docket No. 94-106-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1228, and (2) Clearance Officer, OIRM, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of the proposed rule.

This proposed rule contains paperwork and recordkeeping requirements. Under this proposed rule, officials in foreign countries that wish to have a region recognized and classified by APHIS would be required to submit an application, along with data supporting their request for a specific classification. This rule would necessitate the introduction of various information collection requirements to enable us to monitor accurately the health status of regions and the movement of animals and animal products from those regions into the United States. We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. We need this outside input to help us accomplish the following:

- (1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;
- (2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission responses).

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 7 hours and 4.5 minutes per response for animal importations and 27 minutes per response for animal product importations.

*Respondents:* Importers and veterinarians.

*Estimated number of respondents (for animal importations):* 208,065 total (30,030 of which would be new respondents as a result of our rulemaking).

*Estimated number of respondents (for animal product importations):* 8,955 total (1,829 of which would be new respondents as a result of our rulemaking).

*Estimated number of responses per respondent (for animal importations):* 8.158.

*Estimated number of responses per respondent (for animal product importations):* 11.64.

*Estimated total annual burden on respondents (for animal importations):* 241,067 hours (178,684 of which would be new hours due to our rulemaking).

*Estimated total annual burden on respondents (for animal product importations):* 47,080 hours (15,926 of which would be new hours due to our rulemaking).

Copies of this information collection can be obtained from: Clearance Officer, OIRM, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250.

#### National Environmental Policy Act

This proposed rule raises some issues that could include potential environmental impacts. Such issues are being examined by APHIS in the context of an environmental assessment (EA). We invite comments from the public on this proposed rule, including those regarding potential environmental impacts. Prior to, or in conjunction with, a final rule, APHIS will issue an EA addressing such issues in accordance with: (1) The National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), (2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500-1508), (3) USDA Regulations Implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

#### Unfunded Mandate Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local,

and tribal governments and the private sector. Under section 202 of the UMRA, APHIS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, or tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires APHIS to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule.

This proposed rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) that may result in expenditures to State local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Thus, this proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA.

#### List of Subjects

##### 9 CFR Part 92

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

##### 9 CFR Part 93

Animal diseases, Imports, Reporting and recordkeeping requirements.

##### 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

##### 9 CFR Part 95

Animal feeds, Hay, Imports, Livestock, Reporting and recordkeeping requirements, Straw, Transportation.

##### 9 CFR Part 96

Imports, Livestock, Reporting and recordkeeping requirements.

##### 9 CFR Part 98

Animal diseases, Imports.

Accordingly, under the authority provided in 7 U.S.C. 147a, 150ee, 161, 162, 450, 1622; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, 136a; 31 U.S.C. 9701; 42 U.S.C. 4331, and 4332, we propose to amend 9 CFR chapter I, subchapter D, as follows:

## PARTS 92 AND 93—[AMENDED]

### §§ 93.1–93.8 [Redesignated as §§ 92.800–92.807]

1. Part 93 would be amended by removing the heading and the authority citation and by redesignating §§ 93.1 through 93.8 as §§ 92.800 through 92.807, and adding a subpart heading before these sections to read: "Subpart H—Elephants, Hippopotami, Rhinoceroses, and Tapirs".

### PART 92—[REDESIGNATED AS PART 93]

2. Part 92 would be redesignated as part 93.

3. A new part 92 would be added to read as follows:

### PART 92—RESTRICTED AGENTS AND VECTORS, AND CRITERIA FOR REGIONAL RISK CLASSIFICATION

#### Sec.

92.1 Definitions.

92.2 Restricted agents and vectors.

92.3 Criteria for risk classification.

92.4 Risk classification by region and restricted disease agent.

92.5 Application for recognition of Risk Class RN, R1, R2, R3, or R4.

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d).

#### § 92.1 Definitions.

Wherever in this subpart the following terms are used, unless the context otherwise requires, they shall be construed, respectively, to mean:

**Active surveillance.** Sample collection using a systematic or statistically designed survey methodology to actively seek out and find cases of animals with a disease agent, or to determine the prevalence of the disease agent in the population.

**Adjacent region.** Any defined geographic land area identifiable by geological, political or surveyed boundaries that shares common boundaries with, or is proximate to any region of a different risk class, as determined by the Administrator.

**Administrator.** The Administrator of the Animal and Plant Health Inspection Service or any other employee of the Animal and Plant Health Inspection Service, United States Department of Agriculture, delegated to act in the Administrator's stead.

**Affected animals.** Animals currently infected or infested with, or exposed to, a communicable disease agent, or that are not known to be infected, infested, or exposed but that because of, proximity, location, season, or lack of surveillance data could reasonably be

expected to be infected, infested, or exposed to a communicable disease agent.

**Affected premises or region.** A premises or region where a communicable disease agent is known to exist; that is adjacent to or proximate to any known infected or infested premises or region so that airborne, vector, or mechanical transmission of the disease agent could occur; or that, because of lack of surveillance data, could reasonably be expected to be infected, infested, or exposed to a communicable disease agent.

**Africa.** The continent of Africa including the countries of: Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cent. African Rep., Chad, Comoros, Congo, Djibouti, Egypt, Equatorial Guinea, Ethiopia, Gabon, Ghana, Guinea, Guinea-Bissau, Ivory Coast, Kenya, Lesotho, Liberia, Libya, Madagascar, Malawi, Mali, Mauritania, Morocco, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Princip, Senegal, Sierra Leone, Somalia, South Africa, Sudan, Swaziland, Tanzania, The Gambia, Togo, Tunisia, Uganda, Western Sahara, Zaire, Zambia, Zimbabwe.

**Animal and Plant Health Inspection Service (APHIS).** The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

**Animals.** All species of the animal kingdom including: Cattle, sheep, goats, other ruminants, swine, horses, asses, mules, zebras, dogs, and poultry that are susceptible to communicable diseases of livestock or capable of being carriers of those diseases or their arthropod vectors.

**APHIS representative.** Any individual employed by the Animal and Plant Health Inspection Service, United States Department of Agriculture, who is authorized to perform the services required by this part.

**Asia.** Part of the continent of Asia, including the countries of: Afghanistan, Armenia, Azerbaijan, Bangladesh, Bhutan, Burma, Cambodia, China, Georgia, Hong Kong, India, Iran, Japan, Kazakhstan, Kyrgyzstan, Laos, Macau, Malaysia, Mongolia, Nepal, North Korea, Pakistan, Russia, Singapore, South Korea, Sri Lanka, Taiwan, Tajikistan, Thailand, Turkistan, Uzbekistan, Vietnam.

**Atlantic.** Island countries located in the Atlantic Ocean including: Bermuda, Cape Verde, Falkland Islands, South Georgia.

**Australia.** The continent of Australia including the country of Australia.

#### Border definitions.

##### (1) Natural physical barriers:



(i) Rivers, lakes or oceans with all crossing points such as bridges, ferries, or ports identified as controlled entry points;

(ii) Mountains with all crossing points (passes, etc.) identified as officially controlled entry points.

(2) *Man-made physical barriers.* Constructed fences, walls, moats, etc., that prevent animals from straying or being transported, trailed, or driven across the borders except at officially controlled entry points.

(3) *Protected borders:* Border areas that are identifiable geo-political boundaries between adjacent geographic regions. Protected border areas may be separated by man-made physical barriers with all gates or crossings identified as officially controlled entry points. Animals shall cross only at officially controlled entry points.

(4) *Uncontrolled borders:* Animals may cross unchecked at any point along the border.

(5) *Officially controlled entry points:* Land border check stations, airports, ship ports or other points of entry where animals or animal products may enter a region from any other region, but at which animals and animal products are barred from entry at all times that the entry points are not staffed.

*Caribbean.* The islands of the Caribbean Sea and nearby areas in the Atlantic Ocean including the countries and territories of: Anguilla, Aruba, Barbados, British Virgin Islands, Cayman Islands, Cuba, Dominica, Dominican Republic, Grenada, Guadeloupe, Haiti, Jamaica, Martinique, Montserrat, Netherlands Antilles, Puerto Rico, Saint Lucia, Saint Vincent, The Bahamas, The Bahamas, Trinidad and Tobago, Turks and Caicos, U.S. Virgin Islands.

*Case.* An individual animal affected by a communicable disease agent. Depending on the condition, this may be an animal with clinical signs, or an animal with serological or pathological evidence of infection, or an infested animal.

*Cattle.* Animals of the bovine species. *Communicable disease.* Any contagious or infectious disease of animals. It can be transmitted either directly or indirectly to a susceptible animal from an infected animal, vector, inanimate source, or other sources.

*Contact.* (1) For animals, being in the same pen, pasture or means of conveyance with animals affected with a communicable disease, or being located in pens, pastures, or means of conveyance that are adjacent to, adjoin or otherwise come into contact with those containing animals affected with a communicable disease.

(2) For premises or regions, having on or within the premises or region, animals, feed, water, air, soil, tools or other objects, insects, or ectoparasites infected or contaminated with a communicable disease agent.

*Contagious disease.* Any communicable disease transmitted from one animal to another by direct contact or by feed, water, aerosol, or contaminated objects.

*Driven.* Moved (animals) from one place to another by walking under their own power and being herded and guided by persons or trained animals.

*Ectoparasites.* Acarid (mites, ticks) or insect members of the Phylum Arthropoda that spend all or part of their life cycle on the exterior of avian, reptilian or mammalian hosts, and that are known or suspected to be vectors of communicable disease agents or are the cause of disease or irritation to animals or birds.

*Europe.* The continent of Europe including the countries of: Albania, Andorra, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Byelorussia, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Gibraltar, Greece, Greenland, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Moldavia, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, United Kingdom (England, Scotland, Wales, Northern Ireland, Channel Islands, Isle of Man), Vatican City, Yugoslavia.

*Exposed.* (1) An animal or means of conveyance that has been in contact with or that can reasonably be expected to have been in contact with an animal, feed, water, air, soil, tools, or other objects, insects, or ectoparasites infected or contaminated with a communicable disease agent, as determined by the Administrator.

(2) A region or premises where an animal, feed, water, air, soil, tools or other objects, insects, or ectoparasites contaminated with a communicable disease agent are or have been present.

(i) *Direct exposure.* Exposure by coming into direct contact with an infected animal, or with feed, water, air, soil, tools, or other objects that have been contaminated by discharges from an infected animal.

(ii) *Indirect exposure.* Exposure by coming into contact with vector insects or ectoparasites, or objects that have been contaminated other than by discharge from an infected animal.

*Herd.* (1) A group of animals under common ownership or supervision that are maintained and intermingle on one

or more parts of a single premises (farm, ranch, feedlot, etc.); or

(2) A group of animals under common ownership or supervision maintained on geographically separated premises, but that have been interchanged between the different premises or have been otherwise intermingled.

*Herd incidence rate.* The proportion of herds, flocks or other groups of animals affected with a communicable disease within a specified period of time (usually 1 year). A herd, flock, or other group of animals would be counted only once during the specified time period regardless of the number of cases that may occur in the group of animals during the time period.

*Import (imported, importation) into the United States.* To bring into the territorial limits of the United States.

*Livestock.* Domesticated species of cattle, swine, sheep, goats, llamas, or horses that normally and historically have been kept and raised on farms. "Livestock" also includes bison, cervidae, and other species kept in captivity for production of food or fiber, or other commercial purposes.

*Middle America.* Part of the continent of North America including the countries of: Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama.

*Middle East.* Parts of the continent of Asia and islands of the Mediterranean Sea, including the countries of: Bahrain, Cyprus, Iraq, Israel, Jordan, Kuwait, Lebanon, Malta, North Yemen, Oman, Palestine, Qatar, Saudi Arabia, South Yemen, Syria, Turkey, United Arab Emirates.

*Moved directly.* Moved (shipped, transported, or otherwise moved) without unloading and without stopping except for refueling, or for traffic conditions such as traffic lights or stop signs.

*New Zealand.* The islands that comprise the country of New Zealand.

*North America.* Part of the continent of North America including the countries of Canada, Mexico, United States.

*Oceania.* Islands of the Pacific and Indian Oceans including the countries of: Brunei, Fiji, French Polynesia, Indonesia, Kiribati, Maldives, Mauritius, Nauru, New Caledonia, Papua New Guinea, Philippines, Seychelles, Solomon Islands, Tonga, Vanuatu, Western Samoa.

*Passive surveillance.* A surveillance system that does not depend on active participation by the responsible agency to seek out and monitor a restricted disease agent. The system relies on mandatory reporting, a pool of trained investigators, diagnostic submission

procedures and laboratory support, and periodic public information and continuing education programs on diseases.

**Person.** Any individual, corporation, company, association, firm, partnership, society, joint stock company, or other legal entity.

**Provisional quarantine.** Restrictions placed on movements of vaccinated livestock where the restricted agent in question is not known to exist, but the livestock may be exposed. Limited movement may be allowed from such a premises for livestock to go directly to slaughter or to a slaughter animal assembly point, or, in the case of vaccinated livestock not known to be affected, the animals may be moved to affected regions or regions that permit vaccination.

**Quarantine.** Confinement of all susceptible animals, animal products, feed, farm machinery, other equipment, means of conveyance, and any other potentially contaminated objects to a premises or region where infection with a specific restricted agent has been found or is suspected to exist.

**Region.** Any defined geographic land region identifiable by geological, political or surveyed boundaries. A region may consist of any of the following:

- (1) A national entity (country);
- (2) Part of a national entity (premises, zone, County, Department, Municipality, Parish, Province, State, etc.);
- (3) Parts of several national entities combined into a region; or
- (4) A group of national entities (countries) combined into a single trading block.

**Restricted agent.** A livestock communicable disease agent, vector, or host of an agent, not known to exist in the United States or that is subject to a Federal or cooperative Federal/State control or eradication program within the United States.

**Risk Class regions.** Exporting regions designated by the Administrator according to the results of qualitative or quantitative risk assessment criteria, as set forth in § 92.3, based on the risk of importing a restricted agent by unrestricted importation of live animals. Exporting regions will be classified into one of the following risk classes:

(1) **Risk Class RN (Negligible Risk).** A Risk Class RN region is not known to be affected with a restricted agent, and is physically isolated from any region known to be affected with a restricted agent. The probability in a Quantitative Risk Assessment of the introduction of a restricted agent through an unrestricted importation from a Risk

Class RN region is less than  $10^{-6}$  per live animal.

(2) **Risk Class R1 Region (Slight Risk).** A Risk Class R1 region is not known to be affected with a restricted agent. The probability in a Quantitative Risk Assessment of the introduction of a restricted agent through an unrestricted importation from a Risk Class R1 region is less than  $10^{-5}$  per live animal.

(3) **Risk Class R2 Region (Low Risk).** A Risk Class R2 region is not known to be affected with a restricted agent. The probability in a Quantitative Risk Assessment of the introduction of a restricted agent through an unrestricted importation from a Risk Class R2 region is less than  $10^{-4}$  per live animal.

(4) **Risk Class R3 Region (Moderate Risk).** A Risk Class R3 region is currently known to be affected with a restricted agent. The probability in a Quantitative Risk Assessment of the introduction of a restricted agent through an unrestricted importation from a Risk Class R3 region is less than  $10^{-3}$  per live animal.

(5) **Risk Class R4 Region (High Risk).** A Risk Class R4 region is currently known to be affected with a restricted agent. The probability in a Quantitative Risk Assessment of the introduction of a restricted agent through an unrestricted importation from a Risk Class R4 region is less than  $10^{-2}$  per live animal.

(6) **Risk Class RU Region (Unknown Risk).** A Risk Class RU region is an unclassified region that, due to lack of reliable information or other reasons, does not meet the requirements of any of the above classifications. The probability in a Quantitative Risk Assessment of the introduction of a restricted agent through an unrestricted importation is greater than  $10^{-2}$  per live animal or unknown.

**Ruminants.** All animals that chew the cud, such as cattle, buffaloes, sheep, goats, deer, antelopes, camels, llamas and giraffes.

**South America.** The continent of South America including the countries of: Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, French Guiana, Guyana, Paraguay, Peru, Suriname, Uruguay, Venezuela.

**Surveillance.** Systems to find, monitor, and confirm the existence or absence of a disease agent or agents in livestock, poultry and other animals. Surveillance may be passive or active.

**Susceptible animals.** Animals that can become infected with a specific disease agent.

**Swine.** The domestic hog and all varieties of wild hogs.

**Trail.** Move animals from one place to another by having them walk under

their own power, and by leading them by ropes or other devices tied to the animal and guided by persons or trained animals.

**Transported.** Moved or shipped from one place to another by means of aircraft, truck, train, cart, or other means of conveyance.

**United States.** All of the States of the United States, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other Territories and Possessions of the United States.

**Vector-borne disease.** A disease transmitted to an animal through an intermediate arthropod vector, including ticks or insects.

## § 92.2 Restricted agents and vectors.

(a) **Restricted contagious disease agents that affect livestock or poultry and that are not known to exist in the United States.**

African swine fever virus  
Bovine spongiform encephalopathy (BSE) agent  
*Brucella melitensis*  
Contagious agalactia of sheep and goats (*Mycoplasma agalactiae*)  
Contagious bovine pleuropneumonia (*Mycoplasma mycoides* subsp. *mycoides*)  
Contagious caprine pleuropneumonia (*Mycoplasma mycoides* subsp. *capri*)  
Foot-and-mouth disease virus  
Goat pox virus  
Hog Cholera (Classical swine fever) virus  
Malignant catarrhal fever virus (African or Wildebeest form)  
Peste des petits ruminants (Kata) virus  
*Pseudomonas pseudomallei* (melioidosis)  
Rinderpest virus  
Sheep pox virus  
Swine vesicular disease virus  
Teschen disease virus  
Vesicular Stomatitis virus

(b) **Restricted contagious disease agents that affect livestock and that exist in the United States, but that are subject to cooperative Federal/State control or eradication programs:**

*Brucella abortus* (brucellosis or Bangs disease)  
*Brucella suis*  
*Mycobacterium bovis* (bovine tuberculosis)  
Pseudorabies virus  
Scrapie disease agent

(c) **Restricted ectoparasites.** The following ectoparasites of animals are not known to exist in the United States or are subject to cooperative Federal/State control programs in the United States:

(1) **Ticks.**  
*Amblyomma astrion*  
*A. cohaerens*  
*A. gemma*  
*A. hebraeum*  
*A. javanense*  
*A. lepidum*

*A. marmoreum*  
*A. pomposum*  
*A. sparsum*  
*A. testudinarium*  
*A. tholloni*  
*A. variegatum*  
*Boophilus annulatus*  
*B. decoloratus*  
*B. florum*  
*B. geigy*  
*B. kohlsi*  
*B. microplus*  
*Dermacentor daghestanicus*  
*D. marginatus*  
*D. nuttalli*  
*D. pictus*  
*D. reticulatus*  
*D. silvarium*  
*Haemaphysalis bispinosa*  
*H. leachii*  
*H. longicornis*  
*H. otophila*  
*H. punctata*  
*H. sulcata*  
*Hyalomma anatolicum anatolicum*  
*H. anatolicum excavatum*  
*H. detritum*  
*H. dromedarii*  
*H. marginatum marginatum*  
*H. marginatum rufipes*  
*H. marginatum turanicum*  
*H. scupense*  
*H. truncatum*  
*Ixodes persulcatus*  
*I. pilosus*  
*I. ricinus*  
*Onithodoros erraticus*  
*O. moubata*  
*O. moubata porcinus*  
*Rhipicephalus appendiculatus*  
*R. bursa*  
*R. capensis*  
*R. compositus*  
*R. evertsi evertsi*  
*R. evertsi mimeticus*  
*R. glabroscutatum*  
*R. kochi*  
*R. lunulatus*  
*R. pulchellus*  
*R. simus*  
*R. turanicus*  
*R. zambeziensis*

(2) *Mites.*

*Chorioptes bovis*, various subspecies of which cause mange in horses, cattle, and sheep.  
*Psorergates ovis*, the causative agent of sheep scabies.  
*Psoroptes cuniculi*, the causative agent of ear mange in goats and rabbits.  
*P. ovis*, various subspecies of which cause Common scabies in sheep, cattle, and horses.  
*Sarcoptes scabiei*, various subspecies of which cause scabies and mange in horses, cattle, sheep, and swine.

(3) *Insects.*

*Chrysomya bezziana* (Old world screwworm)  
*Cochliomyia hominivorax (Callitroga americana)* (New world screwworm)  
*Hippobosca* spp. and *Lipoptema* spp. (louse flies)

(d) *Restricted vector-borne disease agents that affect animals and that are not known to exist in the United States but which could be transmitted by native vectors in the United States.*

(1) *Tick-borne agents.*

Bovine petechial fever (Ondiri disease) due to *(Cytoecetes) ondiri*  
 Congo (Crimean Hemorrhagic Disease) virus  
 Heartwater due to *Cowdria ruminantium*  
 Jembrana (Tabanan) virus  
 Nairobi sheep disease (Dugbe, Ganjam) virus  
*Theileria* spp. (east coast fever, corridor disease, Mediterranean fever)  
 Tick-borne encephalitis (louping ill, Central European encephalitis) virus  
 Tick-borne fever due to *Erllichia (Cytoecetes) phagocytophilia*

(2) *Insect-transmitted agents.*

African (salivarian- or tsetse-transmitted) *Trypanosoma* spp. (*T. brucei*, *T. congolense*, *T. evansi*, *T. suis*, *T. simiae*, *T. uniforme*, *T. vivax*)  
 Aino virus  
 Akabane virus  
*Besnoitia besnoiti* (globidiosis)  
 Bluetongue virus (except serotypes 10, 11, 13 and 17)  
 Bovine ephemeral fever group (Kotonkan, Obodhiang) virus  
 Epizootic hemorrhagic disease of deer (Ibaraki) virus (except serotypes 1 and 2)  
 Getah virus  
 Japanese encephalitis virus  
 Lumpy Skin disease virus  
 Parafilariosis due to *Parafilaria bovicola*  
 Rift Valley fever virus  
*Trypanosoma* spp. transmitted by vectors other than tsetse flies (NTT-Trypanosomas)  
 Wesselsbron virus

(e) *Other agents affecting domestic livestock.*

*Taenia (Multiceps) multiceps* (dog tapeworm) in livestock handling dogs

**§ 92.3 Criteria for risk classification.**

(a) *Risk Class RN Region (Negligible Risk).* A Risk Class RN region must meet either the provisions of paragraphs (a)(1)(i) through (a)(1)(viii) of this section or the provisions of paragraph (a)(2) of this section, and, if applicable, the provisions of paragraph (a)(3) of this section.

(1)(i) The restricted agent has not been diagnosed within the region during the lifetime of any currently living susceptible animal;

(ii) The restricted agent is not known to exist within any adjacent defined region;

(iii) Vaccination for the restricted agent has been prohibited within the region during the lifetime of any currently living susceptible animal (exceptions may be made for certain diseases such as vector-transmitted diseases, or animals specifically vaccinated to meet import requirements of other regions, when the

Administrator determines that such vaccination would not increase the risk of importing restricted agents into the United States);

(iv) Any adjacent R1 or R2 regions for the restricted agent are separated by natural or man-made physical barriers or protected borders;

(v) All border access points from adjacent R1 or R2 regions for the restricted agent are controlled to prevent movement of susceptible animals or animal products from the adjacent regions except under conditions that have been reviewed and approved by the Administrator;

(vi) Movement of animals and animal products into the region from R1, R2, R3, R4 or RU regions for the restricted agent is done only under conditions that have been reviewed by the Administrator and that have been determined to achieve the same level of biosecurity as required for importations from R1, R2, R3, R4, or RU regions into the United States;

(vii) The region maintains a passive surveillance system to detect restricted agents in a timely fashion, as determined by the Administrator; and  
 (viii) The region maintains policies and infrastructure to respond to any occurrences of a restricted agent.

(2) The region or country requesting Risk Class RN classification submits a quantitative risk assessment that is determined by the Administrator to be scientifically valid and to demonstrate that fewer than 1 per 1 million ( $1 \times 10^{-6}$ ) live animals in the region would be expected to be affected with the restricted agent.

(3) A region previously classified as Risk Class RN that has an occurrence of the restricted agent may be reclassified as Risk Class RN 3 years after all known infected and exposed reservoirs of the disease in the region have been eliminated.

(b) *Risk Class R1 Region (Slight Risk).* A Risk Class R1 region must meet either the provisions of paragraphs (b)(1)(i) through (b)(1)(ix) of this section or the provisions of paragraph (b)(2) of this section, and, if applicable, the provisions of paragraph (b)(3) of this section.

(1)(i) Except for BSE, the restricted agent has not been diagnosed within the region within the past 5 years;

(ii) For BSE, no cases have been diagnosed in the region within the last 10 years;

(iii) Vaccination for the restricted agent is prohibited within the region (exceptions may be made for certain restricted agents such as vector transmitted diseases or for animals specifically vaccinated to meet import

requirements of other regions, when the Administrator determines that such vaccination would not increase the risk of importing restricted agents into the United States);

(iv) Any animals previously vaccinated against the disease have been slaughtered or moved out of the region, or are under provisional quarantine (exceptions may be made for certain restricted agents such as vector-transmitted diseases or animals specifically vaccinated to meet import requirements of other regions, when the Administrator determines that such vaccination would not increase the risk of importing restricted agents into the United States);

(v) Any adjacent R2, R3, R4 or RU regions for the restricted agent are separated by natural or man-made physical barriers or protected borders;

(vi) All border access points from adjacent R2, R3, R4 or RU regions for the restricted agent are strictly controlled to prevent movement of susceptible animals or animal products from the adjacent regions, except under conditions that have been reviewed and approved by the Administrator;

(vii) Movement of animals and animal products into the region from R2, R3, R4 or RU regions for the restricted agent is done only under conditions that have been reviewed by the Administrator and have been determined to achieve the same level of biosecurity as required for importation from R2, R3, R4, or RU regions into the United States;

(viii) The region maintains passive and active surveillance systems to detect restricted agents in a timely fashion, as determined by the Administrator; and

(ix) The region maintains policies and infrastructure to respond to any occurrences of a restricted agent.

(2) The region or country requesting Risk Class R1 classification submits a quantitative risk assessment that is determined by the Administrator to be scientifically valid and to demonstrate that fewer than 1 per 100,000 ( $1 \times 10^{-5}$ ) live animals in the region would be expected to be affected with the restricted agent.

(3) A region previously classified as Risk Class RN or R1 that has an occurrence of a restricted agent may be reclassified as R1 2 years after all known infected and exposed reservoirs of the restricted agent in the region have been eliminated.

(c) *Risk Class R2 Region (Low Risk)*. A Risk Class R2 region must meet either the provisions of paragraphs (c)(1)(i) through (c)(1)(viii) of this section or the provisions of paragraph (c)(2) of this section.

(1)(i) Except for BSE or scrapie, the restricted agent has not been diagnosed within the region during the past year and the maximum annual herd incidence of the restricted agent over the past 5 years is less than 0.1 percent;

(ii) For BSE and scrapie, there have been no cases of the disease during the past 5 years;

(iii) Vaccination for the restricted agent is prohibited within the region or is limited to those herds that are at greatest risk of exposure from animals from affected regions (exceptions may be made for certain diseases such as vector-transmitted diseases or animals specifically vaccinated to meet import requirements of other regions, when the Administrator determines that such vaccination would not increase the risk of importing restricted agents into the United States);

(iv) Any adjacent R3, R4 or RU regions for the restricted agent are separated by natural or man-made physical barriers, or protected borders;

(v) All border access points from adjacent R3, R4 or RU regions for the restricted agent are controlled to prevent movement of susceptible animals or animal products from the adjacent regions except under conditions that have been reviewed and approved by the Administrator;

(vi) Movement of animals and animal products into the region from R3, R4 or RU regions for the restricted agent is done only under conditions that have been reviewed by the Administrator and that have been determined to achieve the same level of biosecurity as required for importation from R3, R4, or RU regions into the United States;

(vii) The region maintains passive and active surveillance systems to detect the restricted agent in a timely fashion, as determined by the Administrator; and

(viii) The region maintains policies and infrastructure to respond to any occurrences of the restricted agent.

(2) The region or country requesting Risk Class R2 classification submits a quantitative risk assessment that is determined by the Administrator to be scientifically valid and to demonstrate that fewer than 1 per 10,000 ( $1 \times 10^{-4}$ ) live animals in the region would be expected to be affected with the restricted agent.

(d) *Risk Class R3 Region (Moderate Risk)*. A Risk Class R3 region must meet either the provisions of paragraphs (d)(1)(i) through (d)(1)(viii) of this section or the provisions of paragraph (d)(2) of this section.

(1)(i) The restricted agent has been diagnosed within the region during the past year, but the annual herd incidence

of the disease over the past 5 years has not exceeded 0.1 percent;

(ii) An active control program with a goal of eradication for the restricted agent is in operation in the region;

(iii) Vaccination for the restricted agent is currently limited to those herds at greatest risk of infection (exceptions may be made for certain diseases, such as vector-transmitted diseases, or for animals specifically vaccinated to meet import requirements of other regions, when the Administrator determines that such vaccination would not increase the risk of importing restricted agents into the United States);

(iv) Any adjacent R4 or RU regions for the restricted agent are separated by natural or man-made physical barriers or protected borders;

(v) All border access points from adjacent R3, R4 or RU regions for the restricted agent are strictly controlled to prevent movement of susceptible animals or animal products from the adjacent regions except under conditions that have been reviewed and approved by the Administrator;

(vi) Movement of animals and animal products into the region is done only under conditions that have been reviewed by the Administrator and that have been determined to achieve the same level of biosecurity as required for importation from R4 or RU regions into the United States;

(vii) The region maintains passive and active surveillance systems to detect the restricted agent in a timely fashion, as determined by the Administrator; and

(viii) The region maintains policies and infrastructure to eliminate any outbreaks of the restricted agent that may occur.

(2) The region or country requesting Risk Class R3 classification submits a quantitative risk assessment that is determined by the Administrator to be scientifically valid and to demonstrate that fewer than 1 per 1,000 ( $1 \times 10^{-3}$ ) live animals in the region would be expected to be affected with the restricted agent.

(e) *Risk Class R4 Region (High Risk)*. A Risk Class R4 region must meet either the provisions of paragraphs (e)(1)(i) through (e)(1)(vi) of this section or the provisions of paragraph (e)(2) of this section. (1)(i) A restricted agent has been diagnosed within the region within the past year and the annual herd incidence of the disease over the past 5 years may have exceeded 0.1 percent in 1 or more years or is unknown;

(ii) A control program for restricted agents may be in operation in the region but does not meet the minimum standards for a Risk Class R3 region;

(iii) Vaccination for the restricted agent may vary from herd to herd. If

vaccination is used as the primary control procedure, at least 80 percent of the livestock in 80 percent of the herds must be vaccinated as often as recommended by the manufacturers of the vaccine;

(iv) Movement of animals and animal products into the region may not be adequately controlled from regions that are Risk Class R3, R4, or RU for the restricted agent;

(v) The region maintains a passive and active surveillance system for the restricted agent at a level that may not fully meet standards for a Risk Class R3 region; and

(vi) The region maintains policies and infrastructure to effectively control and restrict spread of any outbreaks of the restricted agent that may occur.

(2) The region or country requesting Risk Class R4 classification submits a quantitative risk assessment that is determined by the Administrator to be scientifically valid and to demonstrate that fewer than 1 per 100 ( $1 \times 10^{-2}$ ) live animals in the region would be expected to be affected with the restricted agent.

(f) *Risk Class RU Region (Unknown Risk)*. A Risk Class RU region will be classified using the following criteria:

(1) All countries and regions of the world that do not have specific classification as Risk Class RN, R1, R2, R3 or R4, and that have not been previously designated as a country not affected with a restricted agent will be classified as an RU region.

(2) Any region classified in this part as an RU region for any restricted agents of livestock may request classification as an RN, R1, R2, R3, or R4 region. All requests for reclassification will be

reviewed and acted upon according to the procedures set forth in § 92.5.

#### § 92.4 Risk classification by region and restricted disease agent.

(a) *Risk classification by region.*

Abbreviations used:

AIN = Aino virus

AKA = Akabane virus

ASF = African swine fever virus

BB = *Besnoitia besnoiti* (giboidiosis)

BEF = Bovine ephemeral fever group

(Kotonkan Obodhiang) virus

BLU = Bluetongue virus (except

serotypes 10, 11, 13 and 17)

BPF = Bovine petechial fever (Ondiri disease) due to *Erichia (Cytoecetes) ondiri*

BR-A = *Brucella abortus* (brucellosis or Bangs disease)

BR-M = *Brucella melitensis*

BR-S = *Brucella suis*

BR-S4 = *Brucella suis* biovar 4

BSE = Bovine spongiform

encephalopathy (BSE) agent

CASG = Contagious agalactia of sheep and goats (*Mycoplasma agalactiae*)

CBPP = Contagious bovine pleuropneumonia (*Mycoplasma mycoides* subsp. *mycoides*)

CCPP = Contagious caprine pleuropneumonia (*Mycoplasma mycoides* subsp. *capri*)

CHD = Congo (Crimean Hemorrhagic Disease) virus

ECF = *Theileria spp.* (east coast fever, corridor disease, Mediterranean fever)

ECTO = *Restricted ectoparasites*

EHD = Epizootic hemorrhagic disease of deer (Ibaraki) virus (except serotypes 1 and 2)

FMD = Foot-and-mouth disease virus

GET = Getah virus

GPV = Goat pox virus

HC = Hog Cholera (Classical swine fever) virus

HW = Heartwater due to *Cowdria ruminantium*

JEM = Jembrana (Tabanan) virus

JEV = Japanese encephalitis virus

LSD = Lumpy Skin disease virus

MCF = Malignant catarrhal fever virus (African or Wildebeest form)

MEL = *Pseudomonas pseudomallei* (melioidosis)

NEE = Near East Encephalitis virus

NSD = Nairobi sheep disease (Dugbe, Ganjam) virus

PARF = Parafilariosis due to *Parafilaria bovicola*

PPR = Peste des petits ruminants (Kata) virus

PRV = Pseudorabies virus

RP = Rinderpest virus

RVF = Rift Valley fever virus

SCR = Scrapie disease agent

SPV = Sheep pox virus

SVD = Swine vesicular disease virus

TB = *Mycobacterium bovis* (bovine tuberculosis)

TBE = Tick-borne encephalitis (louping ill, Central European encephalitis) virus

TBF = Tick-borne fever due to *Erichia (Cytoecetes) phagocytophilia*.

TD = Teschen disease virus

TM = *Taenia (Multiceps) multiceps* (dog tapeworm) in livestock handling dogs

TRY-NTT = *Trypanosoma spp.*

transmitted by vectors other than tsetse flies (NTT-Trypanosomas)

TRY-TT = African (salivarian- or tsetse-transmitted) *Trypanosoma spp.* (*T. brucei*, *T. congolense*, *T. evansi*, *T. suis*, *T. simiae*, *T. uniforme*, *T. vivax*)

VSV = Vesicular Stomatitis virus

WB = Wesselsbron virus

Region	Risk class RN regions	Risk class R1 regions	Risk class R2 regions	Risk class R3 regions	Risk class R4 regions	Risk class RU regions
Africa .....  Algeria Angola Benin Botswana Burkina Faso Burundi Cameroon Cent. African Rep. Chad Comoros Congo Djibouti Egypt Equatorial Guinea Gabon Ghana Guinea Guinea-Bissau Ivory Coast Kenya Lesotho Liberia Libya Madagascar Malawi Mali Mauritania Morocco Mozambique Namibia Niger Nigeria Rwanda Sao Tome and Prinsip Senegal Sierra Leone Somalia South Africa Sudan Swaziland Tanzania The Gambia Togo	BSE, BR-S4, GET, JEM, JEV, TD, TBE, VSV.	.....	.....	.....	.....	AIN, AKA, ASF, BLU, BB, BEF, BPF, BR-A, BR-M, BR-S, CASG, CBPP, CHD, CCPP, ECF, ECTO, EHD, FMD, GPV, HC, HW, LSD, MCF, MEL, NEE, NSD, PARF, PPR, PRV, RP, RVF, SCR, SPV, SVD, TM, TB, TBF, TRY-NTT, TRY-TT, WB.





Region	Risk class RN regions	Risk class R1 regions	Risk class R2 regions	Risk class R3 regions	Risk class R4 regions	Risk class RU regions
Atlantic	ASF, AIN, AKA, BB, BEF, BPF, BSE, BR-S4, CHD, CBPP, CCPP, ECF, GET, GPV, JEV, JEM, LSD, MCF, MEL, NEE, NSD, PPR, NEE, RVF, SPV, TD, TBE, TBF, TRY-NTT, TRY-TT, VSV, WB, FMD, RP, TB					BLU, BR-A, BR-M, BR-S, CASG, ECTO, EHD, FMD <i>except</i> Bermuda; HW, HC, PARF, PRV, RP <i>except</i> Bermuda; SCR, SVD, TM, TB <i>except</i> Bermuda and Falkland Islands.
Bermuda						
Cape Verde						
Falkland Islands						
South Georgia						
Australia	TB	BR-A, CBPP, JEM				AIN, AKA, ASF, BLU, BEF, BR-S, CHD, CCPP, ECTO, EHD, GET, GPV, JEV, MEL, PARF, PRV, TM, TB.
Caribbean	ASF, BB, BPF, BR-M, BR-S4, BSE, CASG, ECF, FMD, HW, HC, LSD, MCF, NEE, NSD, PPR, RP, RVF, SCR, SPV, SVD, TBE, TBF, TD, TRY-NTT, TRY-TT, VSV, WB, AIN, AKA, BB, BEF, BPF, BR-S4, CASG, CBPP, CHD, CCPP, ECF, FMD <i>except</i> The Bahamas GET, GPV, JEV, JEM, LSD, MCF, NEE, NSD, PARF, PPR, RVF, RP <i>except</i> The Bahamas, SPV, TM, TBE, TBF, TD, TRY-TT, VSV, WB.	ASF <i>except</i> Cuba and Haiti.				BLU, BR-A, BR-M, BR-S, BSE, ECTO, EHD, HW, HC, MEL, PRV, SCR, SVD <i>except</i> Haiti, Dominican Republic, and The Bahamas; TB <i>except</i> the Bahamas, TRY-NTT.
Anguilla						
Aruba						
Barbados						
British Virgin Islands						
Cayman Islands						
Cuba						ASF
Dominica						
Dominican Republic	SVD					
Grenada						
Guadeloupe						
Haiti	SVD					ASF
Jamaica						
Martinique						
Montserrat						
Netherlands Antilles						
Puerto Rico						
Saint Lucia						
Saint Vincent						
The Bahamas	SVD, TB	FMD, RP				



Region	Risk class RN regions	Risk class R1 regions	Risk class R2 regions	Risk class R3 regions	Risk class R4 regions	Risk class RU regions
Moldavia		CBPP, RP, BSE				BR-A, BR-M, FMD, SVD, RP, TB.
Monaco		CBPP, RP, BSE				BR-A, BR-M, FMD, SVD, RP, TB.
Netherlands	BR-M	CBPP, FMD, BSE, RP				BR-A, SVD, TB.
Norway	BR-A, BR-M, TB	CBPP, FMD, RP, BSE, SVD.				BR-A, SVD, TB.
Poland	BR-M	CBPP, FMD, BSE, RP				BRA-A, SVD.
Portugal		FMD, BSE, RP				CBPP, BR-A, BR-M, SVD, RP, TB.
Romania	BR-A	CBPP, RP, BSE				BR-M, FMD, SVD, RP, TB.
San Marino		CBPP, RP, BSE				BR-A, BR-M, FMD, SVD, RP, TB.
Slovakia	BR-M	CBPP, BR-A, RP				FMD, BSE, SVD, RP, TB.
Slovenia		CBPP, RP, BSE				BR-A, BR-M, FMD, RP, SVD, TB.
Spain		FMD, RP, BSE				BR-A, BR-M, CBPP, RP, TB.
Sweden	BR-A, BR-M	CBPP, FMD, RP, SVD, BSE.				BR-M, BSE, RP, TB.
Switzerland	BR-A	CBPP, FMD, RP, SVD				BSE, TB except Isle of Jersey.
United Kingdom (Channel Islands)	BR-A, BR-M, BR-S	CBPP, RP, SVD				TB.
United Kingdom (England, Northern Ireland, Scotland, Wales, Isle of Man)	BR-M, BR-S	CBPP, BR-A, RP, SVD				
United Kingdom (Isle of Jersey)	TB					
Vatican City		CBPP, RP, BSE				BR-A, BR-M, SVD, RP, TB.
Yugoslavia		CBPP, RP, BSE				BR-A, BR-M, FMD, RP, SVD, TB.
Middle America	ASF, AIN, AKA, BB, BEF, BPF, BSE, BR-S4, CASG, CBPP, CHD, CCPP, ECF, FMD except Panama; GET, GPV, HW, JEV, JEM, LSD, MCF, NEE, NSD, PARF, PPR, RP, RVF, SPV, SVD, TM, TBE, TBF, TD, TRY-TT, WB.					BLU, BR-A except Belize; BR-M; BR-S, ECTO, EHD, HC, MEL, PRV, SCR; TB, TRY-NTT, VSV.
Belize	BR-A					
Costa Rica						
El Salvador						
Guatemala						
Honduras						
Nicaragua						
Panama		FMD				

Middle East .....	ASF, BEF, BPF, BR-S4, ECF, GET, HW, JEV, JEM, NSD, MCF, TBE, TD, TRY-TT, VSV, WB.	BSE except Oman .....	.....	.....	.....	AIN, AKA, BLU, BB, BR-A except Cyprus & Israel; BR-M, BR-S, CASG, CBPP, CHD, CCPP, ECTO, EHD, FMD, GPV, HC, LSD, MEL, NEE, PARF, PPR, PRV, RP, RVF, SCR, SPV, SVD, TM, TB except Cyprus; TBF, TRY-NTT.
Bahrain	BR-A, TB.	.....	.....	.....	.....	BR-A, BR-S, CASG, ECTO, PRV, TM, TB.
Cyprus .....	BR-A.	.....	.....	.....	.....	BR-S4
Iraq .....	.....	.....	.....	.....	.....	.....
Israel .....	.....	.....	.....	.....	.....	.....
Jordan	.....	.....	.....	.....	.....	.....
Kuwait	.....	.....	.....	.....	.....	.....
Lebanon	.....	.....	.....	.....	.....	.....
Malta	.....	.....	.....	.....	.....	.....
North Yemen	.....	.....	.....	.....	.....	.....
Oman	.....	.....	.....	.....	.....	.....
Palestine	.....	.....	.....	.....	.....	.....
Qatar	.....	.....	.....	.....	.....	.....
Saudi Arabia	.....	.....	.....	.....	.....	.....
South Yemen	.....	.....	.....	.....	.....	.....
Syria	.....	.....	.....	.....	.....	.....
Turkey	.....	.....	.....	.....	.....	.....
United Arab Emirates	.....	.....	.....	.....	.....	.....
New Zealand .....	ASF, AIN, AKA, BLU, BB, BEF, BPF, BR-M, BR-S4, BSE, CBPP, CHD, CCPP, ECF, EHD, FMD, GET, GPV, HW, HC, JEV, JEM, LSD, MCF, MEL, NEE, NSD, PARF, PPR, RP, RVF, SCR, SPV, SVD, TBE, TBF, TD, TRY-NTT, TRY-TT, VSV, WB.	.....	.....	.....	.....	.....
North America .....	ASF, AIN, AKA, BB, BEF, BPF, BLU, CASG, CBPP, CHD, CCPP, ECF, EHD, FMD, GET, GPV, HW, JEV, JEM, LSD, MCF, NEE, NSD, PARF, PPR, RP, RVF, SPV, SVD, TBE, TBF, TD, TRY-NTT, TRY-TT, WB.	.....	.....	.....	.....	.....
Canada .....	BR-M, BR-S, ECTO, HC, MEL, PRV.	BR-A .....	TB .....	SCR .....	.....	.....

Region	Risk class RN regions	Risk class R1 regions	Risk class R2 regions	Risk class R3 regions	Risk class R4 regions	Risk class RU regions
Mexico						BR-A, ECTO, HC except the State of Sonora; MEL, BR-M, BR-S, PRV, SCR, TB, VSV.
The State of Sonora in Mexico.		HC.				
United States						
Oceania	ASF, BB, BPF, BSE, BR-M, BR-S4, CHD, HW, LSD, MCF, NEE, NSD, PPR, RVF, TBE, TBF, TD, TRY-TT, VSV, WB.					AIN, AKA, BEF, BLU, BR-A except French Polynesia & Papua New Guinea; BR-S, CASG, CBPP, CCPP, ECF, ECTO, EHD, GET, GPV, HC, JEV, JEM, MEL, PARF, PRV, SCR, SPV, TM, TB, TRY-NTT. FMD, SVD, RP.
Brunei		FMD, RP				
Fiji	SVD					
French Polynesia	BR-A					FMD, SVD, RP.
Indonesia						FMD, SVD, RP.
Kiribati						FMD, SVD, RP.
Maldives						FMD, SVD, RP.
Mauritius						FMD, SVD, RP.
Nauru						FMD, SVD, RP.
New Caledonia		FMD, RP				FMD, SVD.
Papua New Guinea	BR-A					FMD, SVD, RP.
Philippines						FMD, SVD, RP.
Seychelles						FMD, SVD, RP.
Solomon Islands						FMD, SVD, RP.
Tonga						FMD, SVD, RP.
Trust territory of the Pacific Islands.	FMD, RP, SVD					
Vanuatu						
Western Samoa						
South America	AIN, AKA, BEF, BPF, BR-S4, BSE, CASG, CBPP, CHD, CCPP, ECF, GET, HW, JEV, JEM, LSD, MCF, NEE, NSD, PARF, PPR, RP except Chile, RVF, TBE, TBF, TD, TRY-TT, WB.	ASF except Brazil				FMD, SVD, RP. FMD, SVD, RP. BLU, BB, BR-A, BR-M, BR-S, ECTO, EHD, FMD except Argentina, Chile, and Uruguay; GPV, HC, MEL, PPR, SCR, SPV, SVD except Chile; TM, TB, TRY-NTT, VSV.
Argentina			FMD			
Bolivia						
Brazil		FMD, RP, SVD				
Chile						ASF.



Restricted disease agent	Risk class RN regions	Risk class R1 regions	Risk class R2 regions	Risk class R3 regions	Risk class R4 regions	Risk class RU regions
African swine fever	Asia, Atlantic, Australia, Middle America, New Zealand, North America, Oceania.	Europe except Italy, Spain and Portugal; Caribbean except Cuba and Haiti; South America except Brazil.	None	None	None	All regions of the world except those specifically listed as Risk Class RN, R1, R2, R3 or R4
Aino virus	Atlantic, Caribbean, Europe, Middle America, New Zealand, North America, South America.	None	do	do	do	Do.
Akabane virus	Atlantic, Caribbean, Europe, Middle America, New Zealand, North America, South America.	do	do	do	do	Do.
<i>Besnoitia besnoitii</i> (globidosis).	Atlantic, Australia, Caribbean, Middle America, North America, Oceania.	do	do	do	do	Do.
Bluetongue virus (except serotypes 10, 11, 13, 17).	Europe except Greece, New Zealand, Canada, Mexico.	do	do	do	do	Do.
Bovine ephemeral fever virus group (Kotonkan, Obodhiang).	Atlantic, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, South America.	do	do	do	do	Do.
Bovine infectious petechial fever.	Asia, Atlantic, Australia, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, South America.	do	do	do	do	Do.
Bovine spongiform encephalopathy.	Africa, Asia, Atlantic, Australia, Caribbean, Middle America, New Zealand, Oceania, North America, South America.	Middle East except Oman; Europe except Denmark, France, United Kingdom, Republic of Ireland, and Switzerland.	Canada	do	do	Do.
<i>Bruceella abortus</i>	Belize, Bulgaria, Channel Islands (United Kingdom), Cyprus, Denmark, Finland, French Polynesia, Hungary, Israel, Norway, Papua New Guinea, Romania, Sweden, Switzerland.	Australia, Canada, Czech Republic, Germany, Slovakia, United Kingdom except Channel Islands.	do	do	do	Do.



<i>Brucella melitensis</i> .....	Oceania, Australia, New Zealand, Canada, Czech Republic, Denmark, Estonia, Finland, Greenland, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Slovakia, Sweden, United Kingdom, Taiwan.	None	.....do	.....do	.....do	Do.
<i>Brucella suis</i> except biovar 4.	Canada, Ireland, United Kingdom.	.....do	.....do	.....do	.....do	Do.
<i>Brucella suis</i> except biovar 4.	Africa; Asia except Russia; Atlantic; Australia; Caribbean; Europe; Mexico; Middle America; Middle East; New Zealand; Oceania, South America.	.....do	.....do	.....do	.....do	Do.
Congo virus (Crimean Hemorrhagic Disease).	Atlantic, Caribbean, Middle America, New Zealand; North America, Oceania; South America.	.....do	.....do	.....do	.....do	Do.
Contagious agalactia of sheep and goats due to <i>Mycoplasma agalactiae</i> .	Australia, Caribbean, Middle America, New Zealand, North America, South America.	.....do	.....do	.....do	.....do	Do.
Contagious bovine pleuro-pneumonia ( <i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> ).	Europe except Portugal and Spain; Australia; Oceania.	.....do	.....do	.....do	.....do	Do.
Contagious caprine pleuro-pneumonia ( <i>Mycoplasma mycoides</i> subsp. <i>capri</i> ).	None	.....do	.....do	.....do	.....do	Do.
Epizootic hemorrhagic disease of deer (Ibaraki) virus (except serotypes 1 and 2).	Canada, Europe, New Zealand.	Mexico	.....do	.....do	.....do	Do.
Foot-and-mouth disease virus.	Australia; Barbados; Bermuda; all regions of North and Middle America except Panama; all regions of the Caribbean except The Bahamas; Greenland; Iceland; Territory of St. Pierre and Miquelon; Trust territory of the Pacific Islands.	Austria, The Bahamas, Belgium, Chile, Denmark, Fiji, Finland, France, Germany, United Kingdom, Hungary, Japan, New Caledonia, The Netherlands, Norway, Papua New Guinea, Panama, Poland, Portugal, Republic of Ireland, Republic of Korea, Sweden, Spain, Switzerland, Uruguay.	Argentina	.....do	.....do	Do.

Restricted disease agent	Risk class RN regions	Risk class R1 regions	Risk class R2 regions	Risk class R3 regions	Risk class R4 regions	Risk class RU regions
Getah virus	Africa; Atlantic; Caribbean; Europe; Middle America; Middle East; New Zealand; North America; and South America.	None	None	.....do	.....do	Do.
Heartwater due to <i>Cowdria ruminantium</i> .	Asia; Atlantic; Australia; Europe; Middle America; Middle East; New Zealand; North America; Oceania; and South America.	None	None	None	.....do	Do.
Hog cholera (classical swine fever).	Australia, Canada, Dominican Republic, Fiji, United Kingdom, Iceland, New Zealand; Northern Ireland, Norway, the Republic of Ireland, Sweden, and Trust Territory of the Pacific Islands.	Denmark, Finland, Spain, the State of Sonora in Mexico.	.....do	.....do	.....do	Do.
Japanese encephalitis virus.	Africa; Atlantic; Caribbean; Europe; Middle America; Middle East; New Zealand; North America; and South America.	None	.....do	.....do	.....do	Do.
Jembrana (Tabanan) virus.	Africa; Atlantic; Asia except for Bangladesh, Bhutan, Burma, Cambodia, India, Laos, Malaysia, Singapore, Sri Lanka, Thailand, and Vietnam; Caribbean; Europe; Middle America; Middle East; New Zealand; North America; South America.	.....do	.....do	.....do	.....do	Do.
Lumpy skin disease (Neethling virus).	Asia, Atlantic, Australia, Caribbean, Europe, Middle America, New Zealand, North America, Oceania, South America.	.....do	.....do	.....do	.....do	Do.
Malignant catarrhal fever virus (African or wildebeest form).	Asia, Atlantic, Australia, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, and South America.	.....do	.....do	.....do	.....do	Do.

<i>Mycobacterium bovis</i> .....	Bermuda, The Bahamas, Falkland Islands, Luxembourg, Norway, Isle of Jersey (United Kingdom), Cyprus.	.....do	Canada	.....do	.....do	Do.
Nairobi sheep disease (Ganjam, Dugbe) virus.	Atlantic, Australia, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, and South America.	.....do	None	.....do	.....do	Do.
Near East encephalitis virus.	Atlantic, Australia, Caribbean, Europe; Middle America, New Zealand, North America, Oceania, and South America.	.....do	.....do	.....do	.....do	Do.
Paratuberculosis due to <i>Parafilaria bovicola</i> .	North America, Middle America, South America, Caribbean.	.....do	.....do	.....do	.....do	Do.
Peste des petits ruminants (Kata) virus.	Atlantic, Europe, North America, South America, Australia, Oceania, Europe, Canada, Atlantic	.....do	.....do	.....do	.....do	Do.
<i>Pseudomonas pseudomallei</i> (melioidosis).	None	Canada	.....do	.....do	.....do	Do.
Pseudorabies (Aujeszky's) virus.	Canada	None	.....do	.....do	.....do	Do.
Restricted ectoparasites Rift Valley fever virus .....	Asia, Atlantic, Australia, Caribbean, Europe, Middle America, New Zealand, North America, Oceania, South America.	None	.....do	.....do	.....do	Do.
Rinderpest virus .....	Australia; Bermuda; North America; Middle America; South America except Chile; Caribbean except The Bahamas; Greenland; Iceland, Japan, Territory of St. Pierre and Miquelon, Trust territory of the Pacific Islands, Papua New Guinea, Republic of Korea.	Austria, The Bahamas, Belgium, Chile, Denmark, Finland, Fiji, France, Germany, United Kingdom, Hungary, Japan, The Netherlands, New Cal- edonia, Norway, Papua New Guinea, Poland, Ireland, South Korea, Spain, Sweden.	.....do	.....do	.....do	Do.
Scrapie disease agent ...	Australia, New Zealand	None	.....do	.....do	.....do	Do.
Sheep pox and/or goat pox virus.	Atlantic, Australia, Caribbean, Middle America, New Zealand, North America.	.....do	.....do	.....do	.....do	Do.

Restricted disease agent	Risk class RN regions	Risk class R1 regions	Risk class R2 regions	Risk class R3 regions	Risk class R4 regions	Risk class RU regions
Swine vesicular disease virus.	Australia, North America, Middle America, Dominican Republic, Fiji, Finland, Greenland, Haiti, Iceland, New Zealand, Norway, Rumania, Sweden, Trust Territories of the Pacific Islands.	Austria, The Bahamas, Bosnia-Herzegovania, Bulgaria, Chile, Croatia, Denmark, Ireland, Luxembourg, Macedonia, Ireland, Slovenia, Switzerland, United Kingdom, Yugoslavia.	.....do	.....do	.....do	Do.
<i>Taenia (Multiceps) multiceps</i> (dog tapeworm) in livestock handling dogs.	North America, Middle America, Caribbean.	None	.....do	.....do	.....do	Do.
Teschen disease virus ...	Africa, Asia, Atlantic, Australia, Caribbean, Middle America, Middle East, New Zealand, North America, Oceania, South America.	.....do	.....do	.....do	.....do	Do.
Theileriosis (east coast fever, corridor disease Mediterranean fever).	Atlantic, Asia, Australia, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, South America.	.....do	.....do	.....do	.....do	Do.
Tick-borne encephalitis (louping ill, Central European encephalitis) virus.	Africa, Atlantic, Australia, Caribbean, Middle America, Middle East, New Zealand, North America, Oceania, South America.	.....do	.....do	.....do	.....do	Do.
Tick-borne fever due to <i>Erlchia (Cytoecetes) phagocytophilia</i> .	Atlantic, Australia, Caribbean, Middle America, Middle East, New Zealand, North America, Oceania, South America.	.....do	.....do	.....do	.....do	Do.
<i>Trypanosoma</i> African (salivarian-or tsetse-transmitted) spp. ( <i>T. brucei</i> , <i>T. congolense</i> , <i>T. evansi</i> , <i>T. suis</i> , <i>T. simiae</i> , <i>T. uniforme</i> , <i>T. vivax</i> ).	Asia, Atlantic, Australia, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, South America.	.....do	.....do	.....do	.....do	Do.
<i>Trypanosoma</i> spp. transmitted by vectors other than tsetse flies (NTT-Trypano-somas).	Atlantic, Australia, Europe, New Zealand, and North America.	.....do	.....do	.....do	.....do	Do.
Vesicular Stomatitis virus	Africa; Asia; Atlantic; Australia; Caribbean; Europe; Middle East; New Zealand; North America <i>except</i> Mexico; Oceania.	.....do	.....do	.....do	.....do	Do.

Wesselsbron virus .....	Asia, Atlantic, Australia, Caribbean, Europe, Middle America, Middle East, New Zealand, North America, Oceania, South America.	.....do .....	.....do .....	.....do .....	.....do .....	Do.
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**§ 92.5 Application for recognition of Risk Class RN, R1, R2, R3, or R4.**

(a) *Evaluation procedure.* (1) The official of the national government of any country who has the authority in that country to request such a change may request at any time that all or part of the country be classified or reclassified as a Risk Class RN, R1, R2, R3, or R4 region, or be included within an adjacent previously classified region.

(2) Requests for classifying or reclassifying a region must be sent to the Administrator, stating that the official making the request believes the region is prepared to document all claims represented that would permit the region to be eligible for consideration for a change in disease risk classification.

(3) The Chief Veterinary Officer of the region will then be sent a formal questionnaire relating to the specific disease(s) in question.

(4) The Chief Veterinary Officer of the region must submit to APHIS the completed questionnaire, along with a complete set of the region's applicable agricultural laws and regulations, written in English (if the official language of the country or region is other than English, there must be supplied an official certified translation into English), relative to the animal

health infrastructure, livestock populations, diagnostic facilities and procedures, control, eradication, and surveillance of the specific disease(s) in question.

(5) When all of the requested information is received by APHIS, the Administrator will initiate an investigation to document those claims represented in the completed questionnaire. Following this investigation, a committee, composed of USDA veterinary experts, will be convened to evaluate the information provided by the Chief Veterinary Officer for the region and the investigative report submitted by APHIS. This committee will be formed by the Administrator when necessary to address any such requests for change in region risk class status and may be composed of representatives from APHIS, other branches of the USDA, or other persons knowledgeable about the disease(s) in question from other Federal agencies.

(b) *Decision procedures.* (1) Depending upon the information provided by the Chief Veterinary Officer of the region and the results of the investigation by APHIS, the committee may complete a risk analysis of the region and may make one of several

recommendations. These recommendations may include, but are not limited to:

(i) Requesting additional information about the region, or the country if the region is part of a country, or other countries if the region is made up of more than one country;

(ii) Deferring any decision until a veterinary team composed of staff representatives of APHIS can personally visit the region in question and do an on-site evaluation of any concerns;

(iii) Denying the request, but specifying certain conditions that would warrant further consideration, should the region decide to implement the committee's recommendations;

(iv) Denying the request, listing the specific reasons for that action;

(v) Recommending reclassifying the region into a risk class other than the risk class specifically requested; and

(vi) Approving the request by the region and recommending that the region be added to the list of risk class regions for which it applied.

(2) After the committee has met and made a recommendation, a letter to the Administrator will be prepared, stating the recommendation of the committee, and will be signed by the committee chairperson.

(c) *Action on the committee's recommendations.* (1) If the Administrator concurs with the committee's recommendation, a letter will be sent to the foreign official who made the request, informing him or her as follows whether the request was approved or denied, or is still being considered:

(i) If the request is approved, the letter will state that a notice of proposed rulemaking will be published in the Federal Register, proposing the status of the region for the restricted agent in question.

(ii) If the request is denied, the letter will state the reasons for that action. The region will continue to be classified according to its current risk class or be classified as Risk Class RU if the region had not been previously classified as Risk Class RN, R1, R2, R3, or R4. The decision may be appealed by resubmitting the request to the Administrator and specifically responding to each of the reasons stated for denying the request, and supplying any supporting information or data related to the reasons stated for denial. The committee will evaluate the appeal following the procedures outlined in paragraphs (a)(5) and (b) of this section. The Administrator will act on the committee's recommendation of the

appeal as outlined in this paragraph (c) and paragraph (d) of this section.

(iii) If the request is still being considered, the letter will state that:

(A) Additional information is needed; if furnished, the request will be reconsidered according to the procedures outlined in paragraphs (a)(5) and (b) of this section;

(B) An on-site visit is required before a final decision can be made; and/or

(C) The region must implement certain actions for compliance with APHIS requirements before it will be eligible for a reclassification.

(iv) Final approval will be given by the Administrator by publishing a final rule Federal Register stating the status of the region for the restricted agent in question and the effective date of the risk class change. The Administrator will notify the Chief Veterinary Official of the country(ies) where the reclassified region is located when the final rule is published in the Federal Register.

(d) *Committee follow-up, if needed.*

(1) The committee may be reconvened for final recommendation after:

(i) An appeal has been made or additional information needed is received;

(ii) An on-site evaluation report is received; or

(iii) The region has implemented specific recommendations made by the

committee and has furnished that information in writing, and this information has been documented by the APHIS investigator assigned to conduct the investigation.

(2) After the committee has reconvened and reconsidered the request, a letter to the Administrator will be prepared stating the revised recommendation of the committee, and will be signed by the chairperson of the committee.

(e) *Removal or change of status of region due to failure to meet the criteria of the present risk class, or discovery of a restricted agent in the region.*

(1) Whenever the Administrator receives notice from the Chief Veterinary Officer representing any region classified as Risk Class RN, R1 or R2, either directly or through the International Office of Epizootics, that a restricted agent has been discovered within the region or that animals in the region have been exposed to a restricted agent, the Administrator may immediately suspend the current risk classification and reclassify the region as a Risk Class R3, R4 or RU region, and will publish a rule to that effect in the Federal Register.

(2) Whenever the Administrator determines that a region no longer meets the criteria of its current Risk Class classification, the Administrator shall



take action to change the classification of the region as he or she deems appropriate.

(3) Reclassification pursuant to paragraph (e)(1) or (e)(2) of this section shall remain in effect until either:

(i) The official of the national government of the country of origin who has the authority to request a change does so in accordance with the procedures in paragraph (a) of this section; or

(ii) The Administrator makes a determination based on the procedures in paragraph (b) of this section.

**PART 93—IMPORTATION OF CERTAIN ANIMALS AND POULTRY; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN ANIMALS; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCE AND SHIPPING CONTAINERS THEREON**

4. The authority citation for part 93 would continue to read as follows:

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d).

5. The heading for part 93 would be revised to read as set forth above.

**Subpart A—Birds**

**§ 93.101 [Amended]**

6. Newly designated § 93.101 would be amended as follows:

a. In paragraph (b)(1), the reference to “§§ 92.205, 92.214, and 92.216” would be removed and a reference to “§§ 93.205, 93.214, and 93.216” would be added in its place;

b. In paragraph (b)(3)(i)(B), the reference to “§ 92.103(a)(2)(iv)” would be removed, and a reference to “§ 93.103(a)(2)(iv)” would be added in its place;

c. In paragraph (b)(3)(i)(I), the reference to “§ 92.103(a)(2)(iv)” would be removed, and a reference to “§ 93.103(a)(2)(iv)” would be added in its place;

d. In paragraph (b)(3)(i)(J), the reference to “§ 92.104(a)” would be removed, and a reference to “§ 93.104(a)” would be added in its place;

e. In paragraph (b)(3)(i)(K), the reference to “§ 92.104(a)” would be removed, and a reference to “§ 93.104(a)” would be added in its place;

f. In paragraph (c)(1), the reference to “§§ 92.102 or 92.203” would be removed and a reference to “§§ 93.103 or 93.203” would be added in its place, and the reference to “§ 92.105” would

be removed and a reference to “§ 93.105” would be added in its place;

g. In paragraph (c)(2)(i), the reference to “§ 92.101(c)(1)” would be removed and a reference to “§ 93.101(c)(1)” would be added in its place;

h. In paragraph (c)(3), the introductory text, the reference to “§ 92.102(a)” would be removed and a reference to “§ 93.102(a)” would be added in its place;

i. In paragraph (c)(3)(ii), the references to “§ 92.103(a)(3)” would be removed both times they appear and references to “§ 93.103(a)(3)” would be added in their place, and the references to “§ 92.102(a)” would be removed each time they appear and references to “§ 93.102(a)” would be added in their place;

j. In paragraph (c)(3)(iv), the reference to “§ 92.106(a)” would be removed and a reference to “§ 93.106(a)” would be added in its place;

k. In paragraph (c)(3)(v), the reference to “§ 92.210 (b) and (c)” would be removed and a reference to “§ 93.210(b) and (c)” would be added in its place;

l. In paragraph (d), the introductory text, the reference to “§ 92.103” would be removed and a new reference “§ 93.103” would be added in its place;

m. In paragraph (d)(1)(ii), the reference to “§ 92.103(c)” would be removed and a reference to “§ 93.103(c)” would be added in its place;

n. In paragraph (e), the reference to “§§ 92.102(a), 92.103, 92.104, 92.105(a), and 92.106(a)” would be removed and a reference to “§§ 93.102(a), 93.103, 93.104, 93.105(a), and 92.106(a)” would be added in its place; and

o. In paragraph (f), the reference to “§ 92.102 or 92.203” would be removed and a reference to “§ 93.102 or 93.203” would be added in its place; and the reference to “§ 92.103” would be removed and a reference to “§ 93.103” added in its place.

**§ 93.102 [Amended]**

7. Newly designated § 93.102 would be amended as follows:

a. In paragraph (a), the reference to “§ 92.101(c)” would be removed and a reference to “§ 93.101(c)” would be added in its place, and the reference to “§ 92.101(f)” would be removed and a reference to “§ 93.101(f)” would be added in its place;

b. In paragraph (c), the reference to “§ 92.105(a)” would be removed and a reference to “§ 93.105(a)” would be added in its place; and

c. In paragraph (d), the reference to “§ 92.101(c) (1) or (2)” would be removed and a reference to “§ 93.101(c)(1) or (2)” would be added in its place.

**§ 93.103 [Amended]**

8. Newly designated § 93.103 would be amended as follows:

a. In paragraph (a)(1), the reference to “§§ 92.101 (b) and (c), 92.103(c), and 92.214” would be removed and a reference to “§§ 93.101 (b) and (c), 93.103(c), and 93.214” would be added in its place;

b. In paragraph (a)(1)(x), the reference to “§ 92.106(c)(5)” would be removed and a reference to “§ 93.106(c)(5)” would be added in its place;

c. In paragraph (a)(1)(xii), the reference to “§§ 92.100 through 92.107” would be removed and a reference to “§§ 93.100 through 93.107” would be added in its place;

d. In paragraph (a)(2)(i), the reference to “§ 92.106(c)” would be removed and a reference to “§ 93.106(c)” would be added in its place; and

e. In paragraph (a)(2)(v), the reference to “§ 92.101 (b)(3)(i)(G) and (b)(3)(i)(J)” would be removed and a reference to “§ 93.101 (b)(3)(i)(G) and (b)(3)(i)(J)” would be added in its place, and the reference to “§ 92.101 (b)(3)(i)(B) and (b)(3)(i)(C)” would be removed and a reference to “§ 93.101(b)(3)(i)(B) and (b)(3)(i)(C)” would be added in its place.

**§ 93.104 [Amended]**

9. Newly designated § 93.104 would be amended as follows:

a. In paragraph (a), the reference to “§ 92.101 (b) and (c)” would be removed and a reference to “§ 93.101 (b) and (c)” would be added in its place;

b. In paragraph (c)(14), the reference to “§ 92.101(b)(3)(i)(B)” would be removed and a reference to “§ 93.101(b)(3)(i)(B)” would be added in its place, and the reference to “§ 92.101(b)(3)(i)(C)” would be removed and a reference to “§ 93.101(b)(3)(i)(C)” would be added in its place;

c. In paragraph (d)(9), the reference to “§ 92.101(b)(2)(iii)(I)” would be removed and a reference to “§ 93.101(b)(2)(iii)(I)” would be added in its place; and

d. In paragraph (d)(10), the reference to “§ 92.101(b)(3)(i)(B)” would be removed and a reference to “§ 93.101(b)(3)(i)(B)” would be added in its place, and the reference to “§ 92.101(b)(3)(i)(C)” would be removed and a reference to “§ 93.101(b)(3)(i)(C)” would be added in its place.

**§ 93.105 [Amended]**

10. In newly designated § 93.105, paragraph (b) would be amended as follows:

a. The reference to “§ 92.101(c)(2)” would be removed both times it appears and a reference to “§ 93.101(c)(2)” would be added in its place;

b. The reference to “§ 92.102(a)” would be removed and a reference to “§ 93.102(a)” would be added in its place; and

c. The reference to “§ 92.102 and 92.203” would be removed and a reference to “§§ 93.102 and 93.203” would be added in its place.

#### **§ 93.106 [Amended]**

11. Newly designated § 93.106 would be amended as follows:

a. In paragraph (a), the reference to “§ 92.101(c)” would be removed and a reference to “§ 93.101(c)” would be added in its place, and the reference to “§ 92.103” would be removed and a reference to “§ 93.103” would be added in its place;

b. In paragraph (b)(1), the reference to “§ 92.103” would be removed and a reference to “§ 93.103” would be added in its place;

c. In paragraph (c)(2)(ii)(L), the reference to “§ 92.103” would be removed and a reference to “§ 93.103” would be added in its place;

d. In paragraph (c)(2)(ii)(M), the reference to “§ 92.103” would be removed and a reference to “§ 93.103” would be added in its place;

e. In the “Cooperative and Trust Fund Agreement,” paragraph (A)(5), the reference to “§ 92.106(c)” would be removed and a reference to “§ 93.106(c)” would be added in its place;

f. In the “Cooperative and Trust Fund Agreement,” paragraph (A)(13), the reference to “§ 92.106(c)(3)(ii)(C)” would be removed and a reference to “§ 93.106(c)(3)(ii)(C)” would be added in its place; and

g. In the “Cooperative and Trust Fund Agreement,” paragraph (A)(20), the reference to “§ 92.106(c)” would be removed and a reference to “§ 93.106(c)” would be added in its place.

12. In subpart A, footnote 13 would be amended by removing the reference to “§ 92.107” and adding in its place a reference to “§ 93.107”.

#### **§ 93.107 [Amended]**

13. Newly designated § 93.107 would be amended by removing the reference to “§ 92.103” and adding in its place a reference to “§ 93.103”, and by removing the reference to “§ 92.101” and adding in its place a reference to “§ 93.101”.

#### **Subpart B—Poultry**

##### **§ 93.200 [Amended]**

14. In newly designated § 93.200, the definition of Operator would be amended by removing the reference to

“§ 92.209” and adding in its place a reference to “§ 93.209”.

##### **§ 93.201 [Amended]**

15. Newly designated § 93.201 would be amended as follows:

a. In paragraph (b), the introductory text, the reference to “part 92” would be removed and a reference to “part 93” would be added in its place, and the reference to “§ 92.204” would be removed and a reference to “§ 93.204” would be added in its place;

b. In paragraph (b)(1)(ii), the reference to “§ 92.204(c)” would be removed and a reference to “§ 93.204(c)” would be added in its place; and

c. In paragraph (c), the reference to “§ 92.203” would be removed and a reference to “§ 93.203” would be added in its place, and the reference to “§ 92.204” would be removed and a reference to “§ 93.204” would be added in its place.

##### **§ 93.204 [Amended]**

16. In newly designated § 93.204, paragraph (a)(1) would be amended by removing the reference to “§§ 92.204(c), 92.214, 92.217, and 92.218” and adding in its place a reference to “§§ 93.204(c), 93.214, 93.217, and 93.218”.

##### **§ 93.207 [Amended]**

17. Newly designated § 93.207 would be amended by removing the reference to “§§ 92.215 and 92.220” and adding in its place a reference to “§§ 93.215 and 93.220”.

##### **§ 93.209 [Amended]**

18. In newly designated § 93.209, paragraph (a)(1) would be amended by removing the reference to “§ 92.216” and adding in its place a reference to “§ 93.216”.

19. In subpart B, footnote 6 would be amended by removing the reference to “§§ 92.214 to 92.216” and adding in its place a reference to “§§ 93.214 to 93.215”.

##### **§ 93.214 [Amended]**

20. Newly designated § 93.214 would be amended as follows:

a. In paragraph (a), the reference to “§ 92.204” would be removed and a reference to “§ 93.204” would be added in its place, and the reference to “§ 92.203(b)” would be removed and a reference to “§ 93.203(b)” would be added in its place; and

b. In paragraph (b), the reference to “§ 92.206” would be removed and a reference to “§ 93.206” would be added in its place.

##### **§ 93.215 [Amended]**

21. In newly designated § 93.215(a)(1), the reference to “§ 92.204” would be

removed and a reference to “§ 93.204” would be added in its place, and the reference to “§ 92.201” would be removed and a reference to “§ 93.201” would be added in its place.

##### **§ 93.216 [Amended]**

22. Newly designated § 93.216 would be amended by removing the reference to “§ 92.209” and adding in its place a reference to “§ 93.209”.

23. In subpart B, footnote 7 would be amended by removing the reference to “§ 92.217” and adding in its place a reference to “§ 93.217”.

##### **§ 93.217 [Amended]**

24. Newly designated § 93.217 would be amended as follows:

a. In paragraph (a), the reference to “§ 92.204” would be removed and a reference to “§ 93.204” would be added in its place;

b. In paragraph (b), the reference to “§ 92.206” would be removed and a reference to “§ 93.206” would be added in its place; and

c. In paragraph (c), the reference to “§§ 92.205, 92.207, 92.209, and 92.210” would be removed and a reference to “§ 93.205, 93.207, 93.209, and 93.210” would be added in its place.

25. In subpart B, footnote 8 would be amended by removing the reference to “§§ 92.218 to 92.220” and adding in its place a reference to “§§ 93.218 to 93.220”.

##### **§ 93.218 [Amended]**

26. In newly designated § 93.218, paragraph (a) would be amended by removing the reference to “§ 92.204” and adding in its place a reference to “§ 93.204”.

##### **§ 93.219 [Amended]**

27. Newly designated § 93.219 would be amended by removing the reference to “§ 92.206” and adding in its place a reference to “§ 93.206”.

##### **§ 93.220 [Amended]**

28. In newly designated § 93.220, paragraph (b) would be amended by removing the reference to “§ 92.203” and adding in its place a reference to “§ 93.203”.

#### **Subpart C—Horses**

##### **§ 93.301 [Amended]**

29. Newly designated § 93.301 would be amended as follows:

a. In paragraph (b), the reference to “§ 92.304” would be removed and a reference to “§ 93.304”;

b. In paragraph (c)(2)(i), the reference to “§ 92.301(a)” would be removed and a reference to “§ 93.301(a)” would be added in its place;

c. In paragraph (c)(2)(ii), the reference to “§ 92.314” would be removed and a reference to “§ 93.314” would be added in its place;

d. In paragraph (c)(2)(iii), the reference to “§ 92.304” would be removed and a reference to “§ 93.304” would be added in its place;

e. In paragraph (c)(2)(iv), introductory text, the reference to “§ 92.304” would be removed and a reference to “§ 93.304” would be added in its place, and the reference to “§ 92.314” would be removed and a reference to “§ 93.314” would be added in its place;

f. In paragraph (c)(2)(v)(A)(1), the reference to “§ 92.304” would be removed and a reference to “§ 93.304” would be added in its place;

g. In paragraph (c)(2)(v)(A)(2), the reference to “§ 92.314” would be removed and a reference to “§ 93.314” would be added in its place;

h. In paragraph (c)(2)(v)(G), the reference to “§ 92.401(c)(2)(v)” would be removed and a reference to “§ 93.401(c)(2)(v)” would be added in its place;

i. In paragraph (c)(2)(vi)(A)(1), the reference to “§ 92.304” would be removed and a reference to “§ 93.304” would be added in its place;

j. In paragraph (c)(2)(vi)(A)(2), the reference to “§ 92.314” would be removed and a reference to “§ 93.314” would be added in its place;

k. In paragraph (c)(2)(vi)(E), the reference to “§ 92.308” would be removed and a reference to “§ 93.308” would be added in its place;

l. In paragraph (c)(2)(vi)(G), the reference to “§ 92.304(a)” would be removed and a reference to “§ 93.304(a)” would be added in its place;

m. In paragraph (c)(2)(vii)(A), the reference to “§ 92.304” would be removed and a reference to “§ 93.304” would be added in its place;

n. In paragraph (c)(2)(vii)(B), the reference to “§ 92.314” would be removed and a reference to “§ 93.314” would be added in its place;

o. In paragraph (c)(2)(viii)(A), the reference to “§ 92.304” would be removed and a reference to “§ 93.304” would be added in its place;

p. In paragraph (c)(2)(viii)(E), the reference to “§ 92.304” would be removed and a reference to “§ 93.304” would be added in its place;

q. In paragraph (c)(2)(ix), the reference to “§ 92.304(a)” would be removed and a reference to “§ 93.304(a)” would be added in its place, the reference to “§ 92.304(a)(4)(ii)” would be removed and a reference to “§ 93.304(a)(4)(ii)” would be added in its place, and the reference to “§ 92.304(a)(5)(iii)” would

be removed and a reference to “§ 93.304(a)(5)(iii)” would be added in its place;

r. In paragraph (c)(2)(x), the reference to “§ 92.304(a)” would be removed and a reference to “§ 93.304(a)” would be added in its place, the reference to “§ 92.304(a)(7)(ii)” would be removed and a reference to “§ 93.304(a)(7)(ii)” would be added in its place, and the reference to “§ 92.304(a)(8)(iii)” would be removed and a reference to “§ 93.304(a)(8)(iii)” would be added in its place;

s. The second paragraph (c)(2)(xi)(C)(2) would be redesignated as paragraph (c)(2)(xi)(C)(3);

t. In newly designated paragraph (c)(2)(xi)(C)(3), the reference to “§ 92.304” would be removed and a reference to “§ 93.304” would be added in its place; and

u. In paragraph (c)(2)(xi)(E), the reference to “§ 92.308(a), (b), and (c)” would be removed and a reference to “§ 93.308 (a), (b), and (c)” would be added in its place.

#### **§ 93.303 [Amended]**

30. Newly designated § 93.303 would be amended as follows:

a. In paragraph (a), the reference to “§§ 92.308 (a), (b), and (c) and 92.317” would be removed and a reference to “§§ 93.308 (a), (b), and (c) and 93.317” would be added in its place; and

b. In paragraph (e), the reference to “§§ 92.301(c), 92.304(a), 92.306, 92.308 (a), (b), and (c), and 92.314” would be removed and a reference to “§§ 93.301(c), 93.304(a), 93.306, 93.308 (a), (b), and (c), and 93.314” would be added in its place.

#### **§ 93.304 [Amended]**

31. Newly designated § 93.304 would be amended as follows:

a. In paragraph (a)(1)(i), the reference to “§ 92.301(c)(1)” would be removed and a reference to “§ 93.301(c)(1)” would be added in its place, and the reference to “§§ 92.315, 92.319, and 92.321” would be removed and a reference to “§§ 93.315, 93.319, and 93.321” would be added in its place;

b. In paragraph (a)(1)(ii), introductory text, the two references to “§ 92.301(c)(2)(viii)” would be removed and references to “§ 93.301(c)(2)(viii)” would be added in their place;

c. In paragraph (a)(1)(iii), the reference to “§ 92.301(c)(2)(viii)” would be removed and a reference to “§ 93.301(c)(2)(viii)” would be added in its place;

d. In paragraph (a)(2), the reference to “§ 92.301(c)(1)” would be removed and a reference to “§ 93.301(c)(1)” would be added in its place;

e. In paragraph (a)(4)(i), the reference to “§ 92.301(c)(1)” would be removed and a reference to “§ 93.301(c)(1)” would be added in its place, and the reference to “§ 92.301(c)(2)(iv) or § 92.301(c)(2)(ix)” would be removed and a reference to “§ 93.301(c)(2)(iv) or § 93.301(c)(2)(ix)” would be added in its place;

f. In paragraph (a)(4)(ii), the reference to “§ 92.301(c)(2)(iv) and § 92.301(c)(2)(ix)” would be removed and a reference to “§§ 93.301(c)(2)(iv) and 93.301(c)(2)(ix)” would be added in its place;

g. In paragraph (a)(5)(ii)(A), the reference to “§ 92.301(c)(1)” would be removed and a reference to “§ 93.301(c)(1)” would be added in its place, and the reference to “§ 92.301(c)(2)(iv) or § 92.301(c)(2)(ix)” would be removed and a reference to “§ 93.301(c)(2)(iv) or § 93.301(c)(2)(ix)” would be added in its place;

h. In paragraph (a)(5)(iii), introductory text, the reference to “§ 92.301(c)(1)” would be removed and a reference to “§ 93.301(c)(1)” would be added in its place, and the reference to “§ 92.301(c)(2)(iv) or § 92.301(c)(2)(ix)” would be removed and a reference to “§ 93.301(c)(2)(iv) or § 93.301(c)(2)(ix)” would be added in its place;

i. In paragraph (a)(7)(i), the reference to “§ 92.301(c)(1)” would be removed and a reference to “§ 93.301(c)(1)” would be added in its place, and the reference to “§ 92.301(c)(2)(v), § 92.301(c)(2)(vi), § 92.301(c)(2)(vii) or § 92.301(c)(2)(x)” would be removed and a reference to “§ 93.301(c)(2)(v), § 93.301(c)(2)(vi), § 93.301(c)(2)(vii) or § 93.301(c)(2)(x)” would be added in its place;

j. In paragraph (a)(7)(ii), the reference to “§ 92.301(c)(2)(v), § 92.301(c)(2)(vi), § 92.301(c)(2)(vii) and § 92.301(c)(2)(x)” would be removed and a reference to “§§ 93.301(c)(2)(v), 93.301(c)(2)(vi), 93.301(c)(2)(vii) and 93.301(c)(2)(x)” would be added in its place;

k. In paragraph (a)(8), introductory text, the reference to “§ 92.301(c)(2)(v), § 92.301(c)(2)(vi), § 92.301(c)(2)(vii) or § 92.301(c)(2)(x)” would be removed and a reference to “§ 93.301(c)(2)(v), § 93.301(c)(2)(vi), § 93.301(c)(2)(vii) or § 93.301(c)(2)(x)” would be added in its place;

l. In paragraph (a)(8)(ii), the reference to “§ 92.301(c)(1)” would be removed and a reference to “§ 93.301(c)(1)” would be added in its place, and the reference to “§ 92.301(c)(2)(v), § 92.301(c)(2)(vi), § 92.301(c)(2)(vii) or § 92.301(c)(2)(x)” would be removed and a reference to “§ 93.301(c)(2)(v), § 93.301(c)(2)(vi), § 93.301(c)(2)(vii) or

§ 93.301(c)(2)(x)” would be added in its place;

m. In paragraph (a)(8)(iii), introductory text, the reference to “§ 92.301(c)(1)” would be removed and a reference to “§ 93.301(c)(1)” would be added in its place, and the reference to “§ 92.301(c)(2)(v), § 92.301(c)(2)(vi), § 92.301(c)(2)(vii) or § 92.301(c)(2)(x)” would be removed and a reference to “§ 93.301(c)(2)(v), § 93.301(c)(2)(vi), § 93.301(c)(2)(vii) or § 93.301(c)(2)(x)” would be added in its place;

n. In paragraph (a)(8)(iii)(B), the reference to “§ 92.301(c)(2)(vii)” would be removed and a reference to “§ 93.301(c)(2)(vii)” would be added in its place;

o. In paragraph (a)(8)(iii)(C), introductory text, the reference to “§ 92.304(a)(8)(iii)(B)” would be removed and a reference to “§ 93.301(a)(8)(iii)(B)” would be added in its place;

p. In paragraph (a)(8)(iii)(D), the reference to “§ 92.301(c)(1)” would be removed and a reference to “§ 93.301(c)(1)” would be added in its place, the reference to “§ 92.301(c)(2)(v) or § 92.301(c)(2)(vii)” would be removed and a reference to “§ 93.301(c)(2)(v) or § 93.301(c)(2)(vii)” would be added in its place, and the reference to “§ 92.301(c)(2)(v)(G), § 92.301(c)(2)(vi)(F), or § 92.301(c)(2)(vi)(G)” would be removed and a reference to “§ 93.301(c)(2)(v)(G), § 93.301(c)(2)(vi)(F), or § 93.301(c)(2)(vi)(G)” would be added in its place;

q. In paragraph (a)(8)(iii)(E), the reference to “§ 92.301(c)(1)” would be removed and a reference to “§ 93.301(c)(1)” would be added in its place, and the reference to “§ 92.301(c)(2)(vii) or § 92.301(c)(2)(x)” would be removed and a reference to “§ 93.301(c)(2)(vii) or § 93.301(c)(2)(x)” would be added in its place; and

r. In paragraph (b), the reference to “§ 92.301(c)(1)” would be removed and a reference to “§ 93.301(c)(1)” would be added in its place.

#### **§ 93.306 [Amended]**

32. In newly designated § 93.306, paragraph (a) would be amended by removing the reference to “§§ 92.318 and 92.323” and adding in its place a reference to “§§ 93.318 and 93.323”.

#### **§ 93.308 [Amended]**

33. Newly designated § 92.308 would be amended as follows:

a. In paragraph (a), the reference to “§ 92.324” would be removed and a reference to “§ 93.324” would be added in its place, and the reference to “§ 92.303” would be removed and a

reference to “§ 93.303” would be added in its place;

b. In paragraph (a)(1), the reference to “§§ 92.317 and 92.324” would be removed and a reference to “§§ 93.317 and 92.324” would be added in its place, and the reference to “§ 92.303” would be removed and a reference to “§ 93.303” would be added in its place;

c. In paragraph (b), the reference to “§ 92.303(e)” would be removed and a reference to “§ 93.303(e)” would be added in its place; and

d. In paragraph (c)(4)(ii), the reference to “§ 92.308(a)” would be removed and a reference to “§ 93.303(a)” would be added in its place.

#### **§ 93.314 [Amended]**

34. In newly designated § 92.314, the reference to “§ 92.301(c)(2) (i) through (viii)” would be removed and a reference to “§ 93.301(c)(2) (i) through (viii)” would be added in its place, and the reference to “§ 92.301(c)(1)” would be removed and a reference to “§ 93.301(c)(1)” would be added in its place.

35. In subpart C, footnote 18 would be amended by removing the reference to “§§ 92.315, 92.316, 92.317 and 92.318” would be removed and a reference to “§§ 93.315, 93.316, 93.317 and 93.318” would be added in its place.

#### **§ 93.315 [Amended]**

36. Newly designated § 93.315 would be amended by removing the reference to “§ 92.305” and adding in its place a reference to “§ 93.305”.

#### **§ 93.316 [Amended]**

37. Newly designated § 93.316 would be amended by removing the reference to “§ 92.306” and adding in its place a reference to “§ 93.306”.

#### **§ 93.317 [Amended]**

38. In newly designated § 93.317(a), the reference to “§ 92.306” would be removed and a reference to “§ 93.306” would be added in its place, and the reference to “§ 92.314” would be removed both times it appears and a reference to “§ 93.314” would be added each time in its place.

#### **§ 93.318 [Amended]**

39. Newly designated § 93.318 would be amended as follows:

a. In paragraph (a)(1), the reference to “§ 92.304” would be removed and a reference to “§ 93.304” would be added in its place, and the reference to “§ 92.301” would be removed and a reference to “§ 93.301” would be added in its place; and

b. In paragraph (b), the reference to “§ 92.317(b)” would be removed and a

reference to “§ 93.317(b)” would be added in its place.

40. In subpart C, footnote 19 would be amended by removing the reference to “§§ 92.319 and 92.320” and adding in its place a reference to “§§ 93.319 and 93.320”.

#### **§ 93.319 [Amended]**

41. Newly designated § 93.319 would be amended by removing the reference to “§ 92.305” and adding in its place a reference to “§ 93.305”.

#### **§ 93.320 [Amended]**

42. Newly designated § 93.320 would be amended by removing the reference to “§ 92.306” and adding in its place a reference to “§ 93.306”, by removing the reference to “§ 92.314” and adding in its place a reference to “§ 93.314”, and by removing the reference to “§ 92.308 (a), (b) and (c)” and adding in its place a reference to “§ 93.308 (a), (b), and (c)”.

43. In subpart C, footnote 20 would be amended by removing the reference to “§§ 92.321 to 92.326” and adding in their place a reference to “§§ 93.321 to 93.326”.

#### **§ 93.322 [Amended]**

44. Newly designated § 93.322 would be amended by removing the reference to “§ 92.305” and adding in its place a reference to “§ 93.305”.

#### **§ 93.323 [Amended]**

45. In newly designated § 93.323, paragraphs (a) and (b) would be amended by removing the references to “§ 92.324” and adding in their place a reference to “§ 93.324”.

#### **§ 93.324 [Amended]**

46. Newly designated § 93.324 would be amended by removing the reference to “§ 92.303(a)” and adding in its place a reference to “§ 93.303(a)”.

#### **§ 93.325 [Amended]**

47. Newly designated § 93.325 would be amended by removing the reference to “§§ 92.306 and 92.323” and adding in its place a reference to “§§ 93.306 and 92.323”, by removing the reference to “§ 92.314” and adding in its place a reference to “§ 93.314”, and by removing the reference to “§ 92.324” and adding in its place a reference to “§ 93.324”.

#### **§ 93.326 [Amended]**

48. Newly designated § 93.326 would be amended by removing the reference to “§§ 92.321, 92.322, 92.323” and adding in its place a reference to “§§ 93.321, 93.322, and 93.323”, and by removing the reference to “§ 92.324” the second time it appears and adding in its place a reference to “§ 93.324”.

49. Subparts D and E would be revised to read as follows:

**Subpart D—Ruminants**

Sec.

- 93.400 Definitions.
- 93.401 General prohibitions; exceptions.
- 93.402 Inspection of certain aircraft and other means of conveyance and shipping containers thereon; unloading, cleaning, and disinfection requirements.
- 93.403 Ports designated for the importation of ruminants.
- 93.404 Import permits for ruminants and for ruminant specimens for diagnostic purposes; and reservation fees for space at quarantine facilities maintained by APHIS.
- 93.405 Certificate of export and other requirements for ruminants.
- 93.406 Permit, certificate, declaration and other documents for ruminants.
- 93.407 Inspection at the port of entry.
- 93.408 Articles accompanying ruminants.
- 93.409 Movement from conveyances to quarantine station.
- 93.410 Ruminant quarantine facilities.
- 93.411 Quarantine stations, visiting restricted; sales prohibited.
- 93.412 Milk from quarantined ruminants.
- 93.413 Manure from quarantined ruminants.
- 93.414 Appearance of disease among ruminants in quarantine.
- 93.415 Requirements for importation of live ruminants from various risk class regions.
- 93.416 Importation of ruminants through the Harry S. Truman Animal Import Center (HSTAIC).
- 93.417 Pre-embarkation quarantine facility; criteria and standards for approval.

**Subpart D—Ruminants****§ 93.400 Definitions.**

Wherever in this subpart the following terms are used, unless the context otherwise requires, they shall be construed, respectively, to mean:

**Accredited veterinarian.** A veterinarian approved by the Administrator in accordance with part 161 of this chapter to perform functions specified in parts 1, 2, 3, and 11 of subchapter A, and subchapters B, C, and D of this chapter, and to perform functions required by cooperative State-Federal disease control and eradication programs.

**Adjacent regions.** Any defined geographic land area identifiable by geological, political or surveyed boundaries that shares common boundaries with, or is proximate to any region of a different risk class, as determined by the Administrator.

**Administrator.** The Administrator of the Animal and Plant Health Inspection Service or any other employee of the Animal and Plant Health Inspection Service, United States Department of Agriculture, delegated to act in the Administrator's stead.

**Affected animals.** Animals currently infected or infested with, or exposed to,

a communicable disease agent, or that are not known to be infected, infested, or exposed but that because of information, proximity, location, season, or lack of surveillance data could reasonably be expected to be infected, infested, or exposed to a communicable disease agent.

**Affected premises or region.** A premises or region where a communicable disease agent is known to exist; that is adjacent to or proximate to any known infected or infested premises or region so that airborne, vector, or mechanical transmission of the disease agent could occur; or that, because of lack of surveillance data, could reasonably be expected to be infected, infested, or exposed to a communicable disease agent.

**Animal and Plant Health Inspection Service (APHIS).** The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

**Animals.** All species of the animal kingdom including: Cattle, sheep, goats, other ruminants, swine, horses, asses, mules, zebras, dogs, and poultry that are susceptible to communicable diseases of livestock or capable of being carriers of those diseases or their arthropod vectors.

**APHIS representative.** Any individual employed by the Animal and Plant Health Inspection Service, United States Department of Agriculture, who is authorized to perform the services required by this part.

**Approved bovine tuberculosis test.** Any test recognized as an Official tuberculosis test in the United States according to § 77.1 of this chapter or a test recognized as an equivalent test by the Administrator and that is recognized as an official test in a country exporting animals to the United States.

**Approved brucellosis test.** Any test recognized as an official brucellosis test in the United States according to § 78.1 of this chapter, or a test recognized as an equivalent test by the Administrator and that is recognized as an official test in a country exporting animals to the United States.

**Approved tests for restricted diseases or agents.** Diagnostic tests or procedures that are determined by the Administrator to be scientifically valid to diagnose a restricted animal disease.

**Authorized veterinarian.** A veterinarian accredited, employed or authorized by the National Veterinary Services of the country to carry out the required inspection and certification services.

**Border definitions.** See § 92.1 of this chapter.

**Case.** An individual animal affected by a communicable disease agent.

Depending on the condition, this may be an animal with clinical signs, or an animal with serological or pathological evidence of infection, or an infested animal.

**Cattle.** Animals of the bovine species.

**Communicable disease.** Any contagious or infectious disease of animals. It can be transmitted either directly or indirectly to a susceptible animal from an infected animal, vector, inanimate reservoir, or other source.

**Contagious disease.** Any communicable disease transmitted from one animal to another. Such transmission includes, but is not limited to, contact with other animals or by feed, water, aerosol, or contaminated objects.

**Department.** The United States Department of Agriculture (USDA).

**Driven.** Moved (animals) from one place to another by walking under their own power and being herded and guided by persons or trained animals.

**Ectoparasites.** Acarid (mites, ticks) or insect members of the Phylum Arthropoda that spend all or part of their life cycle on the exterior of avian, reptilian or mammalian hosts and that are known or suspected to be the vectors of communicable disease agents, or are the cause of disease or irritation in animals or birds.

**Equivalent test.** A serologic, microbiologic, chemical, or physical test approved for use in a region exporting livestock or livestock products to the United States and recognized by the Administrator as providing results equal to a test approved by the United States Department of Agriculture. Recognition of a test as an "equivalent test" will be made by the Administrator after he or she reviews scientific data that shows that the results of the test are equal to the USDA-approved test.

**Exposed.** (1) An animal or means of conveyance that has been in contact with or that can reasonably be expected to have been in contact with an animal, feed, water, air, soil, tools, or other objects, insects, or ectoparasites infected or contaminated with a communicable disease agent, as determined by the Administrator.

(2) A region or premises where an animal, feed, water, air, soil, tools or other objects, insects, or ectoparasites contaminated with a communicable disease agent are or have been present within the known incubation period for the disease agent.

(i) **Direct exposure.** Exposure by coming into direct contact with an infected animal, or with feed, water, air, soil, tools, or other objects, that have been contaminated by discharges from an infected animal.

(ii) *Indirect exposure.* Exposure by coming into contact with vector insects or ectoparasites, or objects that have been contaminated other than by discharges from an infected animal.

*Herd.* (1) A group of animals under common ownership or supervision that are maintained and intermingle on one or more parts of a single premises (farm, ranch, feedlot, etc.); or

(2) A group of animals under common ownership or supervision maintained on geographically separated premises but that have been interchanged between the different premises or have been otherwise intermingled.

*Identification.* (1) *Permanent identification.* Brands, tattoos, or electronic identification that cannot be readily removed or altered.

(2) *Semi-permanent identification.* Identification such as metal or plastic ear tags that may remain on an animal permanently but can be easily altered, lost or removed.

(3) *Non-permanent identification.* Identification such as temporary ear tags, chain tags, back tags, or tail tags.

(4) *Temporary identification.* Lot identification if lots are not mixed, or the origin of all lots in a mixed lot.

*Immediate slaughter.* Consignment directly from the port of entry to a recognized slaughtering establishment<sup>1</sup> and slaughter thereat within two weeks from the date of entry.

*Import (imported, importation) into the United States.* To bring into the territorial limits of the United States.

*Inspector.* An employee of the Animal and Plant Health Inspection Service authorized to perform duties required under this subpart.

*Livestock.* Domesticated species of cattle, swine, sheep, goats, llamas, horses, or poultry that normally and historically have been kept and raised on farms. Livestock also includes bison and cervidae or other species kept in captivity for producing food or fiber, or for other commercial purposes.

*Moved directly.* Moved (shipped, transported, other otherwise moved) without unloading and without stopping except for refueling, or for traffic conditions such as traffic lights or stop signs.

*Official seal.* A serially numbered, metal or plastic strip, consisting of a self-locking device on one end and a slot on the other end, which forms a loop when the ends are engaged and

which cannot be reused if opened, or a serially numbered, self-locking button which can be used for this purpose.

*Operator.* Any person operating an approved quarantine facility.

*Permitted treatment.* A treatment authorized by the Administrator to be used in the official treatment of animals for control or removal of ectoparasites.

*Person.* Any individual, corporation, company, association, firm, partnership, society, joint stock company, or other legal entity.

*Port Veterinarian.* A veterinarian employed by APHIS to perform duties required under this part at a port of entry.

*Post-importation quarantines.* Quarantines applied in the importing region at a facility specially designated as an import quarantine facility.

*Pre-embarkation quarantines.* Quarantines applied in the exporting region. May be on the premises of origin, a separate quarantine facility, a border station, or other facility used to hold animals while in transit.

*Quarantine.* Confinement of all susceptible animals, animal products, feed, farm machinery, other equipment, means of conveyance, and any other potentially contaminated objects to a premises or area where infection or infestation with a specific restricted agent has been found or is suspected to exist.

*Recognized slaughtering establishment.* An establishment<sup>2</sup> where slaughtering operations are regularly carried on under Federal or State inspection and that has been approved by APHIS to receive animals for slaughter under this part.

*Region.* Any defined geographic land region identifiable by geological, political or surveyed boundaries.

*Restricted agents.* A livestock communicable disease agent, vector, or host of an agent not known to exist in the United States or that is subject to Federal or cooperative Federal/State control or eradication program within the United States. Restricted agents are listed in § 92.2 of this chapter.

*Risk Class regions.* Exporting regions designated by the Administrator according to the results of a risk assessment as defined in § 92.1 of this chapter, and determined by criteria as set forth in § 92.3 of this chapter, are incorporated herein and are applicable to this part.

*Ruminants.* All animals that chew the cud, such as cattle, buffaloes, sheep, goats, deer, antelopes, camels, llamas and giraffes.

*Shipping container.* For the purposes of § 93.402, any container of a type specially adapted for use in transporting any article on the means of conveyance involved.

*Susceptible animals.* Species of ruminants or other animals that can become infected with a specific disease agent.

*Trail.* Move animals from one place to another by having them walk under their own power, and by leading them by ropes or other devices tied to the animal and guided by persons or trained animals.

*Transported.* Moved or shipped from one place to another by any means of conveyance, such as airplane, ship, boat, barge, truck, train, cart, or other vehicle.

*United States.* All of the States of the United States, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other Territories and Possessions of the United States.

*Vector-borne disease.* A disease transmitted indirectly to an animal through an intermediate arthropod vector, including ticks or insects.

*Veterinarian in Charge.* The veterinary official of the Animal and Plant Health Inspection Service, United States Department of Agriculture, who is assigned by the Administrator to supervise and perform the official animal health work of the Animal and Plant Health Inspection Service in the State or area concerned.

*Wether.* A castrated male sheep or goat.

*Zoological park.* A zoo, park, garden or other place, maintained under the surveillance of a licensed Doctor of Veterinary Medicine, for the exhibition of live animals, pigeons or birds, for the purpose of public recreation or education.

#### § 93.401 General prohibitions; exceptions.

(a) No ruminant subject to the provisions of this part may be imported into the United States except in accordance with the regulations in this part, nor may any such ruminant be handled or moved after physical entry into the United States before final release from quarantine or any other form of Federal governmental detention except in compliance with such regulations; *Provided that:* Except as prohibited by section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), the Administrator may, upon request in specific cases, allow ruminants to be brought into or through the United States under such conditions as he or she may prescribe, when he or she determines in the specific case that

<sup>1</sup> The name of recognized slaughtering establishments approved under this part may be obtained from the Area Veterinarian in Charge (AVIC), Veterinary Services, Animal and Plant Health Inspection Service, for the State of destination of the shipment. AVIC telephone numbers can be found in the local telephone book.

<sup>2</sup> See footnote 1 in § 93.400.

such action will not endanger the livestock or poultry of the United States.

(b) Except for ruminants prohibited entry by section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), the provisions in this part relating to ruminants shall not apply to healthy ruminants in transit through the United States if they are not known to be infected with or exposed, within 60 days preceding the date of export from the region of origin, to communicable diseases of ruminants, and if an import permit<sup>3</sup> has been properly applied for and obtained under § 93.404 of this chapter and all conditions therein are observed; and if the following conditions are also met:

(1)(i) The ruminants are maintained under continuous confinement in transit through the United States aboard an aircraft, ocean vessel, or other means of conveyance; or

(ii) The ruminants are unloaded, in the course of such transit, into a ruminant holding facility that is provided by the carrier or its agent and has been approved<sup>4</sup> in advance by the Administrator in accordance with paragraph (c) of this section as adequate to prevent the spread within the United States of any livestock disease, and the ruminants are maintained there under continuous confinement until loaded aboard a means of conveyance for transportation from the United States and are maintained under continuous confinement aboard such means of conveyance until it leaves the United States; the import permit will specify any additional conditions necessary to ensure that the transit of the ruminants through the United States can be made without endangering the livestock or poultry of the United States, and that Department inspectors may inspect the ruminants on board such means of conveyance or in such holding facility as provided in section 5 of the Act of July 2, 1962 (21 U.S.C. 134d) to ascertain whether the requirements of this paragraph are met, and dispose of them in accordance with section 2 of the Act of July 2, 1962 (21 U.S.C. 134a) if such conditions are not met; and

(2) The carrier or its agent executes and furnishes to the collector of U.S. Customs at the first port of arrival in the United States a declaration stating that the ruminants will be retained aboard

such means of conveyance or in an approved holding facility during transshipment as required by this paragraph.

(c) Provisions for the approval of facilities required in this paragraph are:

(1) They must be sufficiently isolated to prevent direct or indirect contact with all other animals and birds while in the United States.

(2) They must be so constructed that they provide adequate protection against environmental conditions and can be adequately cleaned, washed and disinfected.

(3) They must provide for disposal of ruminant carcasses, manure, bedding, waste and any related shipping materials in a manner that will prevent dissemination of disease.

(4) They must have provisions for adequate sources of feed and water and for attendants for the care and feeding of ruminants in the facility.

(5) They must comply with additional requirements as may be imposed by the Administrator if deemed applicable for a particular shipment.

(6) They must also comply with all applicable local, State and Federal requirements for environmental quality and with the provisions of the Animal Welfare Regulations in chapter I of this title, as applicable.

**§ 93.402 Inspection of certain aircraft and other means of conveyance and shipping containers thereon; unloading, cleaning, and disinfection requirements.**

(a) *Inspection.* All aircraft and other means of conveyance (including shipping containers thereon) moving into the United States from any foreign country are subject to inspection without a warrant by properly identified and designated APHIS inspectors to determine whether they are carrying any animal, carcass, product or article regulated or subject to disposal under any law or regulation administered by the Secretary of Agriculture for prevention of the introduction or dissemination of any communicable animal disease (21 U.S.C. 134d).

(b) *Unloading requirements.* Whenever in the course of any such inspection at any port in the United States the APHIS inspector has reason to believe that the means of conveyance or container is contaminated with material of animal origin, such as, but not limited to, meat, organs, glands, extracts, secretions, fat, bones, blood, lymph, urine, or manure, so as to present a danger of the spread of any communicable animal disease, the inspector may require the holding and unloading of the means of conveyance and the emptying of the container if he

or she deems it necessary to enable him or her to determine whether the means of conveyance or container is in fact so contaminated. The principal operator of the means of conveyance and his or her agent in charge of the means of conveyance must comply with any such requirements under the immediate supervision of, and in the time and manner prescribed by, the inspector.

(c) *Cleaning and disinfection.*

Whenever, upon inspection under this section, an inspector determines that a means of conveyance or shipping container is contaminated with material of animal origin so as to present a danger of the spread of any communicable animal disease, he or she shall notify the principal operator of the means of conveyance or his or her agent in charge, of such determination and the requirements under this section. The person so notified must cause the proper cleaning and disinfection of such means of conveyance and container under the immediate supervision of, and in the time and manner prescribed by, the inspector.

**§ 93.403 Ports designated for the importation of ruminants.**

(a) *Air and ocean ports.* The following ports have APHIS inspection and quarantine facilities necessary for quarantine stations and all ruminants shall be entered into the United States only through these stations, except as otherwise provided in this section; Miami, Florida; Honolulu, Hawaii; and Newburgh, New York.

(b) *Canadian border ports.* The following land border ports are designated as having the necessary inspection facilities for the entry of ruminants from Canada: Eastport, Idaho; Houlton and Jackman, Maine; Detroit, Port Huron, and Sault Ste. Marie, Michigan; Baudette, Minnesota; Opheim, Raymond, and Sweetgrass, Montana; Alexandria Bay, Buffalo, and Champlain, New York; Dunseith, Pembina, and Portal, North Dakota; Derby Line and Highgate Springs, Vermont; Blaine, Lynden, Oroville, and Sumas, Washington.

(c) *Mexican border ports.* The following land border ports are designated as having the necessary inspection facilities for the entry of ruminants from Mexico: Brownsville, Hidalgo, Laredo, Eagle Pass, Del Rio, and Presidio, Texas; Douglas, Naco, Nogales, Sasabe, and San Luis, Arizona; Calexico and San Ysidro, California; and Antelope Wells, Columbus, and Santa Teresa, New Mexico.

(d) *Special ports.* Charlotte Amalie, St. Thomas, and Christiansted, St. Croix, in the United States Virgin Islands, are

<sup>3</sup> Such permit may be obtained from the National Center for Import and Export, Veterinary Services, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231.

<sup>4</sup> Requests for approval of ruminant holding facilities should be made to the National Center for Import and Export, Veterinary Services, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231.



hereby designated as quarantine stations for the entry of ruminants from the British Virgin Islands into the United States Virgin Islands for immediate slaughter.

(e) Limited ports. The following ports are designated as having inspection facilities for the entry of ruminants and ruminant test specimens that do not appear to require restraint and holding inspection facilities: Anchorage and Fairbanks, Alaska; San Diego, California; Jacksonville, St. Petersburg-Clearwater, and Tampa, Florida; Atlanta, Georgia; Chicago, Illinois; New Orleans, Louisiana; Portland, Maine; Baltimore, Maryland; Boston, Massachusetts; Minneapolis, Minnesota; Great Falls, Montana; Portland, Oregon; San Juan, Puerto Rico; El Paso, Galveston and Houston, Texas; and Seattle, Spokane, and Tacoma, Washington.

(f) *Designation of other ports.* The Secretary of the Treasury has approved the designation as quarantine stations of the ports specified in this section. In special cases other ports may be designated as quarantine stations under this section by the Administrator, with the concurrence of the Secretary of the Treasury.

(g) *Ports and privately operated quarantine facilities for sheep.* Sheep may be entered into the United States at any port specified in paragraph (a) of this section, or at any other port designated as an international port or airport by the U.S. Customs Service and quarantined at privately operated quarantine facilities provided the applicable provisions of §§ 93.401, 93.404(a), 93.405, 93.406, and 93.407 are met.

**§ 93.404 Import permits for ruminants and for ruminant specimens for diagnostic purposes; and reservation fees for space at quarantine facilities maintained by APHIS.**

(a) *Application for import permit; reservation required.* (1) To import ruminants and ruminant test specimens for diagnostic screening purposes from any part of the world, the importer must first apply for and obtain from APHIS an import permit, except that, the following types of ruminants are exempt from import permit requirements when they are imported through a land border port: sheep and goats from regions classified as Risk Class RN for foot-and-mouth disease and rinderpest, when imported for immediate slaughter; and cattle, bison, and wethers whether or not they are imported for immediate slaughter. The application must specify the name and address of the importer; the species, breed, number or quantity of ruminants or ruminant test specimens

to be imported; the purpose of the importation; individual ruminant identification that includes a description of the ruminant, name, age, markings, if any, registration number, if any, and tattoo or eartag; the region of origin; the name and address of the exporter; the port of embarkation in the foreign country; the mode of transportation, route of travel, and the port of entry in the United States; the proposed date of arrival of the ruminants or ruminant test specimens to be imported; and the name of the person to whom the ruminants or ruminant test specimens will be delivered and the location of the place in the United States to which delivery will be made from the port of entry. Additional information may be required in the form of certificates concerning specific diseases to which the ruminants are susceptible, as well as vaccinations or other precautionary treatments to which the ruminants or ruminant test specimens have been subjected. Notice of any such requirement will be given to the applicant in each case.<sup>5</sup>

(2) An application for permit to import ruminants and/or ruminant test specimens may also be denied because of: Communicable disease conditions in the region of origin, or in a region where the shipment has been or will be held or through which the shipment has been or will be transported; deficiencies in the regulatory programs for the control or eradication of animal diseases and the unavailability of veterinary services in the above mentioned regions; the importer's failure to provide satisfactory evidence concerning the origin, history, and health status of the ruminants; the lack of satisfactory information necessary to determine that the importation will not be likely to transmit any communicable disease to livestock or poultry of the United States; or any other circumstances that the Administrator believes require such denial to prevent the dissemination of any communicable disease of livestock or poultry into the United States.

(3)(i) The importer or importer's agent must pay or ensure payment of a reservation fee for each lot of ruminants to be quarantined in a facility maintained by USDA. For ruminants, the reservation fee shall be 100 percent of the cost of providing care, feed, and handling during quarantine, as estimated by the quarantine facility's veterinarian in charge.

(ii) At the time the importer or the importer's agent requests a reservation of quarantine space, the importer or

importer's agent must pay the reservation fee by check or U.S. money order or ensure payment of the reservation fee by an irrevocable letter of credit from a commercial bank (the effective date on such letter of credit must run to 30 days after the date the ruminants are scheduled to be released from quarantine); except that anyone who issues a check to the Department for a reservation fee that is returned because of insufficient funds shall be denied any further request for reservation of a quarantine space until the outstanding amount is paid.

(iii) Any reservation fee paid by check or U.S. money order shall be applied against the expenses incurred for services received by the importer or importer's agent in connection with the quarantine for which the reservation was made. Any part of the reservation fee that remains unused after being applied against the expenses incurred for services received by the importer or the importer's agent in connection with the quarantine for which the reservation was made, shall be returned to the individual who paid the reservation fee. If the reservation fee is ensured by a letter of credit, the Department will draw against the letter of credit unless payment for services received by the importer or importer's agent in connection with the quarantine is otherwise made at least 3 days prior to the expiration date of the letter of credit.

(iv) Any reservation fee shall be forfeited if the importer or the importer's agent fails to present for entry, within 24 hours following the designated time of arrival, the lot of ruminants for which the reservation was made: Except that a reservation fee shall not be forfeited if:

(A) Written notice of cancellation from the importer or the importer's agent is received by the office of the veterinarian in charge of the quarantine facility<sup>6</sup> during regular business hours (8:00 a.m. to 4:30 p.m. Monday through Friday, excluding holidays) no later than 15 days prior to the beginning of the time of importation of the ruminants as specified in the import permit or as arranged with the veterinarian in charge of the quarantine facility if no import permit is required (the 15 days period shall not include Saturdays, Sundays, or holidays); or

(B) The Administrator determines that services, other than provided by carriers, necessary for the importation of

<sup>6</sup>The addresses of USDA quarantine facilities may be found in telephone directories listing the facilities or by contacting the National Center for Import and Export, Veterinary Services, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231.

<sup>5</sup>See §§ 93.405, 93.406, and 93.415 for additional requirements for the importation of ruminants.



the ruminants within the requested period are unavailable because of unforeseen circumstances as determined by the Administrator (such as the closing of an airport due to inclement weather or the unavailability of the reserved space due to the extension of another quarantine).

(v) If the reservation fee was ensured by a letter of credit and the fee is to be forfeited under paragraph (a)(3)(iv) of this section, the Department will draw against the letter of credit unless the reservation fee is otherwise paid at least 3 days prior to the expiration date of the letter of credit.

(vi) When a reservation is canceled in accordance with paragraph (a)(3)(iv)(A) of this section and the provisions of paragraph (a)(3)(iv)(B) of this section do not apply, a \$40.00 cancellation fee shall be charged. If a reservation fee was paid, the cancellation fee shall be deducted from any reservation fee returned to the importer or the importer's agent. If the reservation fee was ensured by a letter of credit, the Department will draw the amount of the cancellation fee against the letter of credit unless the cancellation fee is otherwise paid at least 3 days prior to the expiration date of the letter of credit.

(b) *Import Permit.* When an import permit is issued, the original and two copies will be sent to the importer. It shall be the responsibility of the importer to forward the original import permit and one copy to the shipper in the country of origin, and it shall also be the responsibility of the importer to insure that the shipper presents the copy of the import permit to the carrier and makes proper arrangements for the original permit to accompany the shipment to the specified U.S. port of entry for presentation to the collector of customs. All ruminants and ruminant test specimens for diagnostic screening purposes intended for importation into the United States for which an import permit has been issued, must be received at the specified port of entry within the time prescribed in the import permit and shall not exceed 14 days from the first day that the permit is effective for all permits relevant to the shipment or shipments. All ruminants and ruminant test specimens for which an import permit is required by these regulations will not be eligible for entry into the United States if an import permit has not been issued; if the ruminants or ruminant test specimens are unaccompanied by such a permit; if the shipment is from any port other than the one designated in the permit; if arrival in the United States is at any port other than the one designated in the permit; if the ruminants or ruminant test

specimens imported are different from those described in the permit; if the ruminants or ruminant test specimens are not handled as outlined in the application for the import permit and as specified in the permit issued; or if ruminants or swine other than those covered by the import permits are aboard the transporting carrier.

**§ 93.405 Certificate of export and other requirements for ruminants.**

(a) All ruminants imported or offered for importation from any part of the world, except for ruminants that are imported for immediate slaughter from regions classified as Risk Class RN for all restricted agents of ruminants, and except as provided in paragraphs (c) and (d) of this section,<sup>7</sup> must be accompanied by a certificate of export issued and signed by an authorized veterinarian and endorsed by an official of the National Veterinary Services of the country of export, who certifies that the veterinarian signing and issuing the certificate is authorized to do so and who certifies that:

(1) The ruminants originate from premises that are not known to have been affected with any communicable diseases of ruminants during the previous 60 days;

(2) The ruminants originate from premises that are not known to have been affected with restricted ectoparasites of ruminants during the previous 60 days;

(3) During transportation to the port of embarkation there was no direct or indirect exposure to any potential carrier animals from any region affected with restricted agents that affect ruminants;

(4) While en route to the port of entry, the ruminants were not trailed or driven through any Risk Class R3, R4 or RU region for any tick-borne restricted agents that affect ruminants;

(5) While en route to the port of entry, the ruminants were not trailed, driven, transported, or otherwise moved through any Risk Class R3, R4, or RU region for any restricted insect-transmitted agents that affect ruminants, during a time of year when insect vectors were active;

(6) The ruminants were either inspected on the day of embarkation and were found to be free of restricted ectoparasites as listed in § 92.2 of this chapter, or were treated with one of the permitted treatments listed in § 72.13(b) of this chapter within 10 to 14 days of embarkation. If treated, the pesticide, active ingredient, concentration, and

date applied must be recorded on the health certificate; and

(7) The ruminants were transported to the United States only in means of conveyance or vehicles that were cleaned and disinfected prior to use.

(b) Prior to entry into the United States, the ruminants must be identified in accordance with § 71.18 of this chapter.

(c) Cattle, sheep, and goats that are from a region classified as RN for all restricted diseases affecting the type of animal in question, and that are to be transported in-bond through the United States for immediate export, shall be inspected at the border port of entry and, when accompanied by an import permit obtained under § 93.404 and when all conditions therein are observed, shall be allowed entry into the United States and shall be otherwise handled in accordance with § 93.401(b).

(d) Ruminants originating in the United States and transported directly through a region classified as RN for all restricted diseases for the type of ruminant being transported, may re-enter the United States without foreign health or test certificates when accompanied by copies of the United States export health certificates properly issued and endorsed in accordance with the regulations in part 91 of this chapter: *Provided*, That, to qualify for reentry into the United States, the date, time, port of entry, and signature of the port veterinarian of the foreign country that inspected the ruminants for entry into the foreign country shall be recorded on the United States health certificate, or a paper containing such information shall be attached to the certificate that accompanies the ruminants. In all cases, it shall be determined by the veterinary inspector at the United States port of entry that the ruminants are the identical ruminants covered by said certificate.

(e) If any ruminants are unaccompanied by the export certificate as required by paragraph (a) of this section, or if such ruminants are found upon inspection at the United States port of entry to be affected with or to have been exposed to a communicable disease, they shall be refused entry and shall be handled thereafter in accordance with the provisions of section 8 of the Act of August 30, 1890 (26 Stat. 416; 21 U.S.C. 103), or quarantined, or otherwise disposed of as the Administrator may direct.

**§ 93.406 Permit, certificate, declaration and other documents for ruminants.**

(a) The export certificates, import permits, declarations, and affidavits required by the regulations in this part

<sup>7</sup> See § 93.415 for additional requirements for ruminants imported from specific risk class regions.

must be presented by the importer or his or her agent to the collector of customs at the port of entry upon arrival of ruminants at such port, for the use of the veterinary inspector at the port of entry.

(b) For all ruminants imported or offered for importation, the importer or his or her agent must first present two copies of a declaration that lists the port of entry, the name and address of the importer, the name and address of the broker, the origin of the ruminants, the number, breed, species, and purpose of the importation, the name of the person to whom the ruminants will be delivered, and the location of the place to which such delivery will be made.

**§ 93.407 Inspection at the port of entry.**

Ruminants imported from any part of the world must be inspected at the United States port of entry. All ruminants found to be free from communicable disease and not to have been exposed thereto within 60 days prior to their exportation to the United States shall be admitted subject to the other provisions in this part; all other ruminants shall be refused entry. Ruminants refused entry, unless exported within a time fixed in each case by the Administrator, and in accordance with other provisions he or she may require in each case for their handling, shall be disposed of as the Administrator may direct, in accordance with provisions of section 2 of the Act of July 2, 1962 (21 U.S.C. 134a), or the provisions of section 8 of the Act of August 30, 1890 (21 U.S.C. 103). Such portions of the transporting vessel, and of its cargo, that have been exposed to any such ruminants or their emanations, must be disinfected in such manner as may be considered necessary by the inspector in charge at the port of entry to prevent the introduction or spread of livestock or poultry disease, before the cargo is allowed to land.

**§ 93.408 Articles accompanying ruminants.**

No litter or manure, fodder or other aliment, nor any equipment such as boxes, buckets, ropes, chains, blankets, or other things used for or about ruminants governed by the regulations in this subpart, may be landed from any conveyance except under such restrictions as the inspector in charge at the port of entry shall direct.

**§ 93.409 Movement from conveyances to quarantine station.**

Platforms and chutes used for handling imported ruminants must be cleaned and disinfected under APHIS supervision after being so used. The

said ruminants may not be moved over any highways nor allowed to come in contact with other animals, but must be transferred from the conveyance to the quarantine grounds only in boats, cars, or vehicles approved by the inspector in charge at the port of entry. Such cars, boats, or vehicles must be cleaned and disinfected under APHIS supervision immediately after such use, by the carrier moving the same. The railway cars so used must be either cars reserved for this exclusive use or box cars not otherwise employed in the transportation of animals or their fresh products. When movement of the aforesaid ruminants upon or across a public highway is unavoidable, it shall be under such careful supervision and restrictions as the inspector in charge at the port of entry and the local authorities may direct.

**§ 93.410 Ruminant quarantine facilities.**

(a) *Privately operated quarantine facilities.* The importer, or his or her agent, of ruminants subject to quarantine under the regulations in this subpart must arrange for acceptable transportation to the privately operated quarantine facility and for the care, feed, and handling of the ruminants from the time of unloading at the quarantine port to the time of release from quarantine. Such arrangements shall be agreed to in advance by the Administrator. All expenses resulting therefrom or incident thereto shall be the responsibility of the importer; APHIS assumes no responsibility with respect thereto. The quarantine facility must be suitable for the quarantine of such ruminants and must be approved by the Administrator prior to the issuance of any import permit. The facilities occupied by ruminants must be kept clean and sanitary. If for any cause the care, feed, or handling of ruminants, or the sanitation of the facilities, is neglected, in the opinion of the inspector assigned to supervise the quarantine, such services may be furnished by APHIS in the same manner as though arrangements had been made for such services as provided by paragraph (b) of this section, and/or the ruminants may be disposed of as the Administrator may direct, including sale in accordance with the procedure described in paragraph (b) of this section. The importer, or his or her agent, must request in writing such inspection and other services as may be required, and shall waive all claim against the United States and APHIS or any employee of APHIS for damages that may arise from such services. The Administrator may prescribe reasonable rates for the services provided under this paragraph.

When it is found necessary to extend the usual minimum quarantine period, the importer, or his or her agent, shall be so advised in writing and must pay for such additional quarantine and other services required. Payment for all services received by the importer, or his or her agent, in connection with each separate lot of ruminants must be made by certified check or U.S. money order prior to release of the ruminants. If such payment is not made, the ruminants may be sold in accordance with the procedure described in paragraph (b) of this section, or otherwise disposed of as directed by the Administrator.

(b) *Quarantine facilities maintained by APHIS.* The importer, or his or her agent, of ruminants subject to quarantine under the regulations in this subpart must arrange for acceptable transportation to the quarantine facility, and for the care, feed, and handling of the ruminants from the time they arrive at the quarantine port to the time of release from quarantine. Such arrangements shall be agreed to in advance by the Administrator. The importer or his or her agent shall request in writing such inspection and other services as may be required, and shall waive all claim against the United States and APHIS or any employee of APHIS, for damages that may arise from such services. All expenses resulting therefrom or incident thereto shall be the responsibility of the importer; APHIS assumes no responsibility with respect thereto. The Administrator may prescribe reasonable rates for the services provided under this paragraph. When it is found necessary to extend the usual minimum quarantine period, the importer, or his or her agent, shall be so advised in writing and must pay for such additional quarantine and other services required. Payment for services received by the importer, or his or her agent, in connection with each separate lot of ruminants must be made by certified check or U.S. money order prior to release of the ruminants. If such payment is not made, the ruminants may be sold in accordance with the procedure described in this paragraph or otherwise disposed of as directed by the Administrator. When payment is not made and the ruminants are to be sold to recover payment for services received, the importer, or his or her agent, will be notified by the inspector that if said charges are not immediately paid or satisfactory arrangements made for payment, the ruminants will be sold at public sale to pay the expense of care, feed, and handling during that period. The sale will be held after the expiration of the quarantine period, at such time

and place as may be designated by the General Services Administration of the United States Government or other designated selling agent. The proceeds of the sale, after deducting the charges for care, feed, and handling of the ruminants and other expenses, including the expense of the sale, shall be held in a Special Deposit Account in the United States Treasury for 6 months from the date of sale. If not claimed by the importer, or his or her agent, within 6 months from the date of sale, the amount so held shall be transferred from the Special Deposit Account to the General Fund Account in the United States Treasury.

**§ 93.411 Quarantine stations, visiting restricted; sales prohibited.**

Visitors shall not be admitted to the quarantine enclosure during any time that ruminants are in quarantine except that an importer (or his or her accredited agent or veterinarian) may be admitted to the yards and buildings containing his or her quarantined ruminants at such intervals as may be deemed necessary, and under such reasonable conditions and restrictions as may be imposed, by the inspector in charge of the quarantine station. On the last day of the quarantine period, owners, officers or registry societies, and others having official business or whose services may be necessary in the removal of the ruminants may be admitted upon written permission from the said inspector. No exhibition or sale shall be allowed within the quarantine grounds.

**§ 93.412 Milk from quarantined ruminants.**

Milk or cream from ruminants quarantined under the provisions of this subpart may not be used by any person other than those in charge of such ruminants, nor be fed to any animals other than those within the same enclosure, without permission of the inspector in charge of the quarantine station and subject to such restrictions as he or she may consider necessary to each instance. No milk or cream may be removed from the quarantine premises except in compliance with all State and local regulations.

**§ 93.413 Manure from quarantined ruminants.**

No manure may be removed from the quarantine premises until the release of the ruminants producing the manure.

**§ 93.414 Appearance of disease among ruminants in quarantine.**

(a) If any restricted agent or other communicable disease appears among ruminants during the pre-embarkation or post-importation quarantine periods,

special precautions shall be taken to prevent spread of the infection to other animals in the quarantine station or to those outside the grounds. The affected ruminants in post-importation quarantine shall be disposed of as the Administrator may direct, depending upon the nature of the disease.

(b) If there are test-positive animals during the post-importation quarantine (in the absence of clinical signs of disease), the Administrator may require additional testing of the test-positive animal(s) and/or test-negative animals to determine if any of the animals will be eligible for entry into the United States.

**§ 93.415 Requirements for importation of live ruminants from various risk class regions.**

Ruminants may be imported from any regions of the world only if they meet the requirements of this section, and all other applicable requirements of this part.<sup>8</sup>

(a) *Regions classified as Risk Class RN for all restricted agents affecting ruminants.* In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class RN must certify that the ruminants to be imported have only been on premises located in regions listed as Risk Class RN for the specific restricted agent and that they meet all other requirements of this subpart.

(b) *Mycobacterium bovis.* Any ruminant with positive results to an approved test for *M. bovis* shall be refused entry. Ruminants with negative results may be eligible for entry based on their status as determined by part 77 of this chapter. However, all ruminants imported for immediate slaughter are exempt from *M. bovis* testing and quarantine requirements. Such ruminants must be consigned from the port of entry to a recognized slaughtering establishment and there slaughtered within 2 weeks from the date of import. Such ruminants must be moved from the port of entry in conveyances closed with official seals of the United States Government applied and removed by an APHIS representative, or an individual authorized for this purpose by an APHIS representative.

(1) *Regions classified as Risk Class R1 for M. bovis.* In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants over 6 months of age from regions that are classified as Risk Class R1 for *M. bovis*, must certify that the ruminants to

be imported were born and resided only in regions that are classified as Risk Class RN or R1 for *M. bovis*.

(2) *Regions classified as Risk Class R2 for M. bovis.*

(i) In addition to the export requirements of § 93.405, the certificate of export for live ruminants over 6 months of age from regions that are classified as Risk Class R2 for *M. bovis*, must certify that:

(A) The ruminants to be imported were born and resided only in regions that are classified as Risk Class RN, R1, or R2 for *M. bovis*; and

(B) If the ruminants to be imported are not neutered, that the ruminants have had a negative result to an approved test for *M. bovis* not less than 60 nor more than 90 days (not less than 90 nor more than 120 days for any non-neutered cervidae) prior to export.

(ii) Non-neutered ruminants must be detained at the port of entry or designated entry quarantine facility for a minimum of 72 hours until tested with negative results to an approved test for *M. bovis*.

(3) *Regions classified as Risk Class R3 for M. bovis.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants over 6 months of age from regions that are classified as R3 for *M. bovis* must certify that:

(A) The ruminants to be imported were born and resided only in regions classified as Risk Class RN, R1, R2, or R3 for *M. bovis*;

(B) The ruminants to be imported have had a negative result to an approved test for *M. bovis* not less than 60 nor more than 90 (not less than 90 nor more than 120 days for cervidae) days prior to export; and

(C) If the ruminants to be imported are non-neutered ruminants from herds of origin that do not meet the requirements for accredited free herd status in part 77 of this chapter, the ruminants come from herds that have had a negative result to an approved test for *M. bovis* no less than 4 months nor more than 12 months prior to the date of export.

(ii) Neutered ruminants must be identified by a permanent, legible mark on the right hip. The mark must consist of an "M" for neutered males and an "Mx" for neutered females, not less than 2" nor more than 3" high.

(iii) Non-neutered ruminants must be detained at the United States port of entry or designated entry quarantine facility a minimum of 72 hours until tested with negative results to an approved test for *M. bovis*.

(4) *Regions classified as R4 and RU for M. bovis.*

<sup>8</sup> See §§ 93.404, 93.405, and 93.406.

(i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants over 6 months of age from regions that are classified as Risk Class R4 or RU for *M. bovis* must certify that the ruminants to be imported:

(A) Have had a negative result to an approved test for *M. bovis* not less than 30 nor more than 60 days (60–90 days for cervidae) prior to export;

(B) Originate from herds in which the entire herd has had a negative result to an approved test for *M. bovis* not less than 4 nor more than 12 months prior to the date of exportation; and

(C) Non-neutered ruminants have undergone at least 60 days (90 days for cervidae) of pre-embarkation quarantine prior to export.

(ii) Neutered ruminants must be identified by a permanent, legible mark on the right hip. The mark must consist of an "M" for neutered males and an "Mx" for neutered females, not less than 2" nor more than 3" high.

(iii) Non-neutered ruminants to be imported must be quarantined at a post-importation quarantine facility designated and approved by the Administrator for a minimum of 30 days, during which time they must be tested with negative results with an approved test for *M. bovis*.

(c) *Brucella abortus*, *B. suis biovar 4*, and *B. melitensis*. All ruminants imported for immediate slaughter are exempt from all brucellosis test and quarantine requirements. Such ruminants must be consigned from the port of entry to a recognized slaughtering establishment and there be slaughtered within 2 weeks from the date of entry. Such ruminants must be moved from the port of entry in conveyances closed with official seals of the United States Government applied and removed by an APHIS representative, or an individual authorized for this purpose by an APHIS representative.

(1) *Regions classified as Risk Class R1 for B. abortus, B. suis biovar 4, and B. melitensis*. In addition to the export certificate requirements of § 93.405, the certificate of export for live non-neutered ruminants over 6 months of age from regions that are classified as Risk Class R1 for *B. abortus*, *B. suis biovar 4*, and *B. melitensis* must certify that the ruminants to be imported:

(i) Were born and resided only in regions that are classified as Risk Class RN or R1 for *B. abortus*, *B. suis biovar 4*, and *B. melitensis*; and

(ii) Have not been vaccinated with any live brucella vaccine.

(2) *Regions classified as Risk Class R2 or (if brucellosis certified-free herds)*

*regions classified as Risk Class R3 for B. abortus, B. suis biovar 4, and B. melitensis*.

(i) To be considered as from a brucellosis certified-free herd, an animal's herd must be the requirements for a brucellosis certified-free herd in part 78 of this chapter.

(ii) In addition to the export certificate requirements of § 93.405, the certificate of export for live non-neutered ruminants over 6 months of age from regions that are classified as Risk Class R2 or (if the ruminants are from brucellosis certified-free herds) as Risk Class R3 for *B. abortus*, *B. suis biovar 4*, and *B. melitensis* must certify that the ruminants to be imported:

(A) Were born and resided only in regions that are classified as Risk Class RN, R1, or R2, or regions that are classified as Risk Class R3 (if brucellosis certified-free herds) for *B. abortus*, *B. suis biovar 4*, and *B. melitensis*;

(B) If vaccinated, have only been vaccinated with *B. abortus* Strain 19 according to the procedures in part 78 of this chapter; and

(C) Had a negative result to an approved test for brucellosis no less than 30 nor more than 60 days prior to the date of exportation.

(iii) The ruminants must be detained at the port of entry or quarantine facility until tested with negative results for *B. abortus*, *B. suis biovar 4*, and *B. melitensis* under the supervision of the port veterinarian.

(3) *Regions classified as Risk Class R3 (if the ruminants are not from herds certified free of brucellosis), R4, and RU for B. abortus, B. suis biovar 4, and B. melitensis*. (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live non-neutered ruminants from regions that are classified as Risk Class R3 (if the ruminants are not from herds certified as free of brucellosis), R4, and RU for *B. abortus*, *B. suis biovar 4*, and *B. melitensis* must certify that the ruminants to be imported:

(A) Originated from a herd where all non-neutered ruminants over 6 months of age had negative results to an approved brucellosis test not more than 12 months nor less than 6 months prior to export; If any test-positive animals were found during the herd test, they were removed from the herd and all remaining animals were re-tested with negative results not less than 6 months after any test positive animals were removed;

(B) If vaccinated, have been vaccinated only with *B. abortus* Strain 19 according to the procedures in part 78 of this chapter;

(C) Have undergone a minimum of 30 days pre-embarkation quarantine prior to export; and

(D) Have had a negative result to an approved test for *B. abortus*, *B. suis biovar 4*, and *B. melitensis* within the 30 days prior to export.

(ii) The ruminants must be quarantined for at least 15 days at a post-importation quarantine designated and approved by the Administrator.

(iii) The ruminants must have a negative result to approved tests for *B. abortus*, *B. suis biovar 4*, and *B. melitensis* during the post-importation quarantine period.

(d) *Foot-and-mouth disease (FMD) virus*. All ruminants imported for immediate slaughter that are born and raised in regions classified as Risk Class R1 or R2 for FMD are exempt from the test and quarantine requirements of this section. The ruminants must be consigned from the port of entry to a recognized slaughtering establishment and there slaughtered within 48 hours from the date of entry. The ruminants must be moved from the port of entry in conveyances closed with official seals of the United States Government applied and removed by an APHIS representative, or an individual authorized for this purpose by an APHIS representative.

(1) *Regions classified as Risk Class R1 for FMD virus*. In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R1 for FMD must certify that the ruminants to be imported:

(i) Were born and resided only in regions listed as Risk Class RN or R1 for FMD;

(ii) Have not been vaccinated for FMD; and

(iii) Have had a negative result to an approved serological test for FMD within 30 days prior to the date of export.

(2) *Regions classified as Risk Class R2 for FMD virus*. (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R2 for FMD virus must certify that the ruminants to be imported:

(A) Were born and resided only in regions classified as Risk Class RN, R1 or R2 for FMD;

(B) Have not been vaccinated for FMD;

(C) Have had a negative result to an approved serological test for FMD within 30 days prior to export; and

(D) Underwent pre-embarkation quarantine for a minimum of 30 days prior to export.

(ii) The ruminants must undergo post-importation quarantine for a minimum of 15 days at a facility designated and approved by the Administrator.

(iii) The ruminants must have a negative result to an approved serological test for FMD during the post-importation quarantine period.

(3) *Regions classified as Risk Class R3 for FMD virus.*

(i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R3 for FMD virus, must certify that the ruminants to be imported:

(A) Were born and resided only in regions listed as Risk Class RN, R1, R2 or R3 for FMD;

(B) Have not been vaccinated for FMD;

(C) Have not been on any premises affected with FMD virus during the 12 months prior to export;

(D) Have not been on any premises located within 25 miles (40 km) of any premises affected with FMD virus in the 90 days prior to export;

(E) Have undergone pre-embarkation quarantine for at least 60 days prior to export under USDA supervision in a facility approved by the Administrator according to § 93.431 of this subpart; and

(F) Have had, during the pre-embarkation quarantine, negative results to two tests not less than 15 days apart for FMD virus using an approved serological test. If indicated, oesophageal-pharyngeal fluid samples will be taken for further testing.

(ii) The ruminants to be imported must be quarantined at the Harry S Truman Animal Import Center according to the procedures of § 93.430 for at least 60 days without sentinel animals, during which time such animals will be subjected to a test for FMD virus at least once using an approved serological test. If indicated, oesophageal-pharyngeal fluid samples will be taken for further testing.

(4) *Regions classified as Risk Class R4 or RU for FMD virus.*

(i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R4 or RU for FMD must certify that the ruminants to be imported:

(A) Have not been vaccinated for FMD;

(B) Have not been on any premises affected with FMD virus during the 12 months prior to export;

(C) Have not been on a premises located within 25 miles (40 km) of any premises affected with FMD virus in the 90 days prior to export;

(D) Have undergone pre-embarkation quarantine for at least 60 days prior to export under USDA supervision in a facility approved by the Administrator according to § 93.431; and

(E) During pre-embarkation quarantine, have had negative results to two tests conducted not less than 15 days apart for FMD virus using an approved serological test. If indicated, oesophageal-pharyngeal fluid samples were taken for further testing.

(ii) The ruminants to be imported must be quarantined at the Harry S Truman Animal Import Center according to the procedures of § 93.430 for at least 90 days with sentinel animals, during which time such animals will be subjected to a test for FMD virus at least once using an approved serological test. If indicated, oesophageal-pharyngeal fluid samples will be taken for further testing.

(5) *Wild ruminants from R3, R4, or RU regions affected with foot-and-mouth disease or rinderpest.* (i) Wild ruminants originating in regions classified as Risk Class R3, R4 or RU for foot-and mouth disease or rinderpest may be carriers of such diseases even though the animals do not show clinical evidence of the diseases. In view of these circumstances and in order to prevent the introduction and dissemination of restricted agents of livestock and to protect the livestock of the United States, import permits for the importation of wild ruminants, such as, but not limited to, giraffes, deer and antelopes, will be issued only if such animals are intended for exhibition purposes in a zoological park previously approved by the Administrator, in accordance with the standards specified in paragraph (d)(5)(ii) of this section and if the operator of such approved zoological park and the importer, if such operator and importer are different parties, has or have entered into the agreement set forth in paragraph (d)(5)(iv) of this section with APHIS for the maintenance and handling of such wild ruminants in the manner specified in the agreement to prevent the introduction and dissemination of communicable disease. The New York port of entry is the only port at which facilities are available that are adequate for the quarantining of wild ruminants. Accordingly, permits issued for the importation of such wild ruminants will require that the ruminants be imported through the port of New York and be quarantined at that port. The Administrator may cancel such a permit when he or she finds that any provision of this section or any other provision of the regulations has not been or is not being complied with.

(ii) Approval of a zoological park for the receipt and maintenance of imported wild ruminants as described in this paragraph, shall be on the basis of an inspection, by an authorized representative of the Department, of the physical facilities of the establishment and its methods of operation. Standards for acceptable physical facilities shall include satisfactory pens, cages, or enclosures in which the ruminants can be maintained so as not to be in contact with the general public and free from contact with domestic livestock; natural or established drainage from the zoological park that will avoid contamination of land areas where domestic livestock are kept or with which domestic livestock may otherwise come in contact; provision for the disposition of manure, other wastes, and dead ruminants within the zoological park; and other reasonable facilities considered necessary to prevent the dissemination of diseases from the zoological park. The operator of the zoological park must have available the services of a full-time or part-time veterinarian, or a veterinarian on a retainer basis, who must make periodic examinations of all animals maintained at the zoological park for evidence of disease; who must make a post-mortem examination of each animal that dies; and who must make a prompt report of suspected cases of contagious or communicable diseases to appropriate State or Federal livestock sanitary officials.

(iii) Manure and other animal wastes must be disposed of within the zoological park for a minimum of 1 year following the date a ruminant enters the park. If an APHIS veterinarian determines that a ruminant shows no signs of any illness at the end of this 1-year period, its manure and other wastes need not be disposed of within the park. If, however, an APHIS veterinarian determines that a ruminant does show signs of any illness at the end of this 1-year period, an APHIS veterinarian will investigate the illness and determine whether the ruminant's manure and other wastes may safely be disposed of outside the zoological park.

(iv) Prior to the issuance of an import permit under this section and § 93.404, the operator of the approved zoological park to which the wild ruminants are to be consigned, and the importer of the wild ruminants, if such operator and importer are different parties, must execute an agreement covering each wild ruminant or group of wild ruminants for which the import permit is requested. The agreement shall be in the following form:

Agreement for the Importation, Quarantine and Exhibition of Certain Wild Ruminants and Wild Swine

\_\_\_\_\_, operator(s) of the zoological park known as \_\_\_\_\_ (Name) located at \_\_\_\_\_ (City and state), and \_\_\_\_\_

(Importer) hereby request a permit for the importation of \_\_\_\_\_ (Number and kinds of animals) for exhibition purposes at the said zoological park, said animals originating in a Risk Class R3, R4, or RU region for foot-and-mouth disease or rinderpest, and being subject to restrictions under regulations contained in part 93, title 9, Code of Federal Regulations.

In making this request, it is understood and agreed that:

1. The animals for which an import permit is requested will be held in isolation at a port of embarkation in the country of origin, approved by the Administrator as a port having facilities that are adequate for maintaining wild animals in isolation from all other animals and having veterinary supervision by officials of the country of origin of the animals. Such animals will be held in such isolation for not less than 60 days under the supervision of the veterinary service of that country to determine whether the animals show any clinical evidence of restricted agents or other communicable disease and to assure that the animals will not have been exposed to such a disease within the 60 days prior to their exportation from that country.

2. Shipment will be made directly from such port of embarkation to the port of New York as the port of entry into the United States. If shipment is made by ocean vessel the animals will not be unloaded in any foreign port en route. If shipment is made by air, the animals will not be unloaded at any port or other place of landing except at a port approved by the Administrator as a port not located in a region classified as R3, R4, or RU for rinderpest or foot-and-mouth disease or as a port in such a region having facilities and inspection approved by the Administrator as adequate for maintaining wild animals in isolation from all other animals.

3. No ruminants or swine will be aboard the transporting vehicle, vessel or aircraft except those for which an import permit has been issued.

4. The animals will be quarantined for not less than 30 days in the Department's Animal Import Center in Newburgh, New York.

5. Upon release from quarantine, the animals will be delivered to the zoological park named in this agreement to become the property of the park and they will not be sold, exchanged or removed from the premises without the prior consent of APHIS.

\_\_\_\_\_  
(Signature of importer)

Subscribed and sworn to before me this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
(Title or designation)

\_\_\_\_\_  
(Name of zoological park)

By \_\_\_\_\_ (Signature of officer of zoological park)

\_\_\_\_\_  
(Title of officer)

Subscribed and sworn to before me this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
(Title or designation)

(e) *Rinderpest and peste de petits ruminants (PPR)*. Ruminants imported for immediate slaughter that are born and raised in regions classified as Risk Class R1 or R2 for rinderpest and/or PPR are exempt from the test and quarantine requirements of this section. Such ruminants must be consigned from the port of entry to a recognized slaughtering establishment and there slaughtered within 2 weeks from the date of entry, and be moved from the port of entry in conveyances closed with official seals of the United States Government applied and removed by an APHIS representative, or an individual authorized for this purpose by an APHIS representative.

(1) *Regions classified as Risk Class R1 for rinderpest and PPR*. In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R1 for rinderpest and/or PPR must certify that the ruminants to be imported:

(i) Were born and resided only in regions classified as Risk Class RN or R1 for rinderpest and/or PPR;

(ii) Have not been vaccinated for rinderpest or PPR; and

(iii) Have had a negative result to an approved serological test for rinderpest and/or PPR within 30 days prior to export.

(2) *Regions classified as Risk Class R2 for rinderpest and PPR*. (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R1 for Rinderpest and/or PPR must certify that the ruminants offered to be imported:

(A) Were born and resided only in regions listed as Risk Class RN, R1 or R2 for rinderpest and/or PPR;

(B) Have not been vaccinated for rinderpest or PPR;

(C) Have undergone pre-embarkation quarantine for a minimum of 30 days prior to export; and

(D) Have had a negative result to an approved serological test for rinderpest and/or PPR 30 days prior to export.

(ii) The ruminants must undergo post-importation quarantine for a minimum of 15 days at a facility designated and approved by the Administrator.

(iii) The ruminants must have a negative result to an approved serological test for rinderpest and/or PPR during the post-importation quarantine period.

(3) *Regions classified as Risk Class R3 for rinderpest and PPR*.

(i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R3 for rinderpest and/or PPR must certify that the ruminants to be imported:

(A) Were born and resided only in regions listed as Risk Class RN, R1, R2 or R3 for rinderpest and/or PPR;

(B) Have not been vaccinated for rinderpest or PPR;

(C) Have not been on any premises affected with rinderpest and/or PPR virus during the 12 months prior to export;

(D) Have not been on a premises located within 25 miles (40 km) of any premises affected with rinderpest and/or PPR virus in the 90 days prior to export;

(E) Have undergone pre-embarkation quarantine for a minimum of 30 days prior to export under USDA supervision in a facility approved by the Administrator in accordance with § 93.431;

(F) During pre-embarkation quarantine, have had negative results to two tests conducted not less than 15 days apart for rinderpest and/or PPR virus using an approved serological test. If indicated, nasal swabs or other tissues or samples will be taken for further testing.

(ii) The ruminants to be imported must be quarantined at the Harry S Truman Animal Import Center according to the procedures of § 93.430 for at least 30 days without sentinel animals, during which time the animals will be subjected to a test for rinderpest and/or PPR virus at least once using an approved serological test. If indicated, nasal swabs or other samples will be taken for further testing.

(4) *Regions classified as Risk Class R4 or RU for rinderpest and PPR*.

(i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R4 or RU for rinderpest and PPR must certify that the ruminants to be imported:

(A) Have not been vaccinated for rinderpest or PPR;

(B) Have not been on any premises affected with rinderpest and PPR virus during the 12 months prior to export;

(C) Have not been on a premises located within 25 miles (40 km) of any premises affected with rinderpest and PPR virus in the 90 days prior to export;

(D) Have undergone pre-embarkation quarantine for a minimum of 30 days prior to export under USDA supervision

in a facility approved by the Administrator according to § 93.431; and

(E) During pre-embarkation quarantine, have had negative results to two tests conducted not less than 15 days apart for rinderpest and PPR virus using an approved serological test. If indicated, nasal swabs or other samples will be taken for further testing.

(ii) The ruminants to be imported must be quarantined at the Harry S Truman Animal Import Center according to the procedures of § 93.430 for at least 30 days with sentinel animals, during which time such animals will be subjected to a test for Rinderpest and/or PPR virus at least once using an approved serological test. If indicated, nasal swabs or other samples will be taken for further testing.

(f) *Restricted ectoparasites*—(1) *Regions classified as Risk Class R1 or R2 regions for restricted ectoparasites.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R1 or R2 for restricted ectoparasites must certify that the ruminants to be imported resided for the 60 days prior to export only in regions listed as Risk Class RN, R1, or R2 for restricted ectoparasites.

(ii) All ruminants to be imported must be inspected at the port of entry for ectoparasites, and given a precautionary treatment with one of the permitted treatments listed in § 72.13(b) of this chapter. If found to be infested with restricted ectoparasites, the ruminants will be refused entry until treated with one of the permitted treatments listed in § 72.13(b) of this chapter, and retreated 10 to 14 days after the initial treatment.

(2) *Regions classified as Risk Class R3, R4, or RU for restricted ectoparasites.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R3, R4 or RU for restricted ectoparasites must certify that the ruminants to be imported:

(A) Were treated for ectoparasites with an approved treatment 10 to 14 days prior to export. If quarantine in a pre-embarkation facility is required under this subpart, the ruminants were treated immediately prior to entering a pre-embarkation facility; and

(B) Were inspected while at the pre-embarkation facility and found to be free of any ectoparasites.

(ii) The ruminants to be imported must be inspected at the port of entry for any ectoparasites, and given a precautionary treatment. If found to be infested with any ectoparasites, the

ruminants will be refused entry until treated with one of the permitted treatments listed in § 72.13(b) of this chapter, and retreated 10 to 14 days after the initial treatment.

(g) *Bovine Spongiform Encephalopathy (BSE)*—(1) *Regions classified as Risk Class R1 or R2 for BSE.* In addition to the export certificate requirements of § 93.405, the certificate of export for live cattle from regions classified as Risk Class R1 or R2 for BSE must certify that the cattle offered to be imported were born and resided only in R1 or R2 regions, and that the cattle have only been on premises where no cases of BSE have been diagnosed during the 10 years immediately preceding the date of exportation.

(2) *Regions classified as Risk Class R3, R4, RU for BSE.* The importation of live cattle from regions that are classified as Risk Class R3, R4, or RU for BSE is prohibited.

(h) *Scrapie*—(1) *Regions classified as Risk Class R1 or R2 for scrapie.* In addition to the export certificate requirements of § 93.405, the certificate of export for live sheep or goats from regions that are classified as Risk Class R1 or R2 for scrapie must certify that the imported sheep or goats have only been on premises where no cases of scrapie have been diagnosed during the 5 years immediately preceding the date of intended exportation, and have resided only in regions listed as R1 or R2.

(2) *Regions classified as Risk Class R3 for scrapie.* In addition to the requirements of § 93.405, the certificate of export for live sheep or goats from regions that are classified as Risk Class R3 for scrapie must certify that the sheep and goats to be imported:

(i) Have been inspected on the premises of origin and found free of scrapie;

(ii) That, as far as can be determined, scrapie has not existed on any premises on which such sheep or goats were located during the 42 months immediately prior to shipment to the United States; and

(iii) That each of the animals is not the progeny of a sire or dam that has been affected with scrapie.

(3) *Regions classified as Risk Class R4 or RU for scrapie.* The importation of live sheep or goats from regions that are classified as R4 or RU for scrapie is prohibited.

(i) *Contagious agalactia (CA) due to Mycoplasma agalactiae, sheep pox virus (SP), goat pox virus (GP), and contagious caprine pleuropneumonia due to Mycoplasma mycoides subsp. capri (CCPP).*

(1) *Regions classified as Risk Class R1 for CA, SP, GP, and/or CCPP.* In

addition to the export certificate requirements of § 93.405, the certificate of export for sheep or goats from regions that are classified as Risk class R1 for CA, SP, GP, and/or CCPP must certify that the sheep and goats to be imported:

(i) Were born and resided only in regions classified as Risk Class RN or R1 for CA, SP, GP, or CCPP;

(ii) Have had a negative result to an approved serological test for CA, SP, GP, and/or CCPP within 30 days prior to export; and

(iii) Have not been vaccinated for CA, SP, GP, and/or CCPP.

(2) *Regions classified as Risk Class R2 for CA, SP, GP, and/or CCPP.*

(i) In addition to the export certificate requirements of § 93.405, the certificate of export for sheep or goats from regions classified as Risk Class R2 for CA, SP, GP, and/or CCPP must certify that the sheep or goats to be imported:

(A) Were born and resided only in regions listed as Risk Class RN, R1 or R2 for CA, SP, GP, and/or CCPP;

(B) Have had a negative result to an approved serological test for CA, SP, GP, and/or CCPP 30 to 60 days prior to export to the United States; and

(C) Have not been vaccinated for CA, SP, GP, or CCPP.

(ii) The sheep or goats to be imported must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) The sheep or goats must have a negative result to an approved serological test for CA, SP, GP, and/or CCPP during the post-importation quarantine period.

(3) *Regions listed as Risk Class R3 for CA, SP, GP, and/or CCPP.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for sheep or goats from regions classified as Risk class R3 for CA, SP, GP, and/or CCPP must certify that the sheep or goats to be imported:

(A) Were born and resided only in regions listed as Risk Class RN, R1, R2 or R3 for CA, SP, GP, and/or CCPP;

(B) Have not been vaccinated for CA, SP, GP, or CCPP;

(C) Meet one of the following requirements:

(1) Have had a negative result to an approved serological test for CA, SP, GP, and/or CCPP 30 to 60 days prior to export to the United States; or

(2) Originate from a herd or flock in which all sheep and goats over 6 months of age have had a negative result to an approved serological test within 12 months prior to the time of export; and

(D) Were quarantined for at least 30 days prior to export from all animals not



part of the group to be imported in facilities approved by the Administrator.

(ii) The sheep and goats to be imported must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) The sheep and goats must have a negative result to an approved serological test for CA, SP, GP, and/or CCPP during the post-importation quarantine period.

(4) *Regions classified as Risk Class R4 or RU for CA, SP, GP, and/or CCPP.*

(i) In addition to the export certificate requirements of § 93.405, the certificate of export for sheep and goats from regions that are classified as Risk Class R4 or RU for CA, SP, GP, and/or CCPP must certify that the sheep and goats to be imported:

(A) Have not been vaccinated for CA, SP, GP, or CCPP;

(B) Have undergone a minimum 60-day pre-embarkation quarantine; and

(C) Have had negative results to two approved tests conducted no sooner than 30 days apart for CA, SP, GP and/or CCPP, with the second test during the pre-embarkation quarantine period and not more than 30 days before export.

(ii) The sheep and goats to be imported must be quarantined for at least 30 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) The sheep or goats to be imported must have a negative result to an approved serological test for CA, SP, GP, and/or CCPP during the post-importation quarantine period.

(j) *Malignant catarrhal fever—African type (MCF)*—(1) *Regions classified as Risk Class R1 for MCF.* In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R1 for MCF must certify that the ruminants to be imported:

(i) Were born and resided only in regions classified as Risk Class RN or R1 for MCF;

(ii) Have had a negative result to an approved serological test for MCF within 30 days prior to the date of export; and

(iii) Have not been vaccinated for MCF.

(2) *Regions classified as Risk Class R2 for MCF.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions classified as Risk Class R2 for MCF must certify that the ruminants to be imported:

(A) Were born and resided only in regions classified as Risk Class RN, R1 or R2 for MCF;

(B) Have not been vaccinated for MCF; and

(C) Have had a negative result to an approved serological test for MCF 30 to 60 days prior to the date of export.

(ii) The ruminants to be imported must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) The imported ruminants must have a negative result to an approved serological test for MCF during the post-importation quarantine period.

(3) *Regions classified as Risk Class R3 for MCF.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions classified as Risk Class R3 for MCF must state that the ruminants to be imported:

(A) Were born and resided only in regions classified as Risk Class RN, R1, R2 or R3 for MCF;

(B) Have not been vaccinated for MCF;

(C) Meet one of the following requirements:

(1) Have had a negative result to an approved serological test for MCF 30 to 60 days prior to the date of export; or

(2) Originate from a herd in which all ruminants in the herd over 6 months of age have had a negative result with an approved test for MCF within the previous 12 months; and

(D) Have been in a pre-embarkation quarantine facility approved by the Administrator for a minimum of 30 days prior to export.

(ii) The ruminants to be imported must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) The imported ruminants must have a negative result to an approved serological test for MCF during the post-importation quarantine period.

(4) *Regions classified as Risk Class R4 or RU for MCF.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions classified as Risk Class R4 or RU for MCF must certify that the ruminants to be imported:

(A) Originate from herds that have not been affected with MCF during the previous 12 months;

(B) Have not been vaccinated for MCF;

(C) Have undergone a minimum of 60 days pre-embarkation quarantine; and

(D) During pre-embarkation quarantine, have had negative results to

two tests conducted not less than 15 days apart with an approved serological test for MCF.

(ii) The ruminants to be imported must undergo post-importation quarantine for at least 15 days at a facility designated and approved by the Administrator.

(iii) The imported ruminants must have a negative result to an approved serological test for MCF during the post-importation quarantine period.

(k) *Contagious bovine pleuropneumonia (CBPP)*—(1) *Regions classified as Risk Class R1 for CBPP.* In addition to the export certificate requirements of § 93.405, the certificate of export for live cattle from regions classified as Risk Class R1 for CBPP must certify that the cattle to be imported:

(i) Were born and resided only in regions classified as Risk Class RN or R1 for CBPP;

(ii) Have not been vaccinated for CBPP;

(iii) Have undergone a minimum 30-day pre-embarkation quarantine; and

(iv) Have had a negative result to an approved serological test for CBPP within 30 days prior to export.

(2) *Regions classified as Risk Class R2 for CBPP.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live cattle from regions classified as Risk Class R2 for CBPP must certify that the cattle to be imported:

(A) Were born and resided only in regions classified as Risk Class RN, R1 or R2 for CBPP;

(B) Have not been vaccinated for CBPP; and

(C) Have had a negative result to an approved serological test for CBPP 30 to 60 days prior to the date of export.

(ii) The imported cattle must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) The imported cattle must have a negative result to an approved serological test for CBPP during the post-importation quarantine period.

(3) *Regions classified as Risk Class R3 for CBPP.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live cattle from regions classified as Risk Class R3 for CBPP must certify that the cattle to be imported:

(A) Were born and resided only in regions classified as Risk Class RN, R1, R2 or R3 for CBPP;

(B) Have not been vaccinated for CBPP;

(C) Meet one of the following requirements:



(1) Have had a negative result to an approved serological test for CBPP 30 to 60 days prior to export; or

(2) Originate from a herd in which all cattle in the herd over 6 months of age have had a negative result to an approved test for CBPP within the previous 12 months; and

(D) Have been quarantined and isolated for at least 30 days prior to export from all animals not part of the group to be imported.

(ii) The imported cattle must be quarantined for at least 15 days at a post-embarkation quarantine facility designated and approved by the Administrator.

(iii) The imported cattle must have a negative result to an approved serological test for CBPP during the post-embarkation quarantine period.

(4) *Regions classified as Risk Class R4 or RU for CBPP.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live cattle from regions that are classified as Risk Class R4 or RU for CBPP must certify that the cattle to be imported:

(A) Originate from herds that have not been affected with CBPP during the previous 12 months;

(B) Have not been vaccinated for CBPP;

(C) Have undergone a minimum 60-day pre-embarkation quarantine; and

(D) During pre-embarkation quarantine, have had negative results to two tests for CBPP conducted not less than 30 days apart with an approved serological test.

(ii) The imported cattle must be quarantined for at least 30 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) The imported cattle must have a negative result to an approved serological test for CBPP during the post-importation quarantine period.

(1) *Aino and Akabane virus*—(1) *Regions classified as Risk Class R1 and R2 for aino and/or akabane virus.* In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions classified as Risk Class R1 and R2 for aino and/or akabane must certify that the ruminants to be imported:

(i) For at least 60 days have been only on premises in regions classified as Risk Class RN, R1 and R2;

(ii) Have not been vaccinated for akabane or aino virus;

(iii) Have had a negative result using an approved serological test for akabane and/or aino virus within 30 days prior to the date of export. If any of the ruminants in the shipment to be

imported had a positive result to the test, then:

(A) All positive pregnant female ruminant animals were removed from the group to be imported; and

(B) All remaining ruminants (both positive and negative) were re-tested at least 30 days following the first test, and all had negative, decreasing or stabilized test results.

(2) *Regions classified as Risk Class R3, R4, and RU for aino and/or akabane virus.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants imported from regions classified as Risk Class R3, R4, or RU for aino and/or akabane must certify that the ruminants to be imported:

(A) Do not originate from a herd that has been known to be infected with aino and/or akabane virus within 12 months prior to the date of export;

(B) Have not been vaccinated for aino or akabane virus;

(C) If offered for export during a time of year when vectors are active, were quarantined for at least 60 days prior to export in a vector-proof facility approved by the Administrator and by the national veterinary services in the country of origin;

(D) If offered for export during a time of year when insect vectors are not active, at least 60 days has passed since the first killing frost of the season, and

(E) Were tested twice with negative results at least 30 days apart with the second test within 30 days prior to the date of export, using an approved serological test for akabane and/or aino virus. The tests must be conducted at least 30 days apart. If any of the ruminants in the shipment to be imported had a positive result to either test, then:

(1) All pregnant female ruminant animals were removed from the group to be imported; and

(2) All remaining ruminants (both positive and negative) were re-tested at least 30 days following the first test, with negative, decreasing or stabilized test results.

(ii) The imported ruminants must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) During the post-importation quarantine period, all the imported ruminants must have negative, decreasing, or stabilized test results to an approved serological test for akabane and/or aino virus.

(m) *Bluetongue virus except for serotypes 10, 11, 13 and 17 (BT); Epizootic Hemorrhagic Disease virus (Ibaraki) except serotypes 1 and 2*

(EHD); *Bovine Ephemeral Fever virus group (Kotonkan, Obodhiang) (BEF); Rift Valley Fever virus (RVF); and/or Wesselsbron(WB) virus*—(1) *Regions classified as Risk Class R1 and R2 for BT, EHD, BEF, RVF, and WB virus.* In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions classified as Risk Class R1 and R2 for BT, EHD, BEF, RVF, and/or WB virus must certify that the ruminants to be imported:

(i) Have resided for at least 60 days prior to export only on premises located in regions classified as Risk Class RN, R1 or R2;

(ii) Have not been vaccinated for BT, EHD, BEF, RVF, or WB virus;

(iii) Have had a negative result to an approved serological test for BT, EHD, BEF, RVF, and/or WB virus within 30 days prior to export. If any of the ruminants in the group to be imported test positive, then all the remaining ruminants in that group must qualify as ruminants from a Risk Class R3, R4 or RU region according to paragraph (m)(2) of this section.

(2) *Regions classified as Risk Class R3, R4, and RU for BT, EHD, BEF, RVF, and/or WB virus.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions classified as Risk Class R3, R4 or RU for BT, EHD, BEF, RVF, and/or WB virus must certify that the ruminants to be imported:

(A) If offered for export during a season of the year when insect vectors are active, or less than 60 days after the first killing frost in the fall of the year, were quarantined and isolated from all animals not part of the group to be imported for at least 60 days prior to embarkation in a vector-proof facility approved by the Administrator;

(B) If offered for export during a season of the year when insect vectors are not active, have remained on premises located in areas where the first killing frost in the fall occurred at least 60 days prior to date of embarkation;

(C) Have not been vaccinated for BT, EHD, BEF, RVF, or WB virus;

(D) Have had negative results to an approved serological test 30 to 60 prior to embarkation;

(E) If any of the ruminants in the group to be imported tests positive, then the positive animals must be removed from the group and all ruminants that tested negative to the first test required in paragraph (m)(2)(i)(D) of this section have had negative results to a second approved serological test for BT, EHD, BEF, RVF, and/or WB virus within 30 days prior to embarkation; and

(F) If any of the ruminants in the group to be imported tests positive to the second test required in paragraph (m)(2)(i)(E) of this section, then:

(1) If during a season of year in the exporting region when insect vectors are active, the remaining animals may not be exported to the United States during the insect vector season; or

(2) If during a season of year when insect vectors are not active:

(i) All positive animals were removed from the group to be imported; and

(ii) All remaining animals were negative to a third test at least 30 days following the second test required in paragraph (m)(2)(i)(E) of this section.

(ii) Imported ruminants must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator if imported during a season of the year in the United States when vectors are not active, and must be quarantined for 60 days if imported during a season of the year when vectors are active in the United States.

(iii) During the post-importation quarantine period, all the imported ruminants must have negative results to an approved serological test for BT, EHD, BEF, RVF, and/or WB virus.

(n) *Nairobi Sheep Disease (Dugbe, Ganjam) virus (NSD)*—(1) *Regions classified Risk Class R1 and R2 for NSD.* In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions classified as Risk Class R1 and R2 for NSD must certify that the ruminants to be imported:

(i) Have resided for at least 60 days on premises located in regions classified as Risk Class RN, R1 or R2 for NSD;

(ii) Have not been vaccinated for NSD;

(iii) Have had a negative result to an approved serological test for NSD virus within 30 days prior to export. If any of the ruminants tests positive, then all the remaining ruminants in the group to be imported must meet the requirements for ruminants from Risk Class R3, R4 or RU regions, as set forth in paragraph (n)(2) of this section.

(2) *Regions classified as Risk Class R3, R4, and RU for NSD.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions classified as Risk Class R3, R4, or RU for NSD virus must certify that the ruminants to be imported:

(A) Were quarantined from all animals not part of the group to be imported, for at least 60 days prior to export, in a vector-proof facility approved by the Administrator and by the national Veterinary Services in the country of export;

(B) Have not been vaccinated for NSD virus; and

(C) During the pre-embarkation quarantine period, were tested twice, within 60 days prior to export and at least 30 days apart, with negative results, using an approved serological test for NSD virus. If any ruminants in the group to be imported tested positive to the first serological test, then all animals (positive and negative) were retested at least 30 days following the previous test with negative, decreasing, or stabilized test results to an approved serological test. Only those ruminants that are negative on both tests, or that were negative on virus isolation procedures may be exported to the United States.

(ii) The imported ruminants must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) During the post-importation quarantine period, all the imported ruminants must have a negative test result to an approved serological test for NSD.

(o) *Cowdria ruminantium (Heartwater), tick-borne encephalitis, and/or Louping Ill*—(1) *Regions classified as Risk Class R1 and R2 for Cowdria ruminantium, tick-borne encephalitis, and Louping Ill.* In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions classified as Risk Class R1 and R2 for *Cowdria ruminantium*, tick-borne encephalitis, and Louping Ill must certify that the ruminants to be imported:

(i) Have resided on premises located in Risk Class RN, R1 and R2 regions for *Cowdria ruminantium*, tick-borne encephalitis, or Louping Ill for at least 60 days immediately prior to export;

(ii) Have not been vaccinated for *Cowdria ruminantium*, tick-borne encephalitis, or Louping Ill; and

(iii) Have had a negative result to an approved serological test for *Cowdria ruminantium*, tick-borne, and/or Louping Ill within 30 days prior to export.

(2) *Regions classified as Risk Class R3, R4, and RU for Cowdria ruminantium, tick-borne encephalitis, and/or Louping Ill.* (i) In addition to the export requirements of § 93.405, the certificate of export for ruminants imported directly from regions classified as Risk Class R3, R4, and RU for *Cowdria ruminantium*, tick-borne encephalitis, and/or Louping Ill must certify that the ruminants to be imported:

(A) Were quarantined for at least 60 days immediately prior to export in a vector-proof facility approved by the Administrator and the national Veterinary Services in the country of export;

(B) Have not been vaccinated for *Cowdria ruminantium*, tick-borne encephalitis, and Louping Ill; and

(C) During the pre-embarkation quarantine period, were tested twice, within 60 days prior to export and at least 30 days apart, with negative results using an approved serological test for *Cowdria ruminantium*, tick-borne encephalitis, and/or Louping Ill.

(ii) The imported ruminants must be quarantined for at least 30 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) During the post-importation quarantine period the imported ruminants must be tested at least once, with negative results, for *Cowdria ruminantium*, tick-borne encephalitis, and/or Louping Ill using an approved serological test.

(p) *Theileria*—(1) *Regions classified as Risk Class R1 and R2 for Theileria.* In addition to the export certificate requirements of § 93.405, the certificate of export for the live ruminants from regions that are classified as Risk Class R1 and R2 for *Theileria* must certify that the ruminants to be imported:

(i) For at least 1 year immediately prior to export, have resided only on premises located in regions classified as Risk Class RN, R1 or R2;

(ii) Have not been vaccinated for *Theileria*; and

(iii) Had a negative result to an approved serological test for *Theileria* within 30 days prior to export.

(2) *Regions classified as Risk Class R3, R4, and RU for Theileria.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants imported from regions classified as Risk Class R3, R4, and RU for *Theileria* must certify that the ruminants to be imported:

(A) Were quarantined for at least 60 days prior to export in a vector-proof facility approved by the Administrator and the National Veterinary services of the country of export;

(B) Have not been vaccinated for *Theileria*; and

(C) During the pre-embarkation quarantine period, were tested twice, at least 30 days apart, with negative results using an approved serological test for *Theileria*.

(ii) The imported ruminants must be quarantined for at least 30 days at a post-importation quarantine facility

designated and approved by the Administrator.

(iii) During the post-importation quarantine period, the imported ruminants must be tested at least once with negative results using an approved serological test for Theileria.

(q) *African (Salivarian or Tsetse-transmitted) Trypanosomes*—

(1) *Regions classified as Risk Class R1 and R2 for African trypanosomes.* In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R1 and R2 for African trypanosomes must certify that the ruminants to be imported:

(i) Have resided only on premises located in Risk Class RN, R1 or R2 regions for trypanosomes and tsetse flies (*Glossina* spp.) for their entire life;

(ii) Have not been vaccinated for trypanosomes; and

(iii) Have had a negative result to an approved serological test for African trypanosomes within 30 days prior to export.

(2) *Regions classified as Risk Class R3, R4, and RU for African trypanosomes.*

(i) In addition to the export certificate requirements of § 93.405, the certificate of export for ruminants imported from regions classified as Risk Class R3, R4, and RU for African trypanosomes and Tsetse flies (*Glossina* spp.) must certify that the ruminants to be imported:

(A) Originated from premises that have not had trypanosomiasis diagnosed during the previous 24 months;

(B) Were quarantined for at least 60 days prior to export in a vector-proof facility approved by the Administrator and the National Veterinary Services of the country of export;

(C) Have not been vaccinated for trypanosomes; and

(D) During the pre-embarkation quarantine period, had negative results to an approved serological test for trypanosomes.

(ii) The imported ruminants must be quarantined for at least 30 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) During the post-importation quarantine period, the imported ruminants must be tested at least once for trypanosomes, with negative results, using approved serological tests.

(r) *Globidiosis due to Besnoitia besnoiti, Lumpy Skin Disease (LSD) virus, and/or Parafilaria bovicola (parafilariasis)*—(1) *Regions classified as Risk Class R1 and R2 for Besnoitia besnoiti, LSD, and/or Parafilaria bovicola.* In addition to the export

certificate requirements of § 93.405, the certificate of export for live ruminants from regions that are classified as Risk Class R1 and R2 for *Besnoitia besnoiti, LSD, and/or Parafilaria bovicola* must certify that the ruminants to be imported:

(i) For at least 60 days immediately prior to export, have resided only on premises located in Risk Class RN, R1 and R2 regions for *Besnoitia besnoiti, LSD, and/or Parafilaria bovicola*;

(ii) Have not been vaccinated for *Besnoitia besnoiti, LSD, or Parafilaria bovicola*; and

(iii) Had a negative result to an approved serological test for *Besnoitia besnoiti, LSD, and/or Parafilaria bovicola* within 30 days prior to export.

(2) *Regions classified as Risk Class R3, R4, and RU for Besnoitia besnoiti, LSD, and/or Parafilaria bovicola.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants imported from regions that are classified as Risk Class Regions R3, R4, and/or RU for *Besnoitia besnoiti, LSD, and/or Parafilaria bovicola* must certify that the ruminants to be imported:

(A) Were quarantined, for at least 60 days prior to export, from all animals not part of the shipment, in a vector-proof facility approved by the Administrator;

(B) Have not been vaccinated for *Besnoitia besnoiti, LSD, or Parafilaria bovicola*; and

(C) During the pre-embarkation quarantine period, were tested twice at least 30 days apart with negative results, using an approved serological test for *Besnoitia besnoiti, LSD, and/or Parafilaria bovicola*.

(ii) The imported ruminants must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) During the post-importation quarantine period the ruminants must be tested at least once, with negative results, using approved serological tests.

(s) *Trypanosoma spp. transmitted by vectors other than tsetse flies (Glossina spp.) (NTT-Trypanosomas), tick-borne fever due to Erlichia (Cytoecetes) phagocytophilia (TBF), bovine infectious petechial fever (Ondiri disease) due to Erlichia (Cytoecetes) ondiri (BPF)*—(1) *Regions classified as Risk Class R1 and R2 for NTT-Trypanosomas, TBF, and/or BPF.* In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants from regions classified as Risk Class R1 and R2 for NTT-Trypanosomas, TBF, and/or

BPF must certify that the ruminants to be imported:

(i) Have resided for their entire life only on premises located in regions classified as Risk Class RN, R1 and R2 for NTT-Trypanosomas, TBF, and BPF;

(ii) Have not been vaccinated for NTT-Trypanosomas, TBF, or BPF; and

(iii) Had a negative result to an approved serological test for NTT-Trypanosomas, TBF, and/or BPF within 30 days prior to export.

(2) *Regions classified as Risk Class R3, R4, and RU for NTT-Trypanosomas, TBF, and/or BPF.* (i) In addition to the export certificate requirements of § 93.405, the certificate of export for live ruminants imported from regions that are classified as Risk Class R3, R4, and/or RU for NTT-Trypanosomas, TBF, and/or BPF must certify that the ruminants to be imported:

(A) Were quarantined from all animals not part of the group to be imported, for at least 60 days prior to export, in a vector-proof facility approved by the Administrator and the National Veterinary Services of the country of export;

(B) Have not been vaccinated for NTT-Trypanosomas, TBF, or BPF; and

(C) During the pre-embarkation quarantine period, were tested twice at least 30 days apart with negative results, using an approved serological test for NTT-Trypanosomas, TBF, and/or BPF.

(ii) If imported during a season of the year when vectors are not active in the United States, the ruminants imported must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator

(iii) If imported during a season of the year when vectors are active in the United States, the ruminants imported must be quarantined for at least 60 days at a post-importation quarantine facility designated and approved by the Administrator.

(iv) During the post-importation quarantine period the imported ruminants must be retested at least once with negative results to an approved serological test for NTT-Trypanosomas, TBF, and/or BPF.

(t) *Vesicular Stomatitis virus (VSV)*—(1) *Regions classified as Risk Class R1 for VSV.* In addition to the requirements of § 93.405 of this part, the certificate of export for live ruminants from regions that are classified as Risk Class R1 for VSV must certify that the ruminants to be imported:

(i) Have resided for at least 60 days prior to export only on premises located in Risk Class RN or R1 regions for VSV; and

(ii) Have not been vaccinated for VSV.

(2) *Regions classified as Risk Class R2 for VSV.* In addition to the requirements of § 93.405 of this part, the certificate of export for live ruminants imported from regions that are classified as Risk Class R2 for VSV must certify that the ruminants to be imported:

(i) Have resided for at least 60 days prior to export only on premises located in Risk Class RN, R1 or R2 regions for VSV;

(ii) Have not been vaccinated with any live attenuated vaccines for VSV; and

(iii) Have not been vaccinated with inactivated vaccines for VSV within 60 days prior to export.

(3) *Regions classified as Risk Class R3, R4, and RU regions for VSV.* (i) In addition to the requirements of § 93.405 of this part, the certificate of export for live ruminants imported from regions that are classified as Risk Class R3, R4, and/or RU for VSV must certify that the ruminants to be imported:

(A) Have not been vaccinated with any live attenuated vaccines for VSV;

(B) Have not been vaccinated with inactivated vaccines for VSV within 60 days prior to export;

(C) Have not been located on any premises where VSV has occurred within 60 days prior to export; and

(D) If exported during a season of the year when insect vectors were active:

(1) Were quarantined and isolated from all other animals not part of the shipment for at least 30 days prior to export in a vector-proof facility approved by the Administrator; and

(2) During the pre-embarkation quarantine period, had negative results to an approved serological test for VSV within 14 days prior to export.

(ii) If imported during a season of the year when insect vectors are active within the United States, the imported ruminants:

(1) Must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator; and

(2) During the post-importation quarantine period, must have negative results to an approved serological test for VSV.

**§ 93.416 Importation of ruminants through the Harry S Truman Animal Import Center (HSTAIC).**

(a) *Exclusive right to use HSTAIC.* The Animal and Plant Health Inspection Service will enter into a cooperative-service agreement with only one importer for each importation through the Harry S Truman Animal Import Center (HSTAIC). Applications for the HSTAIC lottery will not be accepted from, and a cooperative-service

agreement to use HSTAIC will not be offered to or entered into with, any person who has debts owing to APHIS that have not been paid by the date specified in APHIS's original billing notification to the person. Any person who has debts owing to APHIS that have not been paid by the date specified in APHIS's original billing notification to that person will be removed from the current priority list. An importer granted the exclusive right to use HSTAIC may include in his or her allotted number, animals of the same species belonging to other persons interested in importing animals through HSTAIC, except that llamas and alpacas may be included in the same importation. However, APHIS will deal exclusively with the importer in whose name the application for use of HSTAIC was submitted. The Animal and Plant Health Inspection Service will hold this importer solely responsible for all costs (excepting capital expenditures at HSTAIC) incurred during the animal qualification process. The animal qualification process begins on the date the cooperative-service agreement is delivered to the address listed on the importer's HSTAIC application, for the importer's signature, if HSTAIC is not available to other importers, up to a maximum of 30 days. A cooperative-service agreement will be deemed to have been delivered when the importer signs the U.S. Postal Service domestic return receipt, or the importer refuses delivery of the cooperative-service agreement by the U.S. Postal Service, or the cooperative-service agreement is returned by the U.S. Postal Service as either unclaimed or undeliverable. HSTAIC can accommodate a finite number of animals at one time, but the maximum allowed for a particular importation will vary, depending on the size of the species. The Animal and Plant Health Inspection Service will specify this figure in the cooperative-service agreement, reproduced in paragraph (d) of this section.

(b) *Scheduling.* Applications from prospective users of HSTAIC are processed according to the following system:

(1) *All applications for use of HSTAIC.* (i) To qualify to use HSTAIC, an importer must submit a completed application,<sup>9</sup> providing estimates when exact information as required on the application form is unavailable.

<sup>9</sup> Application forms are available from, and must be submitted to Import/Export Animals Staff, National Center for Import and Export, Veterinary Services, Animal and Plant Health Inspection Service, 4700 River Road Unit 39, Riverdale, MD 20737-1231.

(ii) Each applicant for the importation of animals through HSTAIC must make a deposit of \$32,000 in the form of a certified check or money order, payable in U.S. funds. The deposit of each applicant who is not given the opportunity to use HSTAIC will be returned to the applicant at the end of the calendar year of the prospective importation, or whenever the applicant removes his or her name from the priority list described in paragraph (b)(4) of this section. The Animal and Plant Health Inspection Service will draw on the deposit of the applicant whose application is selected, to pay for the costs of preparing and maintaining HSTAIC in readiness for the applicant's animals. A charge of \$1,067 will be made for each day that HSTAIC is not available to another importer, starting on the date the cooperative-service agreement is delivered to the address listed on the importer's HSTAIC application, and ending either with the day that APHIS receives the signed cooperative-service agreement or the day the applicant notifies APHIS in writing that he or she does not intend to sign the cooperative-service agreement, up to a maximum of 30 days. A cooperative-service agreement will be deemed to have been delivered when the importer signs the U.S. Postal Service domestic return receipt, or refuses delivery of the cooperative-service agreement by the U.S. Postal Service, or the cooperative-service agreement is returned by the U.S. Postal Service as either unclaimed or undeliverable.

(2)(i) During the first seven days of December,<sup>10</sup> APHIS will hold a lottery, randomly drawing the names of applicants in an order that will determine the order in which they will be offered use of HSTAIC for an importation during the next calendar year. To be included in the annual December lottery, applications must reach the Import-Export Animals Staff, Veterinary Services, no earlier than October 1 and no later than October 15 of that year.

(ii) One application is required for each importation proposed. Deposits required by paragraph (b)(1)(ii) of this section must be received by APHIS at least 7 calendar days prior to the date of the lottery.

(3) The priority list established by the annual December lottery will remain effective from January 1 through December 31 of the next calendar year,

<sup>10</sup> The Animal and Plant Health Inspection Service will publish a notice announcing the exact date in the Federal Register at least 30 days in advance of the December drawing.

superseding all previous lists. Which year's list is used is governed by the date exclusive use of HSTAIC is offered and not by the date the applicant's animals are scheduled to arrive at HSTAIC.

(4) The names of all applicants whose applications have reached the Import-Export Animals Staff, Veterinary Services, no earlier than October 1 and no later than October 15 (see paragraphs (b) (1) and (2) of this section), and whose deposits have reached APHIS at least 7 calendar days prior to the date of the lottery, will be drawn during the December lottery. The order in which names appear on the priority list will correspond to that established by the lottery. If the person first offered the right to use HSTAIC does not ensure receipt of the cooperative-service agreement by the Import-Export Animals Staff, Veterinary Services, within 30 days of receiving the cooperative-service agreement, APHIS will void that offer, and make an offer to the applicant next on the priority list. The Animal and Plant Health Inspection Service will limit importations to one per importer for the period encompassing the calendar year for which the lottery is held and the following two calendar years, except when no other lottery participants are prepared to use HSTAIC during the time it would be available in those years. The priority list established during the December lottery will remain in effect during the calendar year following the lottery, and will take precedence over any applications received after October 15th. Applications received after October 15th will be added to the priority list, with precedence established by the order in which the Import-Export Animals Staff, Veterinary Services, receives them.

(5) If the Import-Export Animals Staff, Veterinary Services, does not receive more than one application between October 1st and October 15th for the December lottery, the December lottery for that year will be canceled, and APHIS will grant the exclusive right to use HSTAIC for an importation during the next calendar year in the order applications are received.

(6) The Secretary of Agriculture may grant priority over other applications to an application from an agency of the United States Government, if for an importation potentially of value to the general public, and if received before July 15 of the year preceding the proposed importation.<sup>11</sup> However, an

agency of the United States Government must submit its application in accordance with this section, except that, an agency of the United States Government must enter into an interagency agreement with APHIS for a deposit of \$32,000 by certified check or money order, payable in U.S. funds. HSTAIC importations by agencies of the United States government will be limited to one per year, except when HSTAIC is available and the Import-Export Animals Staff, Veterinary Services, has received no other applications for its use during that year.

(c) *Responsibilities of the Applicant Selected.* By certified mail, return receipt requested, APHIS will send a cooperative-service agreement to the applicant being offered the exclusive right to use HSTAIC, as provided in paragraph (d) of this section. The applicant must, within 30 days of receipt, sign and ensure that the Import-Export Animals Staff, Veterinary Services, receives the cooperative-service agreement. The cooperative-service agreement must be accompanied by a certified check or money order, or an irrevocable letter of credit (the letter of credit having an effective date 90 days after the animals' scheduled release date from HSTAIC), payable in U.S. funds, for the amount specified in the cooperative-service agreement. Any funds remaining from the \$32,000 deposit will be applied to the quarantine costs, and will be deducted from the balance due with the cooperative-service agreement. For importations requiring use of a pre-embarkation quarantine facility, physical plans for the facility, including site-specific blueprints and location, must be included when the cooperative-service agreement is returned to the Import-Export Animals Staff, Veterinary Services.

(1) An importer interested in animals ineligible for importation because officials in the exporting country or area will not allow APHIS to provide the services prescribed in the cooperative-service agreement, may, upon notification of this ineligibility from APHIS, propose to substitute animals available from another location. If this importer has not returned the signed cooperative-service agreement within the 30 days specified in the cooperative-service agreement, APHIS will return any portion of the importer's deposit that has not been expended. In that case, the applicant next in priority will be offered the exclusive right to use

HSTAIC, in accordance with the procedures in this section.

(2) The importer may not abrogate his/her responsibility for costs incurred after the signing of the cooperative-service agreement, regardless of any occurrences that prevent the importation from proceeding as planned.

(3) The importer signing the cooperative-service agreement returned to APHIS is responsible for paying all costs, excluding capital expenditures at HSTAIC, incurred in qualifying the specified animals for importation through HSTAIC. A partial list of costs for which the importer must assume responsibility includes: expenses for preparing and maintaining HSTAIC in readiness for the importation; expenses for sentinel animals in the United States, when required, and for tested animals prevented, for any reason, from moving from HSTAIC elsewhere within the United States; laboratory tests; medical treatment; official travel by APHIS personnel, including per diem expenses in the country from which animals are being exported, when required; courier services to transport test samples to the Foreign Animal Disease Diagnostic Laboratory, when required; salaries of HSTAIC personnel; all supplies for animals care, maintenance, and testing during the quarantine and in the post-quarantine cleaning and disinfection of HSTAIC; utilities and overhead, including support staff, during the quarantine and post-quarantine cleanup.

(4) Capital expenditures at HSTAIC constitute the only costs for which the importer will not be held responsible.

(5) For costs incurred during any stage of the importation through HSTAIC—that is, costs not calculated into the amount collected from the importer in accordance with the cooperative-service agreement—APHIS will bill the importer at a later date. Payment will be due upon receipt of the bill.

(6) The Animal and Plant Health Inspection Service will return to the importer any part of the money remitted with the cooperative-service agreement set forth in paragraph (d) of this section that is not used to cover the non-capital costs of the importation through HSTAIC.

(d) *Cooperative-Service Agreement.* Each importer being granted the right to use HSTAIC must sign, and comply with, the cooperative-service agreement with APHIS. A sample cooperative-service agreement for importers other than agencies of the United States government is reproduced in this paragraph. (Agencies of the United States government being granted the

<sup>11</sup> If the Secretary grants priority to an application from an agency of the United States Government, the Animal and Plant Health Inspection Service

will publish a notice in the *Federal Register* prior to October 1 of the year preceding the proposed importation.

right to use HSTAIC must enter into an interagency agreement with APHIS.) The amount of money the importer must advance, left blank in the following sample, will depend on figures unique to a particular importation. This amount will be specified in the cooperative-service agreement the importer receives.

Cooperative-Services Agreement Between (Name of Importer) and the United States Department of Agriculture, Animal and Plant Health Inspection Service

The importer, \_\_\_\_\_, wishes to qualify animals for importation into the United States. The United States Department of Agriculture, Animal and Plant Health Inspection Service, administers the Harry S Truman Animal Import Center (HSTAIC), a facility through which the importer may import animals into the United States.

To effect this importation, both parties agree to the following terms:

The importer agrees:

1. To have this cooperative-service agreement in the office of the Animal and Plant Health Inspection Service's Import-Export Animals Staff, Veterinary Services, within 30 days of the date of receipt, evidenced by the postal return-receipt.

2. To remit with the cooperative-service agreement a certified check, money order, or irrevocable letter of credit having an effective date that extends 90 days beyond the animals' scheduled release from HSTAIC, payable in U.S. funds to the United States Department of Agriculture, Animal and Plant Health Inspection Service, in the amount of \$ \_\_\_\_\_. (This amount represents the estimated cost (except capital expenditures at HSTAIC) of qualifying the animals for importation through HSTAIC, less any unused portion of the \$32,000 deposited in conjunction with the application for the exclusive right to use HSTAIC.

3. To limit to \_\_\_\_\_ the number of animals, species \_\_\_\_\_ transported to HSTAIC for an importation scheduled to begin on or about \_\_\_\_\_ and to end with the animals' release from HSTAIC, scheduled for \_\_\_\_\_.

4. To assume liability for all costs (except capital expenditures at HSTAIC) attributable to preparing and maintaining HSTAIC in readiness for the importation, and to qualifying animals for and through quarantine in the pre-embarkation quarantine facility (PEQF), when quarantine in a PEQF is required, and in HSTAIC for importation into the United States. (A partial list of these costs would include expenses for sentinel animals in the United States and for tested animals prevented, for any reason, from moving from HSTAIC elsewhere within the United States; laboratory tests; medical treatment; official travel by Animal and Plant Health Inspection Service personnel, including per diem expenses in the country from which the animals are being exported; courier services to transport test samples to the Foreign Animal Disease Diagnostic Laboratory; salaries of HSTAIC personnel; all supplies for animal care, maintenance, and testing during the quarantine and in the post-quarantine cleaning and disinfection of

HSTAIC; utilities and overhead, including support staff, during the quarantine and post-quarantine cleanup.)

5. To obtain from foreign government officials authorizations granting Animal and Plant Health Inspection Service personnel free access to the PEQF, when quarantine in a PEQF is required, and permits for export.

6. To secure from animal carriers permission for Animal and Plant Health Inspection Service personnel to accompany the animals to the PEQF, when quarantine in a PEQF is required, and from the PEQF to HSTAIC.

7. To maintain and operate the PEQF, when quarantine in a PEQF is required, in compliance with 9 CFR 93.417 of the Code of Federal Regulations.

8. To accept as final the findings of the Administrator, Animal and Plant Health Inspection Service, on the animals' eligibility to enter the PEQF, when quarantine in a PEQF is required, to enter HSTAIC, and to be released from HSTAIC.

9. To follow procedures prescribed by the Animal and Plant Health Inspection Service, appropriate to the disease and pest status of the quarantined animals. (When quarantine in a PEQF is required, the presence in the PEQF of even one animal either exposed to, or infected with, rinderpest, foot-and-mouth disease, hog cholera, African swine fever, swine vesicular disease, or certain other contagious, exotic diseases, automatically disqualifies all animals in the PEQF from entering HSTAIC. The presence in HSTAIC of even one animal either exposed to, or infected with, one of the diseases referred to in this paragraph, automatically disqualifies all animals in HSTAIC from moving anywhere within the United States after the period in quarantine.)

10. To assume responsibility for disposal of quarantined animals that do not qualify to move into or within the United States. (In the case of animals disqualified while quarantined in HSTAIC, the Animal and Plant Health Inspection Service will stipulate the conditions under which the disqualified animals in HSTAIC must be destroyed. The importer must, within 10 days of notification from the Animal and Plant Health Inspection Service, remove from the PEQF or HSTAIC, animals untreatable or treated for, but not cured of, a communicable disease other than foot-and-mouth disease or any of certain other exotic diseases. Animals removed from HSTAIC must be moved out of the United States or be destroyed under conditions stipulated by the Animal and Plant Health Inspection Service.)

11. To assume responsibility for all costs the Animal and Plant Health Inspection Service incurs during this importation, excluding capital expenditures at HSTAIC.

12. To pay, upon receipt, post-quarantine billings incurred during this importation, for costs exceeding the amount remitted with this cooperative-service agreement plus the initial \$32,000 deposit.

The Animal and Plant Health Inspection Service Agrees:

1. To provide the personnel required to perform inspections, laboratory procedures, and examinations, and to provide on-site supervision of the isolation, quarantine, care

and handling of animals on premises of origin, in the PEQF when quarantine in a PEQF is required, and in HSTAIC.

2. To inform the importer of any quarantined animals in the PEQF or in HSTAIC that fail to qualify for entry into the United States, and to inform the importer that he/she must assume responsibility for their disposal.

3. To finance capital expenditures at HSTAIC without charging the importer.

4. To account for all money disbursed from the amount remitted, and to provide the importer with a complete written accounting upon termination of this cooperative-service agreement.

5. To refund to the importer any part of the money remitted with this cooperative-service agreement that is not used to cover the non-capital costs of the importation through HSTAIC.

Both parties agree:

1. That this cooperative-service agreement is effective upon signature by both parties.

2. That this cooperative-service agreement will not be signed by the Administrator if the Import-Export Animals Staff, Veterinary Services, Animal and Plant Health Inspection Service, has not received this signed cooperative-service agreement, including the specified remittance for the amount due, by 4:30 p.m. on the thirtieth calendar-day after the date on the United States Postal Service's return receipt, evidencing its receipt by the importer.

3. That this cooperative-service agreement will not be signed by the Administrator if the cooperative-service agreement is not accompanied by the physical plans for the PEQF, including its location and site-specific blueprints (except when quarantine in a PEQF is not required).

4. That this cooperative-service agreement will be voided if the Administrator, Animal and Plant Health Inspection Service, determines that the importer has not completed arrangements with the responsible officials in the exporting country by 4:30 p.m. on the date 42 calendar-days after the importer's signing of this cooperative-service agreement.

5. That, if both parties agree, this cooperative-service agreement may be amended in writing.

6. That either party may terminate this cooperative-service agreement upon giving 30 days written notice to the other party, but premature termination will not relieve the importer of responsibility for costs incurred, as provided in this cooperative-service agreement, nor will it relieve the Animal and Plant Health Inspection Service of responsibility for providing the importer with a complete written accounting of money disbursed from the amounts remitted.

7. That during the performance of this cooperative-service agreement, the importer agrees to be bound by the Equal Employment Opportunity and Nondiscrimination provisions set forth in Exhibit A and the Nonsegregation of Facilities provisions set forth in Exhibit B,<sup>1</sup> which are attached to and

<sup>1</sup> 1 Import-Export Animal Staff, National Center for Import and Export, Veterinary Services, APHIS, Continued

made part of this cooperative-service agreement.

8. That no member of, or delegate to, Congress may participate in, or benefit from, this cooperative-service agreement.

Date

Importer

Date

Administrator, Animal and Plant Health Inspection Service, United States Department of Agriculture.

**§ 93.417 Pre-embarkation quarantine facility; criteria and standards for approval.**

Criteria for establishment of a pre-embarkation quarantine facility outside the United States for the purpose of importing ruminants into the United States that are eligible for importation only through the Harry S Truman Animal Import Center are as follows:

(a) *Establishment.* (1) The Administrator may enter into an agreement with one or more parties for the establishment of such a facility pursuant to the standards in paragraph (b) of this section.

(2) To qualify for designation as a pre-embarkation quarantine facility (PEQF) for a specifically authorized importation, the facility must meet the requirements of paragraph (b) of this section.

(3) All costs associated with the establishment and operation of such a pre-embarkation quarantine facility shall be borne by the owner or operator of such facility.

(4) The Animal and Plant Health Inspection Service requires that the importer submit the physical plans for the PEQF for which he/she is requesting approval. The physical plans must include location of the facility and site-specific blueprints. The importer must send these physical plans, due with the cooperative-service agreement as provided in § 93.430(d) to the Import-Export Animals Staff, National Center for Import-Export, Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, 4700 River Road Unit 39, Riverdale, MD 20737-1231. Approval of a PEQF will expire at the end of the specifically authorized quarantine. Subsequent importers granted use of HSTAIC and proposing to use one of the existing PEQFs must apply for approval as if for a new facility. No more than one PEQF will receive approval for a specific HSTAIC importation. If the PEQF specified in the signed

cooperative-service agreement, as provided in § 93.430(d), is not approved by APHIS, the importer may use an alternative PEQF, provided it is approved by the Animal and Plant Health Inspection Service during the 42 days following the date the importer signs the cooperative-service agreement. If a PEQF closes down or loses its "approved" status for any reason, APHIS may approve a replacement following the method specified in this paragraph (a)(4).

(5) Permission to place ruminants in the foreign PEQF shall be given to any person who has received permission to import ruminants through the Harry S Truman Animal Import Center, unless the Administrator determines that sufficient grounds exist whereby such person may be denied such permission.

(6) Fees charged by the owner or operator for the use of such facility shall be provided in private agreements between the owner or operator of the facility and the owners of the ruminants proposed for importation. Such fees shall be nondiscriminatory and reasonable as determined by the Administrator.

(7) Approval of any approved PEQF may be withdrawn at any time by the Administrator, upon his or her determination that any requirement of this section is not being met. Before such action is taken, the operator of the facility will be informed of the reasons for the proposed action and afforded opportunity to present his or her views thereon in accord with rules of practice adopted by the Administrator. Upon withdrawal of approval, the operator, upon request, shall be afforded opportunity for a hearing with respect to the merits or validity of such action; but such withdrawal or refusal shall continue in effect unless otherwise ordered by the Administrator. Rules of practice concerning the hearing will be adopted by the Administrator.

(b) *Standards for approval of pre-embarkation quarantine facilities—*(1) *Location.* (i) The PEQF must be in a region isolated from ruminants, swine, and poultry. It must be located near the point of embarkation: A dock, if the ruminants will travel by ocean vessel; an airport, if the ruminants will travel by plane.

(ii) The ruminants' route from the PEQF to the point of embarkation must be limited to regions free of ruminants, swine, and poultry.

(iii) The facility must be so situated that there will be no contact between ruminants held in the facility with any other species of animals.

(iv) The facility must be so situated that it will be free from contact with

water and waste effluents from local livestock or poultry. Water and waste effluents from the facility must be disposed of in a manner determined by the Administrator to be adequate to ensure no exposure to local livestock or poultry.

(2) *Building.* (i) The exterior of the building must be of durable low maintenance, waterproof type construction that will withstand repeated cleaning and disinfecting.

(ii) Roofs must be watertight. The styling and configuration of the roof of the ruminant holding building must provide for optimum air circulation throughout the facility.

(iii) The interior finish of the building must be durable, washable, and of low maintenance type construction. The floor must be concrete with no cracks or crevices.

(iv) Mesh double screens must protect all open regions, so that insects cannot gain access to the ruminant holding region. If the ruminants are removed from the double-screened building before export to the HSTAIC, or if the United States Department of Agriculture Veterinarian in Charge of the quarantine operation determines that insects capable of transmitting communicable animal diseases are entering the ruminant holding region, APHIS will require implementation of a program of insect vector control. This vector control program will involve treating ruminants, building interiors, and environs with United States Environmental Protection Agency-registered pesticides. The pesticides must be used in the manner prescribed on the United States Environmental Protection Agency-approved label, and in accordance with the requirements of the government of the country in which the PEQF is located.

(v) Stalls, pens, and runways must be constructed of sufficient height and strength to confine and restrain all ruminants simultaneously for daily veterinary examinations.

(vi) At least 70-foot-candle lighting must be provided in the inspection region. A minimum light of 30-foot-candle must be available in all other regions of the facility.

(vii) A dipping vat of a concrete pit type with inspection chute, holding pen, dripping pen, and post-drip region similar to USDA Extension Plan 5940, revised, must be provided.<sup>12</sup>

USDA, will send each importer copies of Exhibits A and B along with the cooperative-services agreement.

<sup>12</sup> Copies of USDA Extension Plan 5940, revised, may be obtained from the Import-Export Animals Staff, National Center for Import and Export, Animal and Plant Health Inspection Service, United States Department of Agriculture, 4700 River Road Unit 39, Riverdale, MD 20737-1231.



(viii) The waste management system must be carefully designed to meet all applicable sanitation and quarantine requirements and the existing environmental standards of the country in which the pre-embarkation quarantine facility is located.

(3) *Fencing.* (i) The outer perimeter of all facilities must be surrounded by a fence that must be of sufficiently small mesh as to preclude the entrance of small farm animals, including dogs, and of such height and strength as to prevent entrance of larger animals. This fence must be located at least 200 feet from the building in which quarantined ruminants are to be held, except that, in an urban or industrial region the location of the fence may be less than 200 feet as determined by the Administrator, if such action will not increase the risk that communicable diseases of livestock or poultry will be disseminated from the facility.

(ii) In regions affected by cattle fever ticks, all such facilities must be double fenced with the inner perimeter fence located at least 15 feet from the outer perimeter fence. When double fencing is required, the space between the outer and inner perimeter fences must be kept free from all foliage at all times.

(iii) The outer fence of the facility must be posted with signs in appropriate language, which shall convey the following: Restricted Region—Keep Out, Quarantine Region—Keep Out, or Registered Quarantine Region—Keep Out.

(4) *Feed.* The animal feed supply in the PEQF must consist only of feed obtained from a region that is classified as Risk Class RN, R1, or R2 for foot-and-mouth disease, and for any other exotic disease necessitating the quarantine or that could jeopardize the quarantine.

(5) *Other requirements.* (i) Access into the quarantine area must be through a single door that must lead into a walk-through shower area with clothes change areas located on either side of the shower and adjacent thereto.

(ii) Toilet and lavatory facilities as determined by the Administrator to be adequate to preclude transmission of livestock or poultry disease agents from the facility must be located within the ruminant holding areas.

(iii) A sufficient supply of clean clothing, including towels and footwear, as determined by the Administrator to be adequate to prevent the transmission of livestock or poultry disease agents from the facility, must be maintained within the quarantine area.

(iv) A continuous supply of hot and cold running water, including potable water for personnel, must be provided.

(v) If lunch is to be eaten within the facility, a lunch room must be provided and all food entered into the facility must be approved by the supervising United States government veterinarian.

(vi) A separate room containing the equipment for preparation and packaging of laboratory specimens with adequate office space, as determined by the Administrator, to perform his or her duties must be provided for the supervising veterinary official. All records, equipment, and other materials used in the facility must be maintained within the quarantine facility for the entire quarantine period.

(vii) A separate area situated apart from the ruminant holding area must be provided for necropsies, and a means for the removal of the carcasses of dead ruminants must be provided without breaking quarantine security.

(viii) A ruminant receiving area and a chute or stocks for restraint during examination and veterinary inspection, as determined to be appropriate by the Administrator, to permit examination of the ruminant, must be provided.

(ix) Feed must be stored in such a manner that replenishment during the quarantine period does not require transporting vehicles to enter the quarantine area.

(x) Equipment necessary for the care, cleaning, feeding, waste disposal, and handling of the ruminants must be provided and maintained within the quarantine area.

(xi) Additional requirements as to security, physical plant and facilities, and sanitation may be imposed by the Administrator, in each specific case in order to assure that the quarantine of the ruminants in a facility will be adequate to enable determination of their health status, prevent the spread of disease among ruminants in quarantine, and prevent escape of animal disease agents from the facility.

#### Subpart E—Swine

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#### Subpart E—Swine

##### § 93.500 Definitions.

Wherever in this subpart the following terms are used, unless the context otherwise requires, they shall be construed, respectively, to mean:

*Accredited veterinarian.* A veterinarian approved by the Administrator in accordance with the provisions of part 161 of this chapter to perform functions specified in parts 1, 2, 3, and 11 of subchapter A, and subchapters B, C, and D of this chapter, and to perform functions required by cooperative State-Federal disease control and eradication programs.

*Adjacent regions.* Any defined geographic land area identifiable by geological, political or surveyed boundaries that shares common boundaries with, or is proximate to any region of a different risk class, as determined by the Administrator.

*Administrator.* The Administrator of the Animal and Plant Health Inspection Service or any other employee of the Animal and Plant Health Inspection Service, United States Department of Agriculture, delegated to act in the Administrator's stead.

*Affected animals.* Animals currently infected or infested with, or exposed to, a communicable disease agent, or that are not known to be infected, infested, or exposed but that because of information, proximity, location, season, or lack of surveillance data could reasonably be expected to be infected, infested, or exposed to a communicable disease agent.

*Affected premises or region.* A premises or region where a communicable disease agent is known to exist; that is adjacent to or proximate to any known infected or infested premises or region so that airborne, vector, or mechanical transmission of the disease agent could occur; or that, because of lack of surveillance data, could reasonably be expected to be infected, infested, or exposed to a communicable disease agent.



*Animal and Plant Health Inspection Service (APHIS).* The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

*Animals.* All species of the animal kingdom including: Cattle, sheep, goats, other ruminants, swine, horses, asses, mules, zebras, dogs, and poultry that are susceptible to communicable diseases of livestock or capable of being carriers of those diseases or their arthropod vectors.

*APHIS representative.* Any individual employed by the Animal and Plant Health Inspection Service, United States Department of Agriculture, who is authorized to perform the services required by this part.

*Approved brucellosis test.* Any test recognized as an official brucellosis test in the United States according to § 78.1 of this chapter, or a test recognized as an equivalent test by the Administrator and that is recognized as an official test in a country exporting animals to the United States.

*Approved pseudorabies test.* Any test recognized as an official pseudorabies test in the United States according to § 85.1 of this chapter, or a test recognized as an equivalent test by the Administrator and that is recognized as an official test in a country exporting to the United States.

*Approved tests for restricted diseases or agents.* Diagnostic tests or procedures that are determined by the Administrator to be scientifically valid to diagnose a restricted animal disease.

*Authorized veterinarian.* A veterinarian accredited, employed or authorized by the National Veterinary Services of the country to carry out the required inspection and certification services.

*Border definitions.* See § 92.1 of this chapter.

*Case.* An individual animal affected by a communicable disease agent.

Depending on the disease condition, this may be an animal with clinical signs, or an animal with serological or pathological evidence of infection, or an infested animal.

*Cattle.* Animals of the bovine species.

*Communicable disease.* Any contagious or infectious disease of animals. It can be transmitted either directly or indirectly to a susceptible animal from an infected animal, vector, inanimate reservoir, or other source.

*Contagious disease.* Any communicable disease transmitted from one infected animal to another by direct contact or by feed, water, aerosol, or contaminated objects.

*Department.* The United States Department of Agriculture (USDA).

*Driven.* Moved (animals) from one place to another by walking under their own power and being herded and guided by persons or trained animals.

*Ectoparasites.* Acarid (mites, ticks) or insect members of the Phylum Arthropoda that spend all or part of their life cycle on the exterior of avian, reptilian or mammalian hosts and that are known or suspected to be the vectors of communicable disease agents, or are the cause of disease or irritation in animals or birds.

*Equivalent test.* A serologic, microbiologic, chemical, or physical test approved for use in a region exporting livestock or livestock products to the United States and recognized by the Administrator as providing results equal to a test approved by the United States Department of Agriculture. Recognition of a test as an "equivalent test" will be made by the Administrator after he or she reviews scientific data that shows that the results of the test are equal to the USDA-approved test.

*Exposed.* (1) An animal or means of conveyance that has been in contact with or that can reasonably be expected to have been in contact with an animal, feed, water, air, soil, tools, or other objects, insects, or ectoparasites infected or contaminated with a communicable disease agent, as determined by the Administrator.

(2) A region or premises where an animal, feed, water, air, soil, tools or other objects, insects, or ectoparasites contaminated with a communicable disease agent are or have been present within the known incubation period of the disease agent.

(i) *Direct exposure:* Exposure by coming into direct contact with an infected animal, or with feed, water, air, soil, tools, or other objects, that have been contaminated by discharges from an infected animal.

(ii) *Indirect exposure:* Exposure by coming into contact with vector insects or ectoparasites, or objects that have been contaminated other than by discharges from an infected animal.

*Herd.* (1) A group of animals under common ownership or supervision that are maintained and intermingle on one or more parts of a single premises (farm, ranch, feedlot, etc.); or

(2) A group of animals under common ownership or supervision maintained on geographically separated premises but that have been interchanged between the different premises or have been otherwise intermingled.

*Identification.* (1) *Permanent identification:* Brands, tattoos, or electronic identification that cannot be readily removed or altered.

(2) *Semi-permanent identification:* Identification such as metal or plastic ear tags that may remain on an animal permanently but can be easily altered, lost or removed.

(3) *Non-permanent identification:* Identification such as temporary ear tags, chain tags, back tags, or tail tags.

(4) *Temporary identification:* Lot identification if lots are not mixed, or the origin of all lots in a mixed lot.

*Immediate slaughter.* Consignment directly from the port of entry to a recognized slaughtering establishment<sup>1</sup> and slaughter thereat within two weeks from the date of entry.

*Import (imported, importation) into the United States.* To bring into the territorial limits of the United States.

*Inspector.* An employee of the Animal and Plant Health Inspection Service authorized to perform duties required under this subpart.

*Livestock.* Domesticated species of cattle, swine, sheep, goats, llamas, horses, or poultry that normally and historically have been kept and raised on farms. Livestock also includes bison and cervidae or other species kept in captivity for producing food or fiber, or for other commercial purposes.

*Moved directly.* Moved (shipped, transported, or otherwise moved) without unloading and without stopping except for refueling, or for traffic conditions such as traffic lights or stop signs.

*Official seal.* A serially numbered, metal or plastic strip, consisting of a self-locking device on one end and a slot on the other end, which forms a loop when the ends are engaged and which cannot be reused if opened, or a serially numbered, self-locking button which can be used for this purpose.

*Operator.* Any person operating an approved quarantine facility.

*Permitted treatment.* A treatment authorized by the Administrator to be used in the official treatment of animals for control or removal of ectoparasites.

*Persons.* Any individual, corporation, company, association, firm, partnership, society, joint stock company, or other legal entity.

*Port Veterinarian.* A veterinarian employed by APHIS to perform duties required under this part at a port of entry.

*Post-importation quarantines.* Quarantines applied in the importing region at a facility specially designated as an import quarantine facility.

<sup>1</sup> The name of recognized slaughtering establishments approved under this part may be obtained from the Area Veterinarian in Charge (AVIC), Veterinary Services, Animal and Plant Health Inspection Service, for the State of destination of the shipment. AVIC telephone numbers can be found in the local telephone book.

*Pre-embarkation quarantines.*

Quarantines applied in the exporting region. May be on the premises of origin, a separate quarantine facility, a border station, or other facility used to hold animals while in transit.

*Quarantine.* Confinement of all susceptible animals, animal products, feed, farm machinery, other equipment, means of conveyance, and any other potentially contaminated objects to a premises or area where infection or infestation with a specific restricted agent has been found or is suspected to exist.

*Recognized slaughtering establishment.* An establishment<sup>2</sup> where slaughtering operations are regularly carried on under Federal or State inspection and that has been approved by APHIS to receive animals for slaughter under this part.

*Region.* Any defined geographic land region identifiable by geological, political or surveyed boundaries.

*Restricted agent.* A livestock communicable disease agent, vector, or host of an agent not known to exist in the United States or that is subject to a Federal or cooperative Federal/State control or eradication program within the United States. Restricted agents are listed in § 92.2 of this chapter.

*Risk Class regions.* Exporting regions designated by the Administrator according to the results of a risk assessment as defined in § 92.1 of this chapter, and determined by criteria as set forth in § 92.3 of this chapter are incorporated herein and are applicable to this part.

*Ruminants.* All animals that chew the cud, such as cattle, buffaloes, sheep, goats, deer, antelopes, camels, llamas and giraffes.

*Shipping container.* For the purposes of § 93.402, any container of a type specially adapted for use in transporting any article on the means of conveyance involved.

*Susceptible animals.* Species of ruminants or other animals that can become infected with a specific disease agent.

*Trail.* Move animals from one place to another by having them walk under their own power, and by leading them by ropes or other devices tied to the animal and guided by persons or trained animals.

*Transported.* Moved or shipped from one place to another by any means of conveyance, such as airplane, ship, boat, barge, truck, train, cart, or other vehicle.

*United States.* All of the States of the United States, the District of Columbia,

Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other Territories and Possessions of the United States.

*Vector-borne disease.* A disease transmitted indirectly to an animal through an intermediate arthropod vector, including ticks or insects.

*Veterinarian in Charge.* The veterinary official of the Animal and Plant Health Inspection Service, United States Department of Agriculture, who is assigned by the Administrator to supervise and perform the official animal health work of the Animal and Plant Health Inspection Service in the State or area concerned.

*Zoological park.* A zoo, park, garden or other place, maintained under the surveillance of a licensed Doctor of Veterinary Medicine, for the exhibition of live animals, pigeons or birds, for the purpose of public recreation or education.

**§ 93.501 General prohibitions; exceptions.**

(a) No swine subject to the provisions of this part may be imported into the United States except in accordance with the regulations in this part;<sup>3</sup> nor may any such swine be handled or moved after physical entry into the United States before final release from quarantine or any other form of governmental detention except in compliance with such regulations; *Provided That*, except as prohibited by section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), the Administrator may upon request in specific cases permit swine to be brought into or through the United States under such conditions as he or she may prescribe, when he or she determines in the specific case that such action will not endanger the livestock or poultry of the United States.

(b) Except for swine prohibited entry by section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), the provisions in this part relating to swine shall not apply to healthy swine in transit through the United States, if they are not known to be infected with or exposed, within 60 days preceding the date of export from the region of origin, to communicable diseases of swine; and, if an import permit<sup>4</sup> has been obtained under § 93.504 of this chapter and all conditions therein are observed; and if the following conditions are met:

<sup>3</sup> Importations of certain animals from various countries are absolutely prohibited under part 94 because of specified diseases.

<sup>4</sup> Such permit may be obtained from the National Center for Import and Export, Veterinary Services, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231.

(1)(i) The swine are maintained under continuous confinement in transit through the United States aboard an aircraft, ocean vessel, or other means of conveyance; or

(ii) The swine are unloaded, in the course of such transit, into a swine holding facility that is provided by the carrier or its agent and that has been approved in advance by the Administrator in accordance with paragraph (c) of this section as adequate to prevent the spread within the United States of any livestock disease, and the swine are maintained there under continuous confinement until loaded aboard a means of conveyance for transportation from the United States and are maintained under continuous confinement aboard such means of conveyance until it leaves the United States; the import permit will specify any additional conditions necessary to assure that the transit of the swine through the United States can be made without endangering the livestock or poultry of the United States, and that Department inspectors may inspect the swine on board such means of conveyance or in such holding facility as provided in section 5 of the Act of July 2, 1962 (21 U.S.C. 134d) to ascertain whether the requirements of this paragraph are met, and dispose of them in accordance with section 2 of the Act of July 2, 1962 (21 U.S.C. 134a) if such conditions are not met; and

(2) The carrier or its agent executes and furnishes to the collector of U.S. Customs at the first port of arrival a declaration stating that the swine will be retained aboard such means of conveyance or in an approved holding facility during transshipment as required by paragraphs (a)(1)(i) and (a)(1)(ii) of this section.

(c) Provisions for the approval of facilities required in this paragraph are:

(1) They must be sufficiently isolated to prevent direct or indirect contact with all other animals and birds while in the United States;

(2) They must be so constructed that they provide adequate protection against environmental conditions and can be adequately cleaned, washed and disinfected;

(3) They must provide for disposal of swine carcasses, manure, bedding, waste and any related shipping materials in a manner that will prevent dissemination of disease;

(4) They must have provisions for adequate sources of feed and water and for attendants for the care and feeding of swine in the facility;

(5) They must comply with additional requirements as may be imposed by the

<sup>2</sup> See footnote 1 in § 93.500.

Administrator if deemed applicable for a particular shipment; and

(6) They must also comply with all applicable local, State and Federal requirements for environmental quality and with the provisions of the Animal Welfare Regulations in chapter I of this title, as applicable.

**§ 93.502 Inspection of certain aircraft and other means of conveyance and shipping containers thereon; unloading, cleaning, and disinfection requirements.**

(a) *Inspection.* All aircraft and other means of conveyance (including shipping containers thereon) moving into the United States from any foreign country are subject to inspection without a warrant by properly identified and designated APHIS inspectors to determine whether they are carrying any animal, carcass, product or article regulated or subject to disposal under any law or regulation administered by the Secretary of Agriculture for prevention of the introduction or dissemination of any communicable animal disease (21 U.S.C. 134d).

(b) *Unloading requirements.* Whenever, in the course of any such inspection at any port in the United States, the APHIS inspector has reason to believe that the means of conveyance or container is contaminated with material of animal (including poultry) origin, such as, but not limited to, meat, organs, glands, extracts, secretions, fat, bones, blood, lymph, urine, or manure, so as to present a danger of the spread of any communicable animal disease, the inspector may require the unloading of the means of conveyance and the emptying of the container if he or she deems it necessary to enable him or her to determine whether the means of conveyance or container is in fact so contaminated. The principal operator of the means of conveyance and his or her agent in charge of the means of conveyance must comply with any such requirement under the immediate supervision of, and in the time and manner prescribed by, the inspector.

(c) *Cleaning and disinfection.* Whenever, upon inspection under this section, an inspector determines that a means of conveyance or shipping container is contaminated with material of animal origin so as to present a danger of the spread of any communicable animal disease, he or she shall notify the principal operator of the means of conveyance or his or her agent in charge, of such determination and the requirements under this section. The person so notified must cause the cleaning and disinfection of such means of conveyance and container under the immediate supervision of, and in the

time and manner prescribed by, the inspector.

**§ 93.503 Ports designated for the importation of swine.**

(a) *Air and ocean ports.* The following ports have APHIS inspection and quarantine facilities necessary for quarantine stations and all swine must be entered into the United States only through these stations, except as otherwise provided in this section: Los Angeles, California; Miami, Florida; Honolulu, Hawaii; and Newburgh, New York.

(b) *Canadian border ports.* The following land border ports are designated as having the necessary inspection facilities for the entry of swine from Canada: Eastport, Idaho; Houlton and Jackman, Maine; Detroit, Port Huron, and Sault Ste. Marie, Michigan; Baudette, Minnesota; Opheim, Raymond, and Sweetgrass, Montana; Alexandria Bay, Buffalo, and Champlain, New York; Dunseith, Pembina, and Portal, North Dakota; Derby Line and Highgate Springs, Vermont; Blaine, Lynden, Oroville, and Sumas, Washington.

(c) *Mexican border ports.* The following land border ports are designated as having the necessary inspection facilities for the entry of swine from Mexico: Brownsville, Hidalgo, Laredo, Eagle Pass, Del Rio, Presidio, and El Paso, Texas; Douglas, Naco, Nogales, Sasabe, and San Luis, Arizona; Calexico and San Ysidro, California; and Antelope Wells, and Columbus, New Mexico.

(d) *Special ports.* Charlotte Amalie, St. Thomas, and Christiansted, St. Croix, in the United States Virgin Islands, are hereby designated as quarantine stations for the entry of swine from the British Virgin Islands into the United States Virgin Islands for immediate slaughter.

(e) *Limited ports.* The following ports are designated as having inspection facilities for the entry of swine and swine products such as swine test specimens that do not appear to require restraint and holding inspection facilities: Anchorage and Fairbanks, Alaska; San Diego, California; Jacksonville, St. Petersburg-Clearwater, and Tampa, Florida; Atlanta, Georgia; Chicago, Illinois; New Orleans, Louisiana; Portland, Maine; Baltimore, Maryland; Boston, Massachusetts; Minneapolis, Minnesota; Great Falls, Montana; Portland, Oregon; San Juan, Puerto Rico; Galveston and Houston, Texas; and Seattle, Spokane, and Tacoma, Washington.

(f) *Designation of other ports.* The Secretary of the Treasury has approved the designation as quarantine stations of

the ports specified in this section. In special cases, other ports may be designated as quarantine stations under this section by the Administrator, with the concurrence of the Secretary of the Treasury.

**§ 93.504 Import permits for swine and for swine specimens for diagnostic purposes; and reservation fees for space at quarantine facilities maintained by APHIS.**

(a) *Application for import permit; reservation required.* (1) To import swine and swine test specimens for diagnostic screening purposes from any part of the world, the importer must first apply for and obtain from APHIS an import permit. Swine imported through land border ports from regions classified as Risk Class RN for foot-and-mouth disease, rinderpest, hog cholera, African swine fever, and swine vesicular disease are exempt from import permit requirements. The application must specify the name and address of the importer; the species, breed, number or quantity of swine or swine test specimens to be imported; the purpose of the importation; individual swine identification that includes a description of the swine, name, age, markings if any, registration number if any, and tattoo or eartag; the region of origin; the name and address of the exporter; the port of embarkation in the foreign country; the mode of transportation, route of travel, and the port of entry in the United States; the proposed date of arrival of the swine or swine test specimens to be imported; and the name of the person to whom the swine or swine test specimens will be delivered and the location of the place in the United States to which delivery will be made from the port of entry. Additional information may be required in the form of certificates concerning specific disease agents to which the swine are susceptible, as well as vaccinations or other precautionary treatments to which the swine or swine test specimens have been subjected. Notice of any such requirements will be given to the applicant in each case.<sup>5</sup>

(2) An application for permit to import swine and/or swine test specimens may be denied because of: Communicable disease conditions in the region of origin, or in a region where the shipment has been or will be held or through which the shipment has been or will be transported; deficiencies in the regulatory programs for the control or eradication of animal diseases and the unavailability of veterinary services in the above mentioned regions; the

<sup>5</sup> See §§ 93.505, 93.506, and 93.515 for additional requirements for the importation of swine.

importer's failure to provide satisfactory evidence concerning the origin, history, and health status of the swine; the lack of satisfactory information necessary to determine that the importation will not be likely to transmit any communicable disease to livestock or poultry of the United States; or any other circumstances that the Administrator believes require such denial to prevent the dissemination of any communicable disease of livestock or poultry into the United States.

(3)(i) The importer or importer's agent must pay or ensure payment of a reservation fee for each lot of swine to be quarantined in a facility maintained by USDA. For swine, the reservation fee shall be 100 percent of the cost of providing care, feed, and handling during quarantine, as estimated by the quarantine facility's veterinarian in charge.

(ii) At the time the importer or the importer's agent requests a reservation of quarantine space, the importer or importer's agent must pay the reservation fee by check or U.S. money order or ensure payment of the reservation fee by an irrevocable letter of credit from a commercial bank (the effective date on such letter of credit must run to 30 days after the date the swine are scheduled to be released from quarantine); except that anyone who issues a check to the Department for a reservation fee that is returned because of insufficient funds shall be denied any further request for reservation of a quarantine space until the outstanding amount is paid.

(iii) Any reservation fee paid by check or U.S. money order shall be applied against the expenses incurred for services received by the importer or importer's agent in connection with the quarantine for which the reservation was made. Any part of the reservation fee that remains unused after being applied against the expenses incurred for services received by the importer or the importer's agent in connection with the quarantine for which the reservation was made, shall be returned to the individual who paid the reservation fee. If the reservation fee is ensured by a letter of credit, the Department will draw against the letter of credit unless payment for services received by the importer or importer's agent in connection with the quarantine is otherwise made at least 3 days prior to the expiration date of the letter of credit.

(iv) Any reservation fee shall be forfeited if the importer or the importer's agent fails to present for entry, within 24 hours following the designated time of arrival, the lot of swine for which the reservation was

made: Except that a reservation fee shall not be forfeited if:

(A) Written notice of cancellation from the importer or the importer's agent is received by the office of the veterinarian in charge of the quarantine facility<sup>6</sup> during regular business hours (8:00 a.m. to 4:30 p.m. Monday through Friday, excluding holidays) no later than 15 days prior to the beginning of the time of importation of the swine as specified in the import permit or as arranged with the veterinarian in charge of the quarantine facility if no import permit is required (the 15 day period shall not include Saturdays, Sundays, or holidays); or

(B) The Administrator determines that services, other than provided by carriers, necessary for the importation of the swine within the requested period are unavailable because of unforeseen circumstances as determined by the Administrator (such as the closing of an airport due to inclement weather or the unavailability of the reserved space due to the extension of another quarantine).

(v) If the reservation fee was ensured by a letter of credit and the fee is to be forfeited under paragraph (a)(3)(iv) of this section, the Department will draw against the letter of credit unless the reservation fee is otherwise paid at least 3 days prior to the expiration date of the letter of credit.

(vi) When a reservation is canceled in accordance with paragraph (a)(3)(iv)(A) of this section and the provisions of paragraph (a)(3)(iv)(B) of this section do not apply, a \$40.00 cancellation fee shall be charged. If a reservation fee was paid, the cancellation fee shall be deducted from any reservation fee returned to the importer or the importer's agent. If the reservation fee was ensured by a letter of credit, the Department will draw the amount of the cancellation fee against the letter of credit unless the cancellation fee is otherwise paid at least 3 days prior to the expiration date of the letter of credit.

(b) *Import Permit.* When an import permit is issued, the original and two copies will be sent to the importer. It shall be the responsibility of the importer to forward the original permit and one copy to the shipper in the country of origin, and it shall also be the responsibility of the importer to ensure that the shipper presents the copy of the import permit to the carrier and makes proper arrangements for the original permit to accompany the shipment to

<sup>6</sup>The addresses of USDA quarantine facilities may be found in telephone directories listing the facilities or by contacting the National Center for Import and Export, Veterinary Services, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231.

the specified U.S. port of entry for presentation to the collector of customs. All swine and all swine test specimens for diagnostic screening purposes for which an import permit has been issued for importation into the United States will be received at the specified port of entry within the time prescribed in the import permit. That time shall not exceed 14 days from the first day that the permit is effective for all permits relevant to the shipment or shipments. All swine and swine test specimens for which an import permit is required by this subpart will not be eligible for entry into the United States if an import permit has not been issued; if the swine or swine test specimens are unaccompanied by such an import permit; if shipment is from any port other than the one designated in the import permit; if arrival in the United States is at any port other than the one designated in the import permit; if the swine or swine test specimens imported are different from those described in the import permit; if the swine or swine test specimens are not handled as outlined in the application for the import permit and as specified in the permit issued; or if ruminants or swine other than those covered by the import permits are aboard the transporting carrier.

#### **§ 93.505 Certificate of export and other requirements for swine.**

(a) All swine imported or offered for importation from any part of the world, except for swine that are imported for immediate slaughter from regions that are classified as Risk Class RN for all restricted agent(s) of swine, and except as provided in paragraphs (c) and (d) of this section,<sup>7</sup> must be accompanied by a certificate of export signed by an authorized veterinarian and endorsed by the National Veterinary Services of the country of export who certifies that the veterinarian signing and issuing the certificate is authorized to do so and who certifies that:

(1) The swine originate from premises that are not known to have been affected with any communicable diseases of swine during the previous 60 days;

(2) The swine originate from premises that are not known to have been affected with restricted ectoparasites of swine during the last previous days;

(3) During transportation to the port of embarkation there was no direct or indirect exposure to any potential carrier animals from any region affected with restricted agents that affect swine;

(4) While en route to the port of entry, the swine were not trailed or driven

<sup>7</sup>See § 93.515 for additional requirements for swine imported from specific risk class regions.

through any Risk Class R3, R4 or RU region for any tick-borne restricted agents; and

(5) While en route to the port of entry, the swine were not trailed, driven, transported, or otherwise moved through any Risk Class R3, R4 or RU region for any restricted insect-transmitted agents during a time of year when the insect vectors were active;

(6) The swine were inspected on the day of embarkation and found to be free of restricted ectoparasites as listed in § 92.2 of this chapter, or were treated with one of the permitted treatments in § 72.13(b) of this chapter within 10 to 14 days of embarkation. If treated, the pesticide, active ingredient, concentration, and date applied must be recorded on the certificate of export; and

(7) The swine were transported to the United States only in means of conveyance or vehicles that were cleaned and disinfected prior to use.

(b) Prior to entry into the United States, the swine must be identified in accordance with § 71.19 of this chapter.

(c) Swine that are from a region classified as RN for all restricted diseases of swine and that are to be transported in-bond through the United States for immediate export, shall be inspected at the border port of entry and, when accompanied by an import permit obtained under § 93.504 and when all conditions therein are observed, shall be allowed entry into the United States and shall be otherwise handled in accordance with § 93.501(b).

(d) Swine originating in the United States and transported directly through a region classified as RN for all restricted diseases of swine, may reenter the United States without foreign health or test certificates when accompanied by copies of the United States export health certificates properly issued and endorsed in accordance with the regulations in part 91 of this chapter: *Provided*, That, to qualify for reentry into the United States, the date, time, port of entry, and signature of the port veterinarian of the foreign country that inspected the swine for entry into the foreign country shall be recorded on the United States health certificate, or a paper containing such information shall be attached to the certificate that accompanies the swine. In all cases, it shall be determined by the veterinary inspector at the United States port of entry that the swine are the identical swine covered by said certificate.

(e) If the swine are unaccompanied by the certificate of export as required by paragraph (a) of this section, or if such swine are found upon inspection at the port of entry to be affected with or to

have been exposed to a communicable disease, they shall be refused entry and shall be handled thereafter in accordance with the provisions of section 8 of the Act of August 30, 1890 (26 Stat. 416; 21 U.S.C. 103), or quarantined, or otherwise disposed of as the Administrator may direct.

**§ 93.506 Permit, certificate, declaration and other documents for swine.**

(a) The export certificates, import permits, declarations, and affidavits required by the regulations in this part must be presented by the importer or his or her agent to the collector of customs at the port of entry, upon arrival of the swine at such port, for the use of the veterinary inspector at the port of entry.

(b) For all swine imported or offered for importation, the importer or his or her agent must first present two copies of a declaration that lists the port of entry, the name and address of the importer, the name and address of the broker, the origin of the swine, the number, breed, species, and purpose of the importation, the name of the person to whom the swine will be delivered, and the street address of the place to which such delivery will be made.

**§ 93.507 Inspection at the port of entry.**

Inspection shall be made at the port of entry of all swine imported from any part of the world. All swine found to be free from communicable disease and not to have been exposed thereto within 60 days prior to their exportation to the United States shall be admitted subject to the other provisions in this part; all other swine shall be refused entry. Swine refused entry, unless exported within a time fixed in each case by the Administrator, and in accordance with other provisions he or she may require in each case for their handling, shall be disposed of as the Administrator may direct, in accordance with provisions of section 2 of the Act of July 2, 1962 (21 U.S.C. 134a), or the provisions of section 8 of the Act of August 30, 1890 (21 U.S.C. 103). Such portions of the transporting vessel, and of its cargo, that have been exposed to any such swine or their emanations, must be disinfected in such manner as may be considered necessary by the inspector in charge at the port of entry, to prevent the introduction or spread of livestock or poultry disease, before the cargo is allowed to land.

**§ 93.508 Articles accompanying swine.**

No litter or manure, fodder or other aliment, nor any equipment such as boxes, buckets, ropes, chains, blankets, or other things used for or about swine governed by the regulations in this part,

may be landed from any conveyance except under such restrictions as the inspector in charge at the port of entry shall direct.

**§ 93.509 Movement from conveyances to quarantine station.**

Platforms and chutes used for handling imported swine must be cleaned and disinfected under APHIS supervision after being so used. The said swine must not be moved over any highways nor allowed to come in contact with other swine, but must be transferred from the conveyance to the quarantine grounds only in boats, cars, or other vehicles approved by the inspector in charge at the port of entry. Such cars, boats, or vehicles must be cleaned and disinfected under APHIS supervision immediately after such use, by the carrier moving the same. The railway cars so used must be either cars reserved for this exclusive use or box cars not otherwise employed in the transportation of animals or their fresh products. When movement of the aforesaid swine upon or across a public highway is unavoidable, it shall under such careful supervision and restrictions as the inspector in charge at the port of entry may direct.

**§ 93.510 Swine quarantine facilities.**

(a) *Privately operated quarantine facilities.* The importer, or his or her agent, of swine subject to quarantine under the regulations in this part must arrange for acceptable transportation to the privately operated quarantine facility and for the care, feed, and handling of the swine from the time of unloading at the quarantine port to the time of release from quarantine. Such arrangements shall be agreed to in advance by the Administrator. All expenses resulting therefrom or incident thereto shall be the responsibility of the importer; APHIS assumes no responsibility with respect thereto. The quarantine facility must be suitable for the quarantine of such swine and must be approved by the Administrator prior to the issuance of any import permit. The facilities occupied by swine must be kept clean and sanitary. If for any cause the care, feed, or handling of swine, or the sanitation of the facilities, is neglected, in the opinion of the inspector assigned to supervise the quarantine, such services may be furnished by APHIS in the same manner as though arrangements had been made for such services as provided by paragraph (b) of this section, and/or the swine may be disposed of as the Administrator may direct, including sale in accordance with the procedure described in paragraph (b) of this

section. The importer, or his or her agent, must request in writing such inspection and other services as may be required, and shall waive all claim against the United States and APHIS or any employee of APHIS for damages that may arise from such services. The Administrator may prescribe reasonable rates for the services provided under this paragraph. When it is found necessary to extend the usual minimum quarantine period, the importer, or his or her agent, shall be so advised in writing and must pay for such additional quarantine and other services required. Payment for all services received by the importer, or his or her agent, in connection with each separate lot of swine must be made by certified check or U.S. money order prior to release of the swine. If such payment is not made, the swine may be sold in accordance with the procedure described in paragraph (b) of this section, or otherwise disposed of as directed by the Administrator.

(b) *Quarantine facilities maintained by APHIS.* The importer, or his or her agent, of swine subject to quarantine under the regulations in this part must arrange for acceptable transportation to the quarantine facility, and for the care, feed, and handling of the swine from the time they arrive at the quarantine facility, and for the care, feed, and handling of the swine from the time they arrive at the quarantine port to the time of release from quarantine. Such arrangements shall be agreed to in advance by the Administrator. The importer or his or her agent must request in writing such inspection and other services as may be required, and shall waive all claim against the United States and APHIS or any employee of APHIS, for damages that may arise from such services. All expenses resulting therefrom or incident thereto shall be the responsibility of the importer; APHIS assumes no responsibility with respect thereto. The Administrator may prescribe reasonable rates for the services provided under this paragraph. When it is found necessary to extend the usual minimum quarantine period, the importer, or his or her agent, shall be so advised in writing and shall pay for such additional quarantine and other services required. Payment for services received by the importer, or his or her agent, in connection with each separate lot of swine must be made by certified check or U.S. money order prior to release of the swine. If such payment is not made, the swine may be sold in accordance with the procedure described in this paragraph, or otherwise disposed of as directed by the

Administrator. When payment is not made and the swine are to be sold to recover payment for services received, the importer, or his or her agent, will be notified by the inspector that if said charges are not immediately paid or satisfactory arrangements made for payment, the swine will be sold at public sale to pay the expense of care, feed, and handling during that period. The sale will be held after the expiration of the quarantine period, at such time and place as may be designated by the General Services Administration of the Federal Government or other designated selling agent. The proceeds of the sale, after deducting the charges for care, feed, and handling of the swine and other expenses, including the expense of the sale, shall be held in a Special Deposit Account in the United States Treasury for 6 months from the date of sale. If not claimed by the importer, or his or her agent, within 6 months from the date of sale, the amount so held shall be transferred from the Special Deposit Account to the General Fund Account in the United States Treasury.

(c) Amounts collected from the importer, or his or her agent, for service rendered shall be deposited so as to be available for defraying the expenses involved in this service.

**§ 93.511 Quarantine stations, visiting restricted; sales prohibited.**

Visitors shall not be admitted to the quarantine enclosure during any time that swine are in quarantine, except that an importer (or his or her accredited agent or veterinarian) may be admitted to the yards and buildings containing his or her quarantined swine at such intervals as may be deemed necessary, and under such reasonable conditions and restrictions as may be imposed, by the inspector in charge of the quarantine station. On the last day of the quarantine period, owners, officers or registry societies, and others having official business or whose services may be necessary in the removal of the swine may be admitted upon written permission from the said inspector. No exhibition or sale shall be allowed within the quarantine grounds.

**§ 93.512 Milk from quarantined swine.**

Milk or cream from swine quarantined under the provisions of this part may not be used by any person other than those in charge of such swine, nor be fed to any animals other than those within the same enclosure, without permission of the inspector in charge of the quarantine station and subject to such restrictions as he or she may consider necessary to each instance. No milk or cream may be

removed from the quarantine premises except in compliance with all State and local regulations.

**§ 93.513 Manure from quarantined swine.**

No manure may be removed from the quarantine premises until the release of the swine producing the manure.

**§ 93.514 Appearance of disease among swine in quarantine.**

(a) If any restricted agent or other communicable disease appears among swine during the pre-embarkation or post-importation quarantine period, special precautions shall be taken to prevent spread of the infection to other animals in the quarantine station or to those outside the grounds. Affected swine in post-importation quarantine shall be disposed of as the Administrator may direct, depending upon the nature of the disease.

(b) During the post-importation quarantine period, the Administrator may require additional testing of the test positive animal(s) and/or test negative animals to determine if the animals will be eligible for importation into the United States.

**§ 93.515 Requirements for importation of live swine from various risk class regions.**

Swine may be imported from any regions of the world only if they meet the requirements of this section, and all other applicable requirements of this part.<sup>8</sup>

(a) *Regions classified as Risk Class RN for all restricted agents affecting swine.* In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions that are classified as Risk Class RN for all restricted agents of swine must certify that the swine to be imported have only been on premises located in regions classified as Risk Class RN for the specific restricted agent, and that they meet all other requirements of this part.

(b) *B. suis.* Swine imported for immediate slaughter from regions classified as Risk Class R1 or R2 for *B. suis*, or from regions classified as R3 if from herds that would meet the criteria for validated brucellosis-free herds under § 78.1 of this chapter, are exempt from *B. suis* testing and quarantine requirements. Such swine must be consigned from the port of entry to a recognized slaughtering establishment and there be slaughtered within 2 weeks from the date of entry. Such swine must be moved from the port of entry in conveyances sealed with seals of the United States Government, applied and removed by an APHIS representative, or

<sup>8</sup> See §§ 93.504, 93.505, and 93.506.

an individual authorized for this purpose by an APHIS representative.

(1) *Regions classified as Risk Class R1 for B. suis.* In addition to the export certificate requirements of § 93.505, the certificate of export for live non-neutered swine over 6 months of age from regions that are classified as Risk Class R1 for *B. suis* must certify that the swine to be imported:

(i) Were born and resided only in regions classified as Risk Class RN or R1 for *B. suis*; and

(ii) Have not been vaccinated with any live brucella vaccine.

(2) *Regions classified as Risk Class R2 or (for swine from validated swine brucellosis-free herds) regions classified as Risk Class R3 for B. suis.*

(i) In addition to the export certificate requirements of § 93.505, the certificate of export for live non-neutered swine over 6 months of age from regions that are classified as Risk Class R2, or from regions classified as R3 for *B. suis* if from a validated brucellosis-free herd,<sup>9</sup> must certify that the swine to be imported:

(A) Were born and resided only in regions classified as Risk Class RN, R1, or R2, or (if the swine are from validated brucellosis-free herds in Risk Class R3 regions) regions that are classified as Risk Class R3 for *B. suis*;

(B) Have not been vaccinated with any live brucellosis vaccine; and

(C) Had a negative result to an approved test for brucellosis no less than 30 days nor more than 60 days prior to export; and

(ii) The swine must be detained at the port of entry or animal import center until tested with negative results under the supervision of the port veterinarian for *B. suis* with negative results.

(3) *Regions classified as Risk Class R3 (if the swine are not from validated-free swine brucellosis herds), R4, and RU for B. suis.* Herds in regions classified as Risk Class R3 for *B. suis* that do not meet the criteria set forth in § 78.1 of this chapter for a brucellosis validated-free herd, and herds from regions classified as Risk Class R4 or RU must undergo a pre-embarkation complete herd test of all test eligible animals. If no test-positive animals are found the animals may then be imported according to the requirements in paragraph (b)(2) of this section. If test-positive animals are found, the animals are not eligible for export until the herd has completed a herd cleanup plan as stated in part 78 of this chapter. After the herd has completed a herd cleanup

plan, the animals may be imported under paragraph (b)(2) of this section.

(c) *Pseudorabies virus.* Swine imported for immediate slaughter from any region of the world are exempt from pseudorabies virus testing and quarantine requirements. Such swine must be consigned from the port of entry to a recognized slaughtering establishment and there be slaughtered within 2 weeks from the date of entry. Such swine must be moved from the port of entry in conveyances closed with official seals of the United States Government applied and removed by an APHIS representative, or an individual authorized for this purpose by an APHIS representative.

(1) *Regions classified as Risk Class R1 for pseudorabies virus.* In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions that are classified as Risk Class R1 for pseudorabies virus must certify that the swine to be imported:

(i) Were born and resided only in regions classified as Risk Class RN or R1 for pseudorabies virus; and

(ii) Have not been vaccinated with any pseudorabies vaccine.

(2) *Regions classified as Risk Class R2 and (if swine are from qualified pseudorabies-negative herds) regions classified as Risk Class R3 for pseudorabies virus.* In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions classified as Risk Class R2, and for live swine from qualified pseudorabies-negative herds<sup>10</sup> from regions classified as R3 for pseudorabies virus, must certify that the swine to be imported:

(i) Were born and resided only in regions classified as Risk Class RN, R1 or R2 for pseudorabies virus, or (if the swine are from qualified pseudorabies-negative herds in Risk Class R3 regions) regions that are classified as Risk Class R3;

(ii) Have not been vaccinated with any live pseudorabies vaccine; and

(iii) Have had a negative result to an approved test for pseudorabies within 30 days prior to the date of exportation.

(3) *Regions classified as Risk Class R3 (for herds that do not qualify as pseudorabies-negative herds), R4 or RU for pseudorabies virus.*

(i) In addition to the export certificate requirements of § 93.505, the certificate of export for live swine over 6 months of age from herds that do not qualify as pseudorabies-negative herds, from

regions that are classified as Risk Class R3, or for live swine from any herd in regions classified as risk class R4, or RU for pseudorabies virus, must certify that the swine to be imported:

(A) Have not been vaccinated with any pseudorabies vaccine, other than an approved gene-altered vaccine as listed in part 85 of this chapter. If the swine are vaccinated, the date of vaccination and the type of vaccine used must be recorded on the certificate of export;

(B) Have had a negative result to an approved test for pseudorabies within 30 days before exportation; and

(C) Have undergone a 30-day pre-embarkation quarantine.

(ii) The swine must undergo a 15-day minimum post-importation quarantine in a facility designated and approved by the Administrator.

(iii) During the post-importation quarantine, the swine must be tested with negative results using an approved test. This test must be administered a minimum of 30 days after the test administered in the region of origin.

(d) *Restricted ectoparasites—(1) Regions classified as Risk Class R1 and R2 for restricted ectoparasites.* (i) In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions that are classified as Risk Class R1 or R2 for restricted ectoparasites must certify that the swine to be imported resided for the previous 60 days only in regions classified as Risk Class RN, R1, or R2 for restricted ectoparasites.

(ii) All imported swine will be inspected at the port of entry for any ectoparasites, and given a precautionary treatment. If found to be infested with any ectoparasites, the swine will be refused entry until treated with one of the permitted treatments listed in § 72.13(b) of this chapter, and retreated 10 to 14 days after the initial treatment.

(2) *Regions classified as Risk Class R3, R4, or RU for restricted ectoparasites.* (i) In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions classified as Risk Class R3, R4 or RU for restricted ectoparasites must certify that the swine to be imported:

(A) Were treated for ectoparasites with an approved treatment 10 to 14 days prior to export. If quarantine in a pre-embarkation facility is required, the swine were treated immediately prior to entering a pre-embarkation facility; and

(B) Were inspected while at the pre-embarkation facility and found to be free of any ectoparasites.

(ii) The imported swine will be inspected at the port of entry for any ectoparasites, and given a precautionary

<sup>9</sup>To be considered as validated brucellosis-free, a herd must meet the standards set forth in § 78.1 of this chapter.

<sup>10</sup>To be considered as qualified pseudorabies-negative, a herd must meet the standards set forth in § 85.1 of this chapter.



treatment. If found to be infested with any ectoparasites, the swine will be refused entry until treated with one of the permitted treatments listed in § 72.13(b) of this chapter, then retreated 10 to 14 days after the initial treatment.

(e) *Foot and mouth disease (FMD), rinderpest (RP), African swine fever (ASF), hog cholera (classical swine fever) (HC), and swine vesicular disease (SVD)*. Swine imported for immediate slaughter that are born and raised in regions classified as Risk Class R1 or R2 for FMD, RP, ASF, HC and/or SVD are exempt from the test and quarantine requirements in this paragraph. The swine must be consigned from the port of entry to a recognized slaughtering establishment and there slaughtered within 2 weeks from the date of entry. The swine must be moved from the port of entry in conveyances closed with official seals of the United States Government applied and removed by an APHIS representative, or an individual authorized for this purpose by an APHIS representative.

(1) *Regions classified as R1 for FMD, RP, ASF, HC, and/or SVD*. In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions classified as Risk Class R1 for FMD, RP, ASF, HC, and/or SVD must certify that the swine to be imported:

(i) Were born and resided only in regions classified as Risk Class RN or R1 for FMD, RP, ASF, HC, and SVD;

(ii) Have not been vaccinated for FMD, RP, ASF, HC, and/or SVD; and

(iii) Have had a negative result to an approved serological test for FMD, RP, ASF, HC, and/or SVD within 30 days prior to exportation.

(2) *Regions classified as Risk Class R2 for FMD, RP, ASF, HC, and/or SVD*.

(i) In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions classified as Risk Class R2 for FMD, RP, ASF, HC, and/or SVD must certify that the swine to be imported:

(A) Were born and resided only in regions classified as Risk Class RN, R1 or R2 for FMD, RP, ASF, HC, and/or SVD;

(B) Have not been vaccinated for FMD, RP, ASF, HC, or SVD;

(C) Have undergone a 30-day pre-embarkation quarantine. For swine from regions classified as R2 for African swine fever, the pre-embarkation quarantine must be conducted in a vector-proof facility approved by the Administrator; and

(D) Have had a negative result to an approved serological test for FMD, RP, ASF, HC, and/or SVD within 30 days prior to exportation.

(ii) The imported swine must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) The swine must have a negative result to an approved serological test for FMD, RP, ASF, HC, and/or SVD during the post-importation quarantine period.

(3) *Regions classified as Risk Class R3 for FMD, RP, ASF, HC, and/or SVD*.

(i) In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions classified as Risk Class R3 for FMD, RP, HC, and/or SVD must certify that the swine to be imported:

(A) Were born and resided only in regions classified as Risk Class RN, R1, R2 or R3 for FMD, RP, ASF, HC, and/or SVD;

(B) Have not been vaccinated for FMD, RP, ASF, HC, or SVD;

(C) Have not been on any premises affected with FMD, RP, ASF, HC, or SVD virus during the 12 months prior to export;

(D) Have not been on any premises located within 25 miles (40 km) of any premises affected with R3 for FMD, RP, ASF, HC, and/or SVD virus in the 90 days prior to export;

(E) for at least 60 days prior to export, have undergone pre-embarkation quarantine from all animals not part of the group to be imported, under USDA supervision in a facility approved by the USDA according to § 93.517; and

(F) During pre-embarkation quarantine, have had negative results to two tests conducted no sooner than 15 days apart, for R3 for FMD, RP, ASF, HC, and/or SVD, using an approved serological test. If indicated, oesophageal-pharyngeal fluid samples will be taken for further testing.

(ii) The imported swine must be quarantined at the Harry S Truman Animal Import Center for at least 60 days without sentinel animals, during which time the swine must be re-tested at least once with negative results for FMD, RP, ASF, HC, and/or SVD, using an approved serological test. If indicated, oesophageal-pharyngeal fluid samples will be taken for further testing.

(4) *Regions classified as R4 or RU for FMD, RP, ASF, HC, and/or SVD*.

(i) In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions that are classified as Risk Class R4 or RU for FMD, RP, ASF, HC, and/or SVD must certify that the swine to be imported:

(A) Have not been vaccinated for FMD, RP, ASF, HC, and/or SVD;

(B) Have not been on any premises affected with FMD, RP, ASF, HC, or

SVD during the 12 months prior to export;

(C) Have not been on a premises located within 25 miles (40 km) of any premises affected with FMD, RP, ASF, HC, or SVD in the 90 days prior to export;

(D) Have undergone pre-embarkation quarantine, for at least 60 days, from all animals not part of the group to be imported, under USDA supervision in a facility approved by APHIS under § 93.517; and

(E) During pre-embarkation quarantine, have negative results to two tests conducted no sooner than 15 days apart for FMD, RP, ASF, HC, and/or SVD, using an approved serological test. If indicated, oesophageal-pharyngeal fluid samples will be taken for further testing.

(ii) The imported swine must be quarantined with sentinel animals at HSTAIC for at least 90 days, during which time the swine must be re-tested for FMD, RP, ASF, HC, and/or SVD at least twice with negative results using an approved serological test. If indicated, oesophageal-pharyngeal fluid samples will be taken for further testing.

(5) *Wild swine from any Risk Class R3, R4, or RU regions for foot-and-mouth disease, rinderpest, hog cholera, swine vesicular disease, or African swine fever*. (i) Wild swine originating in the regions that are classified as Risk Class R3, R4, or RU for foot-and-mouth disease, hog cholera, rinderpest, African swine fever, and/or swine vesicular disease may be carriers of such restricted agents, even though the swine do not show clinical evidence of the diseases. In view of these circumstances and in order to prevent the introduction and dissemination of communicable diseases affecting livestock and protect the livestock of the United States, import permits for the importation of wild swine will be issued only if such swine are intended for exhibition purposes in a zoological park previously approved by the Administrator, in accordance with the standards specified in paragraph (e)(5)(ii) of this section, and if the operator of such approved zoological park and the importer, if such operator and importer are different parties, has or have entered into the agreement set forth in paragraph (e)(5)(iv) of this section with APHIS for the maintenance and handling of such wild swine in the manner specified in the agreement to prevent the introduction and dissemination of communicable disease. The New York port of entry is the only port at which facilities are available that are adequate for the quarantining of wild swine. Accordingly, permits issued for the



importation of such wild swine will require that the swine be imported through the port of New York and be quarantined at that port. The Administrator may cancel such a permit when he or she finds that any provision of this section or any other provision of the regulations has not been or is not being complied with.

(ii) Approval of a zoological park for the receipt and maintenance of imported wild swine as described in this paragraph (e)(5)(ii) shall be on the basis of an inspection, by an authorized representative of the Department, of the physical facilities of the establishment and its methods of operation. Standards for acceptable physical facilities shall include satisfactory pens, cages, or enclosures in which the swine can be maintained so as not to be in contact with the general public and free from contact with domestic livestock; natural or established drainage from the zoological park that will avoid contamination of land areas where domestic livestock are kept or with which domestic livestock may otherwise come in contact; provision for the disposition of manure, other wastes, and dead swine within the zoological park; and other reasonable facilities considered necessary to prevent the dissemination of disease agents from the zoological park. The operator of the zoological park must have available the services of a full-time or part-time veterinarian, or a veterinarian on a retainer basis, who must make periodic examinations of all swine maintained at the zoological park for evidence of disease; who must make a post-mortem examination of each animal that dies; and who must make a prompt report of suspected cases of contagious or communicable disease agents to appropriate State or Federal livestock sanitary officials.

(iii) Manure and other animal wastes must be disposed of within the zoological park for a minimum of 1 year following the date the swine enters the park. If an APHIS veterinarian determines that the swine shows no signs of any illness at the end of this 1-year period, its manure and other wastes need not be disposed of within the park. If, however, an APHIS veterinarian determines that the swine does show signs of any illness at the end of this 1-year period, an APHIS veterinarian will investigate the illness and determine whether the swine's manure and other wastes may safely be disposed of outside the zoological park.

(iv) Prior to the issuance of an import permit under this section, the operator of the approved zoological park to which the wild swine are to be

consigned, and the importer of the wild swine, if such operator and importer are different parties, must execute an agreement covering wild each swine or group of wild swine for which the import permit is requested. The agreement shall be in the following form:

Agreement for the Importation, Quarantine and Exhibition of Certain Wild Ruminants and Wild Swine

\_\_\_\_\_, operator(s) of the zoological park known as \_\_\_\_\_ (Name) located at \_\_\_\_\_ (City and state), and \_\_\_\_\_ (Importer) hereby request a permit for the importation of \_\_\_\_\_ (Number and kinds of animals) for exhibition purposes at the said zoological park, said animals originating in a Risk Class R3, R4, or RU region for rinderpest or foot-and-mouth disease, and being subject to restrictions under regulations contained in part 93, title 9, Code of Federal Regulations.

In making this request, it is understood and agreed that:

1. The animals for which an import permit is requested will be held in isolation at a port of embarkation in the region of origin, approved by the Administrator as a port having facilities that are adequate for maintaining wild animals in isolation from all other animals and having veterinary supervision by officials of the country of origin of the animals. Such animals will be held in such isolation for not less than 60 days under the supervision of the veterinary service of the country in which the region of origin is located to determine whether the animals show any clinical evidence of restricted agents or other communicable disease and to assure that the animals will not have been exposed to such a disease within the 60 days prior to their exportation from that region.

2. Shipment will be made directly from such port of embarkation to the port of New York as the port of entry into the United States. If shipment is made by ocean vessel, the animals will not be unloaded in any foreign port en route. If shipment is made by air, the animals will not be unloaded at any port or other place of landing except at a port approved by the Administrator as a port not located in a region classified as R3, R4, or RU for rinderpest or foot-and-mouth disease, or as a port in such a region having facilities and inspection approved by the Administrator as adequate for maintaining wild animals in isolation from all other animals.

3. No ruminants or swine will be aboard the transporting vehicle, vessel or aircraft, except those for which an import permit has been issued.

4. The animals will be quarantined for not less than 30 days in the Department's Animal Import Center in Newburgh, New York.

5. Upon release from quarantine, the animals will be delivered to the zoological park named in this agreement to become the property of the park, and they will not be sold, exchanged or removed from the premises without the prior consent of APHIS.

(Signature of importer) Subscribed and sworn to before me this \_\_\_\_ day of \_\_\_\_\_, 19 \_\_\_\_.

\_\_\_\_\_  
(Title or designation)

(Name of zoological park) By \_\_\_\_\_  
(Signature of officer of zoological park)

(Title of officer) Subscribed and sworn to before me this \_\_\_\_ day of \_\_\_\_\_, 19 \_\_\_\_.

\_\_\_\_\_  
(Title or designation)

(f) *Japanese encephalitis virus (JEV) and Getah virus*—(1) *Regions classified as Risk Class R1 for JEV and/or Getah virus*. In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions classified as Risk Class R1 for JEV and/or Getah virus must certify that the swine to be imported:

(i) Have resided for at least 60 days immediately prior to export only on premises located in regions classified as Risk Class RN or R1 for JEV and/or Getah virus;

(ii) Have not been vaccinated for JEV or Getah virus; and

(iii) Have had a negative result to an approved serological test for Japanese encephalitis and/or Getah within 30 days prior to export.

(2) *Regions classified as Risk Class R2 for JEV and/or Getah virus*. (i) In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions that are classified as Risk Class R2 for JEV and/or Getah virus must certify that the swine to be imported:

(A) Have resided for at least 60 days immediately prior to their pre-embarkation quarantine only on premises located in regions classified as Risk Class RN, R1, or R2 for JEV and/or Getah virus;

(B) Have not been vaccinated for JEV or Getah virus;

(C) Have undergone a 30 day pre-embarkation quarantine. The pre-embarkation quarantine must be in a vector-proof facility approved by the Administrator and the National Veterinary Services of the country of export if during a time of year when the insect vectors are active; and

(D) Have had a negative result to an approved serological test for JEV and/or Getah during the pre-embarkation quarantine.

(ii) The imported swine must undergo a minimum 15 day post-importation quarantine in a facility designated and approved by the Administrator.

(3) *Regions classified as Risk Class R3, R4, or RU for JEV and/or Getah virus*.

(i) In addition to the export certificate requirements of § 93.505, the certificate

of export for live swine from regions that are classified as Risk Class R3, R4, or RU for JEV and/or Getah virus must certify that the swine to be imported:

(A) Have undergone pre-embarkation quarantine for at least 60 days immediately prior to export, in a vector-proof facility approved by the Administrator if during a time of year when the insect vectors are active;

(B) Have not been vaccinated for Japanese encephalitis or Getah virus; and

(C) Have been tested twice, within 60 days prior to export and at least 30 days apart, with negative results using a serological test approved by the Administrator for JEV and/or Getah virus.

(ii) The imported swine must be quarantined at a post-importation quarantine facility designated and approved by the Administrator for at least 15 days if imported during a season of the year when vectors are not active or at least 60 days if imported during a season of the year when vectors are active in the United States.

(iii) During the post-importation quarantine period, the swine must be tested with negative results for JEV and/or Getah virus, using approved serological tests.

(g) *Mycobacterium bovis* (*M. bovis*). Any swine responding to an approved test for *M. bovis* shall be refused entry into the United States. Non-responders may be eligible for entry based on their status as determined by part 77 of this chapter. Swine imported for immediate slaughter are exempt from the *M. bovis* testing and quarantine requirements. Such swine must be consigned from the port of entry to a recognized slaughtering establishment and there slaughtered within 2 weeks from the date of entry. Such swine must be moved from the port of entry in conveyances closed with official seals of the United States Government applied and removed by an APHIS representative, or an individual authorized for this purpose by an APHIS representative.

(1) *Regions classified as Risk Class R1 for M. bovis*. In addition to the export certificate requirements of § 93.505, the certificate of export for live swine over 6 months of age from regions that are classified as Risk Class R1 for *M. bovis*, must certify that the swine to be imported were born and resided only in foreign regions that are classified as Risk Class RN or R1 for *M. bovis*;

(2) *Regions classified as Risk Class R2 for M. bovis*. (i) In addition to the export certificate requirements of § 93.505, the certificate of export for such swine must certify that the swine to be imported:

(A) Were born and resided only in regions classified as Risk Class RN, R1, or R2 for *M. bovis*; and

(B) That all boars and intact females have had a negative result to an approved test for *M. bovis* within 60 days prior to export.

(ii) All boars and intact females must be detained at the port of entry or post-importation quarantine a minimum of 72 hours until tested for *M. bovis* with negative results.

(3) *Regions classified as Risk Class R3 for M. Bovis*. (i) In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions that are classified as R3 for *M. bovis* must certify that the swine to be imported:

(A) Have never been on any premises while animals affected with *M. bovis* have been present on those same premises;

(B) Were born and resided only in regions classified as Risk Class RN, R1, R2, or R3 for *M. bovis*;

(C) Have had a negative result to an approved test for *M. bovis* no less than 60 days nor more than 90 days prior to export; and

(D) For boars and intact females, the herd of origin has had a negative result to an approved test for *M. bovis* no less than 4 months nor more than 12 months prior to the date of export.

(ii) All boars and intact females must be detained at the port of entry or post-importation quarantine facility a minimum of 72 hours until tested with negative results for *M. bovis*.

(4) *Regions classified as R4 and RU for M. bovis*. (i) In addition to the export certificate requirements of § 93.505, the certificate of export for live swine over 6 months of age from regions that are classified as Risk Class R4 or RU for *M. bovis* must certify that the swine to be imported:

(A) Have never been on any premises while animals affected with *M. bovis* have been present on those same premises;

(B) Have had a negative result to an approved test for *M. bovis* 60 to 90 days prior to export;

(C) Originate from herds in which the entire herd has had a negative result to an approved test for *M. bovis* no less than 4 months nor more than 12 months prior to the date of exportation; and

(D) For boars and intact females, have undergone at least 60 days of pre-embarkation quarantine prior to export.

(ii) Boars and intact females must be quarantined after being imported for a minimum of 30 days at a post-importation quarantine facility designated and approved by the

Administrator, until tested for *M. bovis* with negative results.

(h) *Teschen disease virus*—(1) *Regions classified as Risk Class R1 or R2 for Teschen disease virus*. In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from foreign regions that are classified as Risk Class R1 or R2 for Teschen disease virus must certify that the swine to be imported:

(i) Were born and resided only in regions classified as Risk Class RN, R1 or R2 for Teschen disease virus;

(ii) Have not been vaccinated with any Teschen disease vaccine; and

(iii) Had a negative result to an approved test for Teschen disease within 30 days of the date of exportation.

(2) *Regions classified as Risk Class R3 for Teschen disease virus*. (i) In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions that are classified as Risk Class R3 for Teschen disease virus must certify that the swine to be imported:

(A) Were born and resided only in regions classified as Risk Class RN, R1, R2 or R3 for Teschen disease virus;

(B) Have not been vaccinated with any Teschen disease vaccine; and

(C) Meet one of the following requirements:

(1) Have had a negative result with an approved test for Teschen disease 30 to 60 days before exportation;

(2) Originated from herds in which the entire herd over 6 months of age, has had negative results to an approved test for Teschen disease within 12 months prior to the date of exportation; or

(3) Were quarantined at least 30 days prior to export.

(ii) Swine must be quarantined after being imported for at least 15 days at a post-importation quarantine station approved by the Administrator.

(iii) During the post-importation quarantine, the imported swine must have negative results to an approved serological test for Teschen disease virus.

(3) *Regions classified as Risk Class R4 and RU for Teschen disease virus*. (i) In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions that are classified Risk Class R4 or RU for Teschen disease virus must certify that the swine to be imported:

(A) Have not been vaccinated with any Teschen disease vaccine;

(B) Originate from herds in which the entire herd over 6 months of age has had a negative result to an approved test for Teschen disease within 60 to 180 days prior to the date of exportation;

(C) Were quarantined for at least 60 days prior to export; and

(D) During pre-embarkation quarantine period, have had negative results to an approved test for Teschen disease 30 to 60 days prior to the date of export.

(ii) The swine must be quarantined after being imported for at least 30 days at a post-importation quarantine facility.

(iii) During the post-importation quarantine the imported swine must have two negative results not less than 30 days apart to an approved test for Teschen disease.

(i) *African (Salivarian or Tsetse transmitted) Trypanosomes*—(1) *Regions classified as Risk Class R1 and R2 for African trypanosomes.* In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions that are classified as Risk Class R1 and R2 for African trypanosomes must certify that the swine to be imported:

(i) Have resided only on premises located in regions classified as Risk Class RN, R1 and R2 for trypanosomes and tsetse flies (*Glossina* spp.) for their entire life;

(ii) Have not been vaccinated for trypanosomes; and

(iii) Have had a negative result to an approved serological test for African trypanosomes within 30 days prior to entry into the United States.

(2) *Regions classified as Risk Class R3, R4, and RU for African Trypanosomes.* (i) In addition to the export certificate requirements of § 93.505, the certificate of export for swine from regions classified as Risk Class R3, R4, and RU for African trypanosomes and Tsetse flies (*Glossina* spp.) must certify that the swine to be imported:

(A) Originated from premises that have not had trypanosomiasis diagnosed during the previous 24 months;

(B) Were quarantined and isolated at least 60 days prior to export in a vector-proof facility approved by the administrator;

(C) Have not been vaccinated for trypanosomes; and

(D) During the pre-embarkation quarantine period, had negative results to an approved serological test for trypanosomes.

(ii) The imported swine must be quarantined for at least 30 days at a post-importation quarantine facility designated and approved by the Administrator.

(iii) During the post-embarkation quarantine period the swine will be retested at least once for trypanosomes using approved serological tests.

(j) *Vesicular Stomatitis virus (VSV)*—(1) *Regions classified as Risk Class R1 for VSV.* In addition to the export certificate requirements of § 93.505, the certificate of export for live swine from regions that are classified as Risk Class R1 for VSV must certify that the swine to be imported:

(i) Have resided for at least 60 days prior to export only on premises located in Risk Class RN or R1 regions for VSV; and

(ii) Have not been vaccinated for VSV.

(2) *Regions classified as Risk Class R2 for VSV.* In addition to the export certificate requirements of § 93.505, the certificate of export for live swine imported from regions that are classified as Risk Class R2 for VSV must certify that the swine to be imported:

(i) Have resided for at least 30 days prior to export only on premises located in Risk Class RN, R1, or R2 regions for VSV;

(ii) Have not been vaccinated with any live attenuated vaccines for VSV; and

(iii) Have not been vaccinated with inactivated vaccines for VSV within 60 days prior to export.

(2) *Regions classified as Risk Class R3, R4, and RU regions for VSV.* (i) In addition to the export certificate requirements of § 93.505, the certificate of export for live swine imported from regions that are classified as Risk Class R3, R4, and/or RU for VSV must certify that the swine to be imported:

(A) Have not been vaccinated with any live attenuated vaccines for VSV;

(B) Have not been vaccinated with inactivated vaccines for VSV within 60 days prior to export;

(C) Have not been located on any premises where VSV has occurred during the 60 days prior to export; and

(D) If exported during a season of the year when insect vectors were active:

(1) Were quarantined and isolated from all animals not part of the shipment for at least 30 days prior to export, in a vector-proof facility approved by the Administrator; and

(2) During the pre-embarkation quarantine period, had negative results to an approved serological test for VSV within 14 days prior to export.

(ii) If imported during a season of the year when insect vectors are active within the United States, the imported swine:

(A) Must be quarantined for at least 15 days at a post-importation quarantine facility designated and approved by the Administrator; and

(B) During the post-importation quarantine period, must have negative results to an approved serological test for VSV.

**§ 93.516 Importation of swine through the Harry S Truman Animal Import Center (HSTAIC).**

(a) *Exclusive right to use HSTAIC.* The Animal and Plant Health Inspection Service will enter into a cooperative-service agreement with only one importer for each importation through the Harry S Truman Animal Import Center (HSTAIC). Applications for the HSTAIC lottery will not be accepted from, and a cooperative-service agreement to use HSTAIC will not be offered to or entered into with, any person who has debts owing to APHIS that have not been paid by the date specified in APHIS's original billing notification to the person. Any person who has debts owing to APHIS that have not been paid by the date specified in APHIS's original billing notification to that person will be removed from the current priority list. An importer granted the exclusive right to use HSTAIC may include in his or her allotted number, animals of the same species belonging to other persons interested in importing animals through HSTAIC, except that llamas and alpacas may be included in the same importation. However, APHIS will deal exclusively with the importer in whose name the application for use of HSTAIC was submitted. The Animal and Plant Health Inspection Service will hold this importer solely responsible for all costs (excepting capital expenditures at HSTAIC) incurred during the animal qualification process. The animal qualification process begins on the date the cooperative-service agreement is delivered to the address listed on the importer's HSTAIC application, for the importer's signature, if HSTAIC is not available to other importers, up to a maximum of 30 days. A cooperative-service agreement will be deemed to have been delivered when the importer signs the U.S. Postal Service domestic return receipt, or the importer refuses delivery of the cooperative-service agreement by the U.S. Postal Service, or the cooperative-service agreement is returned by the U.S. Postal Service as either unclaimed or undeliverable. HSTAIC can accommodate a finite number of animals at one time, but the maximum allowed for a particular importation will vary, depending on the size of the species. The Animal and Plant Health Inspection Service will specify this figure in the cooperative-service agreement, reproduced in paragraph (d) of this section.

(b) *Scheduling.* Applications from prospective users of HSTAIC are processed according to the following system:

(1)(i) *All applications for use of HSTAIC.* To qualify to use HSTAIC, an importer must submit a completed application,<sup>11</sup> providing estimates when exact information as required on the application form is unavailable.

(ii) Each applicant for the importation of animals through HSTAIC must make a deposit of \$32,000 in the form of a certified check or money order, payable in U.S. funds. The deposit of each applicant who is not given the opportunity to use HSTAIC will be returned to the applicant at the end of the calendar year of the prospective importation, or whenever the applicant removes his or her name from the priority list described in paragraph (b)(4) of this section. The Animal and Plant Health Inspection Service will draw on the deposit of the applicant whose application is selected, to pay for the costs of preparing and maintaining HSTAIC in readiness for the applicant's animals. A charge of \$1,067 will be made for each day that HSTAIC is not available to another importer, starting on the date the cooperative-service agreement is delivered to the address listed on the importer's HSTAIC application, and ending either with the day that APHIS receives the signed cooperative-service agreement or the day the applicant notifies APHIS in writing that he or she does not intend to sign the cooperative-service agreement, up to a maximum of 30 days. A cooperative-service agreement will be deemed to have been delivered when the importer signs the U.S. Postal Service domestic return receipt, or refuses delivery of the cooperative-service agreement by the U.S. Postal Service, or the cooperative-service agreement is returned by the U.S. Postal Service as either unclaimed or undeliverable.

(2)(i) During the first seven days of December<sup>12</sup>, APHIS will hold a lottery, randomly drawing the names of applicants in an order that will determine the order in which they will be offered use of HSTAIC for an importation during the next calendar year. To be included in the annual December lottery, applications must reach the Import-Export Animals Staff, Veterinary Services, no earlier than

October 1 and no later than October 15 of that year.

(ii) One application is required for each importation proposed. Deposits required by paragraph (b)(1)(ii) of this section must be received by APHIS at least 7 calendar days prior to the date of the lottery.

(3) The priority list established by the annual December lottery will remain effective from January 1 through December 31 of the next calendar year, superseding all previous lists. Which year's list is used is governed by the date exclusive use of HSTAIC is offered and not by the date the applicant's animals are scheduled to arrive at HSTAIC.

(4) The names of all applicants whose applications have reached the Import-Export Animals Staff, Veterinary Services, no earlier than October 1 and no later than October 15 (see paragraphs (b) (1) and (2) of this section), and whose deposits have reached APHIS at least 7 calendar days prior to the date of the lottery, will be drawn during the December lottery. The order in which names appear on the priority list will correspond to that established by the lottery. If the person first offered the right to use HSTAIC does not ensure receipt of the cooperative-service agreement by the Import-Export Animals Staff, Veterinary Services, within 30 days of receiving the cooperative-service agreement, APHIS will void that offer, and make an offer to the applicant next on the priority list. The Animal and Plant Health Inspection Service will limit importations to one per importer for the period encompassing the calendar year for which the lottery is held and the following two calendar years, except when no other lottery participants are prepared to use HSTAIC during the time it would be available in those years. The priority list established during the December lottery will remain in effect during the calendar year following the lottery, and will take precedence over any applications received after October 15th. Applications received after October 15th will be added to the priority list, with precedence established by the order in which the Import-Export Animals Staff, Veterinary Services, receives them.

(5) If the Import-Export Animals Staff, Veterinary Services, does not receive more than one application between October 1st and October 15th for the December lottery, the December lottery for that year will be canceled, and APHIS will grant the exclusive right to use HSTAIC for an importation during the next calendar year in the order applications are received.

(6) The Secretary of Agriculture may grant priority over other applications to an application from an agency of the United States Government, if for an importation potentially of value to the general public, and if received before July 15 of the year preceding the proposed importation.<sup>13</sup> However, an agency of the United States Government must submit its application in accordance with this section, except that, an agency of the United States Government must enter into an interagency agreement with APHIS for a deposit of \$32,000 by certified check or money order, payable in U.S. funds. HSTAIC importations by agencies of the United States government will be limited to one per year, except when HSTAIC is available and the Import-Export Animals Staff, Veterinary Services, has received no other applications for its use during that year.

(c) *Responsibilities of the applicant selected.* By certified mail, return receipt requested, APHIS will send a cooperative-service agreement to the applicant being offered the exclusive right to use HSTAIC, as provided in paragraph (d) of this section. The applicant must, within 30 days of receipt, sign and ensure that the Import-Export Animals Staff, Veterinary Services, receives the cooperative-service agreement. The cooperative-service agreement must be accompanied by a certified check or money order, or an irrevocable letter of credit (the letter of credit having an effective date 90 days after the animals' scheduled release date from HSTAIC), payable in U.S. funds, for the amount specified in the cooperative-service agreement. Any funds remaining from the \$32,000 deposit will be applied to the quarantine costs, and will be deducted from the balance due with the cooperative-service agreement. For importations requiring use of a pre-embarkation quarantine facility, physical plans for the facility, including site-specific blueprints and location, must be included when the cooperative-service agreement is returned to the Import-Export Animals Staff, Veterinary Services.

(1) An importer interested in animals ineligible for importation because officials in the exporting country or region will not allow APHIS to provide the services prescribed in the cooperative-service agreement, may, upon notification of this ineligibility

<sup>11</sup> Application forms are available from, and must be submitted to Veterinary Services, Animal and Plant Health Inspection Service, Import/Export Animals, National Center for Import and Export, 4700 River Road Unit 39, Riverdale, MD 20737-1231.

<sup>12</sup> The Animal and Plant Health Inspection Service will publish a notice announcing the exact date in the Federal Register at least 30 days in advance of the December drawing.

<sup>13</sup> If the Secretary grants priority to an application from an agency of the United States Government, the Animal and Plant Health Inspection Service will publish a notice in the Federal Register prior to October 1 of the year preceding the proposed importation.

from APHIS, propose to substitute animals available from another location. If this importer has not returned the signed cooperative-service agreement within the 30 days specified in the cooperative-service agreement, APHIS will return any portion of the importer's deposit that has not been expended. In that case, the applicant next in priority will be offered the exclusive right to use HSTAIC, in accordance with the procedures in this section.

(2) The importer may not abrogate his/her responsibility for costs incurred after the signing of the cooperative-service agreement, regardless of any occurrences that prevent the importation from proceeding as planned.

(3) The importer signing the cooperative-service agreement returned to the APHIS is responsible for paying all costs, excluding capital expenditures at HSTAIC, incurred in qualifying the specified animals for importation through HSTAIC. A partial list of costs for which the importer must assume responsibility includes: expenses for preparing and maintaining HSTAIC in readiness for the importation; expenses for sentinel animals in the United States, when required, and for tested animals prevented, for any reason, from moving from HSTAIC elsewhere within the United States; laboratory tests; medical treatment; official travel by APHIS personnel, including per diem expenses in the country from which animals are being exported, when required; courier services to transport test samples to the Foreign Animal Disease Diagnostic Laboratory, when required; salaries of HSTAIC personnel; all supplies for animals care, maintenance, and testing during the quarantine and in the post-quarantine cleaning and disinfection of HSTAIC; utilities and overhead, including support staff, during the quarantine and post-quarantine cleanup.

(4) Capital expenditures at HSTAIC constitute the only costs for which the importer will not be held responsible.

(5) For costs incurred during any stage of the importation through HSTAIC—that is, costs not calculated into the amount collected from the importer in accordance with the cooperative-service agreement—APHIS will bill the importer at a later date. Payment will be due upon receipt of the bill.

(6) The Animal and Plant Health Inspection Service will return to the importer any part of the money remitted with the cooperative-service agreement set forth in paragraph (d) of this section that is not used to cover the non-capital costs of the importation through HSTAIC.

(d) *Cooperative-Service Agreement.* Each importer being granted the right to use HSTAIC must sign, and comply with, the cooperative-service agreement with APHIS. A sample cooperative-service agreement for importers other than agencies of the United States government is reproduced in this paragraph. (Agencies of the United States government being granted the right to use HSTAIC must enter into an interagency agreement with APHIS.) The amount of money the importer must advance, left blank in the following sample, will depend on figures unique to a particular importation. This amount will be specified in the cooperative-service agreement the importer receives.

Cooperative-Services Agreement Between (Name of Importer) and the United States Department of Agriculture, Animal and Plant Health Inspection Service

The importer, \_\_\_\_\_, wishes to qualify animals for importation into the United States. The United States Department of Agriculture, Animal and Plant Health Inspection Service, administers the Harry S Truman Animal Import Center (HSTAIC), a facility through which the importer may import animals into the United States.

To effect this importation, both parties agree to the following terms:

The importer agrees:

1. To have this cooperative-service agreement in the office of the Animal and Plant Health Inspection Service's Import-Export Animals Staff, Veterinary Services, within 30 days of the date of receipt, evidenced by the postal return-receipt.
2. To remit with the cooperative-service agreement a certified check, money order, or irrevocable letter of credit having an effective date that extends 90 days beyond the animals' scheduled release from HSTAIC, payable in U.S. funds to the United States Department of Agriculture, Animal and Plant Health Inspection Service, in the amount of \$\_\_\_\_\_. (This amount represents the estimated cost (except capital expenditures at HSTAIC) of qualifying the animals for importation through HSTAIC, less any unused portion of the \$32,000 deposited in conjunction with the application for the exclusive right to use HSTAIC.)
3. To limit to \_\_\_\_\_ the number of animals, species \_\_\_\_\_ transported to HSTAIC for an importation scheduled to begin on or about \_\_\_\_\_ and to end with the animals' release from HSTAIC, scheduled for \_\_\_\_\_.

4. To assume liability for all costs (except capital expenditures at HSTAIC) attributable to preparing and maintaining HSTAIC in readiness for the importation, and to qualifying animals for and through quarantine in the pre-embarkation quarantine facility (PEQF), when quarantine in a PEQF is required, and in HSTAIC for importation into the United States. (A partial list of these costs would include expenses for sentinel animals in the United States and for tested animals prevented, for any reason, from moving from HSTAIC elsewhere within the

United States; laboratory tests; medical treatment; official travel by Animal and Plant Health Inspection Service personnel, including per diem expenses in the country from which the animals are being exported; courier services to transport test samples to the Foreign Animal Disease Diagnostic Laboratory; salaries of HSTAIC personnel; all supplies for animal care, maintenance, and testing during the quarantine and in the post-quarantine cleaning and disinfection of HSTAIC; utilities and overhead, including support staff, during the quarantine and post-quarantine cleanup.)

5. To obtain from foreign government officials authorizations granting Animal and Plant Health Inspection Service personnel free access to the PEQF, when quarantine in a PEQF is required, and permits for export.

6. To secure from animal carriers permission for Animal and Plant Health Inspection Service personnel to accompany the animals to the PEQF, when quarantine in a PEQF is required, and from the PEQF to HSTAIC.

7. To maintain and operate the PEQF, when quarantine in a PEQF is required, in compliance with 9 CFR 92.431 of the Code of Federal Regulations.

8. To accept as final the findings of the Administrator, Animal and Plant Health Inspection Service, on the animals' eligibility to enter the PEQF, when quarantine in a PEQF is required, to enter HSTAIC, and to be released from HSTAIC.

9. To follow procedures prescribed by the Animal and Plant Health Inspection Service, appropriate to the disease and pest status of the quarantined animals. (When quarantine in a PEQF is required, the presence in the PEQF of even one animal either exposed to, or infected with, rinderpest, foot-and-mouth disease, hog cholera, African swine fever, swine vesicular disease, or certain other contagious, exotic diseases, automatically disqualifies all animals in the PEQF from entering HSTAIC. The presence in HSTAIC of even one animal either exposed to, or infected with, one of the diseases referred to in this paragraph, automatically disqualifies all animals in HSTAIC from moving anywhere within the United States after the period in quarantine.)

10. To assume responsibility for disposal of quarantined animals that do not qualify to move into or within the United States. (In the case of animals disqualified while quarantined in HSTAIC, the Animal and Plant Health Inspection Service will stipulate the conditions under which the disqualified animals in HSTAIC must be destroyed. The importer must, within 10 days of notification from the Animal and Plant Health Inspection Service, remove from the PEQF or HSTAIC, animals untreatable or treated for, but not cured of, a communicable disease other than foot-and-mouth disease or any of certain other exotic diseases. Animals removed from HSTAIC must be moved out of the United States or be destroyed under conditions stipulated by the Animal and Plant Health Inspection Service.)

11. To assume responsibility for all costs the Animal and Plant Health Inspection Service incurs during this importation, excluding capital expenditures at HSTAIC.

12. To pay, upon receipt, post-quarantine billings incurred during this importation, for costs exceeding the amount remitted with this cooperative-service agreement plus the initial \$32,000 deposit.

The Animal and Plant Health Inspection Service Agrees:

1. To provide the personnel required to perform inspections, laboratory procedures, and examinations, and to provide on-site supervision of the isolation, quarantine, care and handling of animals on premises of origin, in the PEQF when quarantine in a PEQF is required, and in HSTAIC.

2. To inform the importer of any quarantined animals in the PEQF or in HSTAIC that fail to qualify for entry into the United States, and to inform the importer that he/she must assume responsibility for their disposal.

3. To finance capital expenditures at HSTAIC without charging the importer.

4. To account for all money disbursed from the amount remitted, and to provide the importer with a complete written accounting upon termination of this cooperative-service agreement.

5. To refund to the importer any part of the money remitted with this cooperative-service agreement that is not used to cover the non-capital costs of the importation through HSTAIC.

Both parties agree:

1. That this cooperative-service agreement is effective upon signature by both parties.

2. That this cooperative-service agreement will not be signed by the Administrator if the Import-Export Animals Staff, Veterinary Services, Animal and Plant Health Inspection Service, has not received this signed cooperative-service agreement, including the specified remittance for the amount due, by 4:30 p.m. on the thirtieth calendar-day after the date on the United States Postal Service's return receipt, evidencing its receipt by the importer.

3. That this cooperative-service agreement will not be signed by the Administrator if the cooperative-service agreement is not accompanied by the physical plans for the PEQF, including its location and site-specific blueprints (except when quarantine in a PEQF is not required).

4. That this cooperative-service agreement will be voided if the Administrator, Animal and Plant Health Inspection Service, determines that the importer has not completed arrangements with the responsible officials in the exporting country by 4:30 p.m. on the date 42 calendar-days after the importer's signing of this cooperative-service agreement.

5. That, if both parties agree, this cooperative-service agreement may be amended in writing.

6. That either party may terminate this cooperative-service agreement upon giving 30 days written notice to the other party, but premature termination will not relieve the importer of responsibility for costs incurred, as provided in this cooperative-services agreement, nor will it relieve the Animal and Plant Health Inspection Service of responsibility for providing the importer with a complete written accounting of money disbursed from the amounts remitted.

7. That during the performance of this cooperative-service agreement, the importer agrees to be bound by the Equal Employment Opportunity and Nondiscrimination provisions set forth in Exhibit A and the Nonsegregation of Facilities provisions set forth in Exhibit B,<sup>1</sup> which are attached to and made part of this cooperative-service agreement.

8. That no member of, or delegate to, Congress may participate in, or benefit from, this cooperative-service agreement.

Date \_\_\_\_\_

Importer \_\_\_\_\_

Date \_\_\_\_\_

Administrator, Animal and Plant Health Inspection Service, United States Department of Agriculture.

**§ 93.517 Pre-embarkation quarantine facility; criteria and standards for approval.**

Criteria for establishment of a pre-embarkation quarantine facility outside the United States for the purpose of importing swine into the United States that are eligible for importation only through the Harry S Truman Animal Import Center are as follows:

(a) *Establishment.* (1) The Administrator may enter into an agreement with one or more parties for the establishment of such a facility pursuant to the standards in paragraph (b) of this section.

(2) To qualify for designation as a pre-embarkation quarantine facility (PEQF) for a specifically authorized importation, the facility must meet the requirements of paragraph (b) of this section.

(3) All costs associated with the establishment and operation of such a pre-embarkation quarantine facility shall be borne by the owner or operator of such facility.

(4) The Animal and Plant Health Inspection Service requires that the importer submit the physical plans for the PEQF for which he or she is requesting approval. The physical plans must include location of the facility and site-specific blueprints. The importer must send these physical plans, due with the cooperative-service agreement as provided in § 93.526(d), to the Import-Export Animals Staff, National Center for Import-Export, Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, 4700 River Road Unit 39, Riverdale, MD 20737-1231. The Animal and Plant Health Inspection Service will, after reviewing

<sup>1</sup> Import-Export Animal Staff, National Center for Import-Export, Veterinary Services, APHIS, USDA, will send each importer copies of Exhibits A and B along with the cooperative-services agreement.

the importer's physical plans and conducting an on-site inspection, approve a PEQF found to meet the requirements of this section. Approval of a PEQF will expire at the end of the specifically authorized quarantine. Subsequent importers granted use of HSTAIC and proposing to use one of the existing PEQFs must apply for approval as if for a new facility. No more than one PEQF will receive approval for a specific HSTAIC importation. If the PEQF specified in the signed cooperative-service agreement, as provided in § 93.526(d), is not approved by APHIS, the importer may use an alternative PEQF, provided it is approved by APHIS during the 42 days following the date the importer signs the cooperative-service agreement. If a PEQF closes down or loses its "approved" status for any reason, APHIS may approve a replacement following the method specified in this paragraph (a)(4).

(5) Permission to place swine in the foreign PEQF shall be given to any person who has received permission to import swine through the Harry S Truman Animal Import Center, unless the Administrator determines that sufficient grounds exist whereby such person may be denied such permission.

(6) Fees charged by the owner or operator for the use of such facility shall be provided in private agreements between the owner or operator of the facility and the owners of the swine proposed for importation. Such fees shall be nondiscriminatory and reasonable as determined by the Administrator.

(7) Approval of any approved PEQF may be withdrawn at any time by the Administrator, upon his or her determination that any requirement of this section is not being met. Before such action is taken, the operator of the facility will be informed of the reasons for the proposed actions and will be afforded opportunity to present his or her views thereon, in accord with rules of practice adopted by the Administrator. Upon withdrawal of approval, the operator, upon request, shall be afforded opportunity for a hearing with respect to the merits or validity of such action; but such withdrawal or refusal shall continue in effect unless otherwise ordered by the Administrator. Rules of practice concerning the hearing shall be adopted by the Administrator.

(b) *Standards for approval of pre-embarkation quarantine facilities—*

(1) *Location.* (i) The PEQF must be in an area isolated from ruminants, swine, and poultry. It must be located near the point of embarkation: A dock, if the

swine will travel by ocean vessel; an airport, if the swine will travel by plane.

(ii) The swine's route from the PEQF to the point of embarkation must be limited to regions free of ruminants, swine, and poultry.

(iii) The facility must be so situated that there will be no contact between swine held in the facility with any other species of animals.

(iv) The facility must be so situated that it will be free from contact with water and waste effluents from local livestock or poultry. Water and waste effluents from the facility must be disposed of in a manner determined by the Administrator to be adequate to insure no exposure to local livestock or poultry.

(2) *Building.* (i) The exterior of the building must be of durable low-maintenance, waterproof type construction that will withstand repeated cleaning and disinfecting.

(ii) Roofs must be watertight. The styling and configuration of the roof of the swine holding building must provide for optimum air circulation throughout the facility.

(iii) The interior finish of the building must be durable, washable, and of low maintenance type construction. The floor must be concrete with no cracks or crevices.

(iv) Mesh double screens must protect all open areas, so that insects cannot gain access to the swine holding area. If the swine are removed from the double-screened building before export to the HSTAIC, or if the United States Department of Agriculture Veterinarian in Charge of the quarantine operation determines that insects capable of transmitting communicable animal disease agents are entering the swine holding area, APHIS will require implementation of a program of insect vector control. This vector control program will involve treating swine, building interiors, and environs with United States Environmental Protection Agency-registered pesticides. The pesticides must be used in the manner prescribed on the United States Environmental Protection Agency-approved label, and in accordance with the requirements of the government of the country in which the PEQF is located.

(v) Stalls, pens, and runways must be constructed of sufficient height and strength to confine and restrain all swine simultaneously for daily veterinary examinations.

(vi) At least 70-foot-candle lighting must be provided in the inspection area. A minimum light of 30-foot-candle must be available in all other areas of the facility.

(vii) A dipping vat of a concrete pit type with inspection chute, holding pen, dripping pen, and post-drip area similar to USDA Extension Plan 5940, revised, must be provided.<sup>14</sup>

(viii) The waste management system must be carefully designed to meet all applicable sanitation and quarantine requirements and the existing environmental standards of the country in which the pre-embarkation quarantine facility is located.

(3) *Fencing.* (i) The outer perimeter of all facilities must be surrounded by a fence that must be of sufficiently small mesh as to preclude the entrance of small farm animals, including dogs, and of such height and strength as to prevent entrance of larger animals. This fence must be located at least 200 feet from the building in which quarantined swine are to be held, except that, in an urban or industrial area the location of the fence may be less than 200 feet as determined by the Administrator, if such action will not increase the risk that communicable disease agents of livestock or poultry will be disseminated from the facility.

(ii) In regions affected by cattle fever ticks all such facilities must be double fenced, with the inner perimeter fence located at least 15 feet from the outer perimeter fence. When double fencing is required, the space between the outer and inner perimeter fences must be kept free from all foliage at all times.

(iii) The outer fence of the facility must be posted with signs in appropriate language, which must convey the following: Restricted Area—Keep Out, Quarantine Area—Keep Out, or Registered Quarantine Area—Keep Out.

(4) *Feed.* The animal feed supply in the PEQF must consist only of feed obtained from a country or region that is classified as Risk Class RN, R1, or R2 for foot-and-mouth disease, and for any other exotic disease necessitating the quarantine or that could jeopardize the quarantine.

(5) *Other requirements.* (i) Access into the quarantine area must be through a single door that must lead into a walk-through shower area with clothes change areas located on either side of the shower and adjacent thereto.

(ii) Toilet and lavatory facilities as determined by the Administrator to be adequate to preclude transmission of livestock or poultry disease agents from

the facility must be located within the swine holding areas.

(iii) A sufficient supply of clean clothing, including towels and footwear, as determined by the Administrator to be adequate to prevent the transmission of livestock or poultry disease agents from the facility, must be maintained within the quarantine area.

(iv) A continuous supply of hot and cold running water, including potable water for personnel, must be provided.

(v) If lunch is to be eaten within the facility, a lunch room must be provided and all food entered into the facility must be approved by the supervising United States government veterinarian.

(vi) A separate room containing the equipment for preparation and packaging of laboratory specimens with adequate office space, as determined by the Administrator, to perform his or her duties must be provided for the supervising veterinary official. All records, equipment, and other materials used in the facility, must be maintained within the quarantine facility for the entire quarantine period.

(vii) A separate area situated apart from the swine holding area must be provided for necropsies and a means for the removal of the carcasses of dead swine must be provided without breaking quarantine security.

(viii) A swine receiving area and a chute or stocks for restraint during examination and veterinary inspection, as determined to be appropriate by the Administrator to permit examination of the swine, must be provided.

(ix) Feed must be stored in such a manner that replenishment during the quarantine period does not require transporting vehicles to enter the quarantine area.

(x) Equipment necessary for the care, cleaning, feeding, waste disposal, and handling of the swine must be provided and maintained within the quarantine area.

(xi) Additional requirements as to security, physical plant and facilities, and sanitation may be imposed by the Administrator in each specific case in order to assure that the quarantine of the swine in such facility will be adequate to enable determination of their health status, prevent the spread of disease among swine in quarantine, and prevent escape of animal disease agents from the facility.

#### **Subpart H—Elephants, Hippopotami, Rhinoceroses, and Tapirs**

50. In subpart H, § 93.800 would be amended by revising the introductory text and the definitions of *Accredited veterinarian*, *Administrator*, and *United States*, to read as follows:

<sup>14</sup> Copies of USDA Extension Plan 5940, revised, may be obtained from the Import/Export Animals Staff, National Center for Import and Export, Animal and Plant Health Inspection Service, United States Department of Agriculture, 4700 River Road Unit 39, Riverdale, MD 20737-1231.



**§ 93.800 Definitions.**

Whenever in this subpart the following terms are used, unless the context otherwise requires, they shall be construed, respectively, to mean:

**Accredited veterinarian.** A veterinarian approved by the Administrator in accordance with part 161 of this chapter to perform functions specified in parts 1, 2, 3, and 11 of subchapter A, and subchapters B, C, and D of this chapter, and to perform functions required by cooperative State-Federal disease control and eradication programs.

**Administrator.** The Administrator of the Animal and Plant Health Inspection Service, or any other employee of the Animal and Plant Health Inspection Service, United States Department of Agriculture, delegated to act in the Administrator's stead.

\* \* \* \* \*

**United States.** All of the States of the United States, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other Territories and Possessions of the United States.

\* \* \* \* \*

51. Part 94 would be revised to read as follows:

**PART 94—IMPORTATION OF MEAT AND UNPROCESSED PRODUCTS FROM ANIMALS**

Sec.

94.0 Definitions.

94.1 Importation of fresh, chilled, or frozen meat from ruminants or swine.

94.2 Additional conditions for importation of fresh, chilled, or frozen meat from ruminants and swine.

94.3 Fresh, chilled, or frozen products (other than meat) and milk and milk products of ruminants and swine.

94.4 Organs, glands, extracts, or secretions of ruminants or swine.

94.5 Importation of cured or cooked meat of ruminants or swine into the United States from regions classified as Risk Class R3, R4, or RU for foot-and-mouth disease, rinderpest, African swine fever, swine vesicular disease, and/or hog cholera.

94.6 Regulation of certain garbage.

94.7 Carcasses, or parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds; importations from countries where Exotic Newcastle disease (VVND) or *S. enteritidis* is considered to exist.

94.8 Disposal of meats ineligible for importation.

94.9 Meat and other animal products; in-transit movement and handling.

94.10 Milk and milk products.

94.11 Dry-cured pork products from regions classified as Risk Class R3, R4, or RU for foot-and-mouth disease, rinderpest, African swine fever, hog cholera, or swine vesicular disease.

94.12 Ruminant meat and edible products from ruminants that have been in regions classified as Risk Class R3, R4, or RU for bovine spongiform encephalopathy.

94.13 Movement of meat and meat products.

94.14 Seizure, quarantine, and disposal of meat and meat products.

94.15 Cancellation of compliance agreements.

Authority: 7 U.S.C. 147a, 150ee, 161, 162, 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.2(d).

**§ 94.0 Definitions.**

As used in this part, the following terms shall have the meanings set forth in this section.

**Administrator.** The Administrator of the Animal and Plant Health Inspection Service, or any other employee of the Animal and Plant Health Inspection Service, United States Department of Agriculture, delegated to act in the Administrator's stead.

**Animal and Plant Health Inspection Service (APHIS).** The Animal and Plant Health Inspection Service, United States Department of Agriculture.

**APHIS representative.** Any individual employed by the Animal and Plant Health Inspection Service, United States Department of Agriculture, who is authorized to perform the services required by this part.

**Approved facility.** A facility approved by the Administrator, upon his or her determination that it has equipment and uses procedures that are adequate to prevent the dissemination of plant pests and livestock or poultry diseases, and that it is certified by an appropriate government official as currently complying with the applicable laws for environmental protection.

**Approved sewage system.** A sewage system approved by the Administrator, upon his or her determination that the system is designed and operated in such a way as to preclude the discharge of sewage effluents onto land surfaces or into lagoons or other stationary waters, and otherwise is adequate to prevent the dissemination of plant pests and livestock or poultry diseases, and that it is certified by an appropriate government official as currently complying with the applicable laws for environmental protection.

**Authorized inspector.** Any employee of the Animal and Plant Health Inspection Service, United States Department of Agriculture, or any other

individual who is authorized by the Administrator to enforce this part.

**Birds.** All members of the class Aves (other than poultry or game birds).

**Carrier.** For the purposes of § 94.6, this term means the principal operator of a means of conveyance.

**Cervid.** All species of deer, elk, and moose.

**Cold spot.** The area in a flexible plastic cooking tube or other type of container loaded with meat product, or the areas at various points along the belt in an oven chamber, slowest to reach the required temperature during the cooking process. The cold spot(s) for each container is experimentally determined before the cooking process begins and, once identified, remains constant.

**Contact.** Known or potential commingling of products of animals during processing or storage, or while being transported from any point to any other point. Contact includes simultaneous processing in the same facility, or storage or shipment in the same room, locker, or container, but not necessarily the same storage facility or conveyance, as long as security measures provided are determined to be adequate by an authorized APHIS representative.

**Container.** A receptacle, sometimes refrigerated, that is designed to be filled with cargo, sealed, and then moved, without unsealing or unloading, aboard a variety of different transporting means of conveyance.

**Continental United States.** The 49 States located on the continent of North America and the District of Columbia.

**Department.** The United States Department of Agriculture (USDA).

**Directly.** Without unloading and without stopping except for refueling, or for traffic conditions such as traffic lights or stop signs.

**Exotic Newcastle disease (VVND).** The velogenic, viscerotropic form of Newcastle disease.

**Flock of origin.** The flock in which the eggs were produced.

**Food Safety and Inspection Service (FSIS).** The Food Safety and Inspection Service of the United States Department of Agriculture.

**FSIS inspector.** An individual authorized by the Administrator, FSIS, to perform the function involved.

**Game birds.** Migratory birds, including certain ducks, geese, pigeons, and doves ("migratory" refers to seasonal flight to and from the United States); and free-flying quail, wild grouse, and wild pheasants (as opposed to those that are commercial, domestic, or pen-raised).



**House.** A structure, enclosed by walls and a roof, in which poultry are raised.

**Import (imported, importation) into the United States.** To bring into the territorial limits of the United States.

**Incineration.** Reduction to ash by burning.

**Indicator piece.** A cube or slice of meat to be used for the pink juice test, required to meet minimum size specifications.

**Operator.** The operator responsible for the day-to-day operations of a facility.

**Person.** Any individual, corporation, company, association, firm, partnership, society, joint stock company, or other legal entity.

**Pink juice test.** Determination of whether meat has been thoroughly cooked by observation of whether the flesh and juices have lost all red and pink color.

**Port of arrival.** Any place in the United States at which a product or article arrives, unless the product or article remains on the means of conveyance on which it arrived within the territorial limits of the United States.

**Poultry.** Chickens, turkeys, swans, partridges, guinea fowl, pea fowl; nonmigratory ducks, geese, pigeons, and doves; commercial, domestic, or pen-raised grouse, pheasants, and quail.

**Premises of origin.** The premises where the flock or herd of origin is kept.

**Region.** Any defined geographic land region identifiable by geological, political or surveyed boundaries.

**Region of origin.** For meat and meat products, the region in which the animal from which the meat or meat product was derived was raised and slaughtered; and for eggs, the region in which the eggs were laid. In those cases where the animal was raised in one region and slaughtered in another, the region of origin is the region with the classification of greater disease risk.

**Restricted agents.** Livestock disease agents, vectors, or hosts of those agents not known to exist in the United States or that are subject to control or eradication programs within the United States. Restricted agents are listed in § 92.2 of this chapter.

**Risk Class regions.** Foreign exporting regions designated by APHIS according to the results of a risk assessment as defined in § 92.1 of this chapter and determined by criteria set forth in § 92.3 of this chapter are incorporated herein and are applicable to this part.

**Ruminants.** All animals that chew the cud, such as cattle, buffaloes, sheep, goats, deer, antelopes, camels, llamas and giraffes.

**Salmonella enteritidis, serotype enteritidis.** Salmonella enteritidis serotype enteritidis, an organism that causes salmonellosis.

**Salmonella enteritidis, phage-type 4.** A virulent type of Salmonella enteritidis serotype enteritidis.

**Salmonellosis.** An infectious disease caused by species of Salmonella bacteria.

**Sentinel bird.** A chicken that has been raised in an environment free of pathogens that cause communicable diseases of poultry and that has not been infected with, exposed to, or immunized with any strain of virus that causes Newcastle disease.

**Shelf-stable.** The condition achieved in a product, by application of heat alone or in combination with other ingredients and/or other treatments, of being rendered free of microorganisms capable of growing in the product under nonrefrigerated conditions (over 50 °F or 10 °C).

**Sterilization.** For purposes of § 94.6, this term means the cooking of regulated garbage at 212 °F. (100 °C.) for 30 minutes.

**Swine.** The domestic hog and all varieties of wild hogs.

**Temperature indicator device (TID).** A precalibrated temperature-measuring instrument containing a chemical compound activated at a specific temperature (the melting point of the chemical compound) identical to the processing temperature that must be reached by the meat being cooked.

**Territories or possessions.** For § 94.6, territories or possessions means Guam, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands of the United States, and all other territories or possessions of the United States.

**Thoroughly cooked.** Heated sufficiently to inactivate any pathogen that may be present, as indicated by the required TID or pink juice test.

**United States.** All of the States of the United States, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and, for the purposes of this part other than § 94.6, all other territories or possessions of the United States.

**Veterinarian in Charge.** The veterinary official of the Animal and Plant Health Inspection Service, United States Department of Agriculture, who is assigned by the Administrator to supervise and perform the official animal health work of the Animal and Plant Health Inspection Service in the State concerned.

**Wild swine.** Any swine that are allowed to roam outside an enclosure.

#### **§ 94.1 Importation of fresh, chilled, or frozen meat from ruminants or swine.**

(a) Importation of fresh, chilled, or frozen meat from ruminants or swine in

regions that are classified as Risk Class R4 or RU for rinderpest or foot-and-mouth disease is prohibited.

(b) Importation of fresh, chilled, or frozen meat from swine in regions that are classified as Risk Class R3, R4 or RU for hog cholera, African swine fever, or swine vesicular disease is prohibited.

(c) Importation of fresh, chilled, or frozen meat from ruminants from regions that are classified as Risk Class R4 or RU for bovine spongiform encephalopathy is prohibited.

(d) Fresh, chilled, or frozen meat from ruminants or swine raised and slaughtered in regions classified as Risk Class RN or R1 for foot-and-mouth disease, rinderpest, bovine spongiform encephalopathy, African swine fever, hog cholera, and/or swine vesicular disease may be imported into the United States provided:

(1) The authorized official of the exporting country certifies on the foreign meat inspection certificate that the shipment originated from regions that are classified as Risk Class RN or R1 for foot-and-mouth disease, rinderpest, bovine spongiform encephalopathy, African swine fever, hog cholera, and swine vesicular disease in ruminants or swine;

(2) The authorized official of the exporting country certifies on the foreign meat inspection certificate that the meat has not been in contact with meat from regions that are classified as Risk Class R2, R3, R4, or RU for foot-and-mouth disease, rinderpest, bovine spongiform encephalopathy, African swine fever, hog cholera, and/or swine vesicular disease.

(e) Fresh, chilled, or frozen meat from ruminants or swine raised and slaughtered in regions that are classified as Risk Class R2 for foot-and-mouth disease or rinderpest may be imported into the United States provided that the authorized official of the exporting country certifies on the foreign meat inspection certificate that:

(1) Each shipment originates from regions that are classified as Risk Class RN, R1, or R2 for foot-and-mouth disease or rinderpest in ruminants or swine;

(2) The meat has not been in contact with meat from regions that are classified as Risk Class R3, R4 or RU for foot-and-mouth disease or rinderpest in ruminants or swine;

(3) The meat originates from premises where foot-and-mouth disease or rinderpest has not been present during the lifetime of any ruminants or swine slaughtered for export;

(4) The meat originates from premises located in regions where foot-and-mouth disease or rinderpest has not

been diagnosed within the previous 12 months;

(5) The meat originates from premises on which ruminants or swine have not been vaccinated with modified or attenuated live viruses for foot-and-mouth disease at any time during the lifetime of any of the ruminants or swine slaughtered for export;

(6) The meat originates from ruminants or swine that have not been vaccinated for rinderpest, African swine fever, hog cholera or swine vesicular disease at any time during the lifetime of any of the ruminants or swine slaughtered for export;

(7) The meat comes from carcasses that have been allowed to mature at 40 to 50 °F (4 to 10 °C) for a minimum of 36 hours after slaughter and have reached a maximum pH of 6.0 in the loin muscle at the end of the maturation period. Any carcass in which the pH does not reach a maximum of 6.0 may be allowed to mature an additional 24 hours and be retested, and, if the carcass still does not reach a maximum pH of 6.0 after 60 hours, the meat from the carcass may not be exported to the United States; and

(8) All bone, blood clots, and lymphoid tissue have been removed from the meat.

(f) Fresh, chilled, or frozen meat from swine raised and slaughtered in regions that are classified as Risk Class R2 for African swine fever, hog cholera, and/or swine vesicular disease may be imported into the United States provided that the authorized official of the exporting country certifies that:

(1) Each shipment originates from regions that are classified as Risk Class RN, R1, or R2 for African swine fever, hog cholera, and/or swine vesicular disease in swine;

(2) The meat has not been in contact with meat from regions that are classified as Risk Class R3, R4 or RU for African swine fever, hog cholera, and/or swine vesicular disease;

(3) The meat originates from premises where African swine fever, hog cholera, and/or swine vesicular disease has not been present during the lifetime of swine slaughtered for export;

(4) The meat originates from premises located in regions where African swine fever, hog cholera, and/or swine vesicular disease has not been diagnosed within the previous 12 months;

(5) The meat originates from premises on which ruminants or swine have not been vaccinated with modified or attenuated live viruses for foot-and-mouth disease at any time during the lifetime of any of the swine slaughtered for export;

(6) The meat originates from swine that have not been vaccinated for rinderpest, African swine fever, hog cholera or swine vesicular disease at any time during the lifetime of any of the swine slaughtered for export; and

(7) All bone, blood clots, and lymphoid tissue have been removed from the meat.

(g) Fresh, chilled, or frozen meat from ruminants or swine raised and slaughtered in regions that are classified as Risk Class R3 for foot-and-mouth disease and/or rinderpest may be imported into the United States, provided the authorized official of the exporting country certifies that:

(1) Each shipment originates from a region that is classified as Risk Class RN, R1, R2 or R3 for foot-and-mouth disease and/or rinderpest in ruminants or swine;

(2) The meat has not been in contact with meat from regions that are classified as Risk Class R4 or RU for foot-and-mouth disease and/or rinderpest;

(3) The meat originates from premises where foot-and-mouth disease and rinderpest have not been present during the lifetime of any ruminants or swine slaughtered for export;

(4) The meat originates from premises where foot-and-mouth disease and/or rinderpest has not been diagnosed within 15 statute miles (25 kilometers) within the previous 12 months;

(5) The meat originates from premises on which ruminants or swine have not been vaccinated with modified or attenuated live viruses for foot-and-mouth disease at any time during the lifetime of any of the ruminants or swine slaughtered for export;

(6) The meat originates from ruminants or swine that have not been vaccinated for rinderpest, African swine fever, hog cholera or swine vesicular disease at any time during the lifetime of any of the ruminants or swine slaughtered for export;

(7) The meat comes from carcasses that have been allowed to mature at 40 to 50 °F (4 to 10 °C) for a minimum of 36 hours after slaughter and that have reached a maximum pH of 6.0 in the loin muscle at the end of the maturation period. Any carcasses in which the pH did not reach a maximum of 6.0 may be allowed to mature an additional 24 hours and be retested, and if the carcass still does not reach a maximum pH of 6.0 after 60 hours, the meat from the carcass may not be exported to the United States;

(8) The meat has all bone, blood clots, and lymphoid tissue removed; and

(9) The meat was held at no more than 40 °F (4 °C) for a minimum of 14 days

before export, during which time the premises of origin of all animals in the shipment remained free of foot-and-mouth disease, rinderpest, African swine fever, hog cholera, and swine vesicular disease.

(h) Fresh, chilled, or frozen meat from cattle from regions that are classified as Risk Class R2 or R3 for bovine spongiform encephalopathy may be imported into the United States provided the authorized official of the exporting country certifies that:

(1) Each shipment originates from a region that is classified as Risk Class RN, R1, R2, or R3 for bovine spongiform encephalopathy;

(2) The meat has not been in contact with meat from regions that are classified as Risk Class R4 or RU for bovine spongiform encephalopathy;

(3) The meat originates from premises where, for at least 10 years, bovine spongiform encephalopathy has not been known to be present;

(4) The meat originates from premises where protein of ruminant origin has not been fed to ruminants during the lifetime of any animals currently living on the premise;

(5) The meat is from cattle that have not been in any region that is classified as Risk Class R3, R4, or RU for bovine spongiform encephalopathy during any period of time when the region permitted the use of ruminant protein in ruminant feed; and

(6) The cattle were examined prior to slaughter by a veterinarian employed by the national government of the country in which the ruminants were slaughtered, and were found not to display any signs indicative of a neurological disorder.

(i) Fresh, chilled or frozen meat derived from animals in the family Cervidae (cervids) from regions that are classified as Risk Class R2, R3, or R4 for bovine spongiform encephalopathy may be imported into the United States, provided the authorized official of the exporting country certifies that:

(1) The meat was derived either from wild cervidae, or from farm-raised cervidae that have never been fed ruminant protein;

(2) All bones and visually identifiable lymphatic tissue and nerve tissue have been removed from the meat;

(3) The meat is from cervidae that have not been in any region that is classified as Risk Class R3, R4, or RU for bovine spongiform encephalopathy, during a period of time when the region permitted the use of ruminant protein in ruminant feed; and

(4) The cervidae were examined prior to slaughter by a veterinarian employed by the national government of the

country in which the ruminants were slaughtered, and were found not to display any signs indicative of a neurological disorder.

**§ 94.2 Additional conditions for importation of fresh, chilled, or frozen meat from ruminants and swine.**

All fresh, chilled, or frozen meat permitted to be imported may be imported into the United States only under the conditions of § 94.1 and the following conditions:

(a) The meat is accompanied by the foreign meat inspection certificate required by § 327.4 of this title and, upon arrival of the meat in the United States, the foreign meat inspection certificate is presented to an authorized inspector at the port of arrival;

(b) The meat is placed in the transporting means of conveyance in a hold or compartment, or, if the meat is containerized, in a container, that was sealed in the region of origin by an official of the country of origin with serially numbered seals approved by the Administrator of APHIS, so as to prevent contact of the meat with any other cargo, handling of the meat after the hold, compartment, or container is sealed, and the loading of any cargo into and the removal of any cargo from the sealed hold, compartment, or container en route to the United States;

(c) If any foreign official breaks a seal applied in the region of origin in order to inspect the meat, he or she must then reseal the hold, compartment, or container with a new serially numbered seal; and, if any member of a ship's crew breaks a seal, the serial number of the seal, the location of the seal, and the reason for breaking the seal must be recorded in the ship's log;

(d) The serial numbers of the seals used to seal the hold, compartment, or container must be recorded on the foreign meat inspection certificate that must accompany the meat;

(e) Upon arrival of the means of conveyance in the United States port of arrival, the seals are found by an APHIS representative to be intact, and the representative finds that there is no evidence indicating that any seal has been tampered with; Provided that, if the representative finds that any seal has been broken or has a different number than is recorded on the foreign meat inspection certificate, then the meat may remain eligible for entry into the United States only if APHIS personnel are available to inspect the hold, compartment, or container, the packages of meat, and all accompanying documentation; and the importer furnishes additional documentation (either copies of pages from the ship's

log signed by the officer-in-charge, or certification from a foreign government that the original seal was removed and the new seal was applied by officials of that government) that demonstrates to the satisfaction of the Administrator that the meat was not contaminated or exposed to contamination during movement from the region of origin to the United States; and

(f) The meat is found by an authorized inspector to be as represented on the foreign meat inspection certificate.

**§ 94.3 Fresh, chilled, or frozen products (other than meat) and milk and milk products of ruminants and swine.**

(a) The importation of fresh, chilled, or frozen products (other than meat, and milk and milk products) derived from ruminants or swine, originating in, shipped from, or transiting any region that is classified as Risk Class R3, R4 or RU for rinderpest or foot-and-mouth disease is prohibited, except as provided in § 94.4 and parts 95 and 96 of this chapter.

(b) The importation of milk and milk products of ruminants and swine originating in, shipped from, or transiting any region that is classified as Risk Class R3, R4 or RU for rinderpest, foot-and-mouth disease, or *Brucella melitensis* is prohibited, except as provided in § 94.10.

**§ 94.4 Organs, glands, extracts, or secretions of ruminants or swine.**

The importation of fresh, chilled, or frozen organs, glands, extracts, or secretions derived from ruminants or swine, from any region of origin classified as Risk Class R3, R4 or RU regions for foot-and-mouth disease, rinderpest, African swine fever, hog cholera, swine vesicular disease, bovine spongiform encephalopathy, or *Brucella melitensis* is prohibited, except for pharmaceutical or biological purposes under conditions prescribed by the Administrator in each instance.

**§ 94.5 Importation of cured or cooked meat of ruminants or swine into the United States from regions classified as Risk Class R3, R4 or RU for foot-and-mouth disease, rinderpest, African swine fever, swine vesicular disease, and/or hog cholera.**

(a) Cured meats derived from ruminants or swine, except dry-cured pork,<sup>1</sup> or cooked meat<sup>2</sup> may be imported into the United States from regions or origin that are classified as Risk Class R3, R4 or RU for foot-and-mouth disease, rinderpest, African swine fever, swine vesicular disease, and/or hog

cholera only under the following conditions and the applicable conditions of paragraph (b), (c), (e), (f), (h), or (i) of this section:

(1) All cured or cooked meat and meat products prepared under this section must be prepared in an inspected establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and § 327.2 of this title. A foreign meat inspection certificate required by § 327.4 of this title shall be issued by an official of the national government of the country of origin who is authorized to issue the certificate, who further certifies on the same foreign meat inspection certificate that the conditions of this section have been fulfilled; and

(2) Upon arrival of the cured or cooked meat or meat products in the United States, the accompanying foreign meat inspection certificate must be presented to an authorized inspector at the port of arrival.

(b) The importation of cured meats derived from ruminants or swine from any region of origin that is classified as Risk Class R3, R4, or RU for foot-and-mouth disease or rinderpest is prohibited, unless the requirements of paragraph (a) of this section and the following conditions have been met:<sup>3</sup>

(1) All bones have been completely removed in the region of origin;

(2) The meat has been held in an unfrozen, fresh condition for at least 3 days immediately following the slaughter of the animals from which it was derived;

(3) The meat has been thoroughly cured and fully dried in such a manner that it may be stored and handled without refrigeration, as in the case of salami and other summer sausages, tasajo, xarque, or jerked beef, bouillon cubes, dried beef, and Westphalia, Italian and similar type hams. The term "fully dried" as used in this paragraph (b)(3) means dried to the extent that the water-protein ratio in the wettest portion of the product does not exceed 2.25 to 1; and

(4) Laboratory analysis of samples to determine the water-protein ratios will not be made in the case of all shipments of cured and dried meats. However, in any case in which the inspector is uncertain whether the meat complies with the requirements of paragraph (b)(3) of this section, he or she will send a sample of the meat representative of the wettest portion to the Meat

<sup>1</sup> See § 94.11 for importation requirements regarding dry-cured pork products.

<sup>2</sup> This does not include any meat that has been sterilized by heat in hermetically sealed containers.

<sup>3</sup> See also other provisions of this part (including § 94.11) and parts 92, 95, and 96 of this chapter, and part 327 of this title for other prohibitions and restrictions upon importation of swine and swine products.

Inspection Division for analysis of the water-protein ratio. Pending such analysis, the meat shall not be released or removed from the port of arrival.

(c) The importation of cooked meat from ruminants or swine originating in any region classified as Risk Class R3, R4, or RU for foot-and-mouth disease or rinderpest is prohibited unless the requirements of paragraph (a) of this section and the following conditions have been met:

(1) The cooked meat is boneless and has been thoroughly cooked;

(2) The cooked meat has been prepared in an establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and the regulations in § 327.2 of this title; that meets all other applicable requirements of the Federal Meat Inspection Act and regulations thereunder (9 CFR Chapter III); and that has been approved by the Administrator in accordance with paragraph (d) of this section;

(3) Canned product (canned meat), as defined in § 318.300(d) of this title, is exempt from the requirements in this section;

(4) *Ground meat cooked in an oven.* The ground meat must be shaped into patties no larger than 5 inches in diameter and 1-inch thick. Each patty must weigh no more than 115 grams, with fat content no greater than 30 percent. These patties must be broiled at 210 °C (410 °F) for at least 133 seconds, then cooked in moist heat (steam heat) in a continuous, belt-fed oven for not less than 20 minutes, to yield an internal exit temperature of at least 99.7 °C, (211.5 °F) as measured by temperature indicator devices (TID's) placed in temperature monitor patties positioned, before the belt starts moving through the oven, on each of the predetermined cold spots along the oven belt. TID's approved by the Administrator as activating at the appropriate temperature must be placed on the front, last, and predetermined interior rows on the belt at the beginning of each processing run;

(5) *Meat cooked in plastic.* The ground meat, cubes of meat, slices of meat, or anatomical cuts of meat (cuts taken from the skeletal muscle tissue) must weigh no more than 5 kilograms, and must be loaded into a flexible cooking tube constructed of plastic film or other material approved by the Food Safety and Inspection Service, U.S. Department of Agriculture. The meat must be cooked in boiling water or in a steam-fed oven to reach a minimum internal temperature of 79.4 °C at the cold spot after cooking for at least 1.75

hours. Thoroughness of cooking must be determined by the TID registering at least 79.4 °C at the cold spot, or by the pink juice test, as follows:

(i) *Cubes of meat.* At least 50 percent of meat pieces per tube must be 3.8 centimeters or larger in each dimension after cooking or, if more than 50 percent of meat pieces per tube are smaller than 3.8 centimeters in any dimension after cooking and no TID is being used, an indicator piece of sufficient size for a pink juice test to be performed (3.8 centimeters or larger in each dimension after cooking) must have been placed at the cold spot of the tube.

(ii) *Slices of meat.* At least 50 percent of the slices of meat must be 3.8 centimeters or larger in each dimension after cooking or, if more than 50 percent of meat pieces are smaller than 3.8 centimeters in any dimension after cooking, and no TID is being used, an indicator piece of sufficient size for a pink juice test to be performed (3.8 centimeters or larger in each dimension after cooking) must be placed at the cold spot of the tube.

(iii) *Anatomical cuts of meat.* An indicator piece removed from an anatomical cut of meat after cooking must be removed from the center of the cut, farthest from all exterior points and must be 3.8 centimeters or larger in each dimension for performance of the pink juice test;

(6) Any TID used in accordance with § 94.5 (c)(4) or (c)(5) must remain in the meat, as originally inserted, and must accompany the cooked meat whose temperature it has gauged when that meat is shipped to the United States; and

(7) The cooked meat must be inspected by an FSIS inspector at a port of arrival in a defrost facility approved by the Administrator<sup>4</sup> and the meat must be found to be thoroughly cooked.

(i) Request for approval of any defrost facility must be made to the Administrator. The Administrator will approve a defrost facility only under the following conditions:

(A) The defrost facility must have equipment and procedures that permit FSIS inspectors to determine whether meat is thoroughly cooked;

(B) The defrost facility must be located at a port of arrival; and

(C) The defrost facility must be approved by FSIS.<sup>5</sup>

<sup>4</sup>The names and addresses of approved defrost facilities and conditions for approval may be obtained from the National Center for Import and Export, 4700 River Road Unit 39, Riverdale, MD 20737-1231.

<sup>5</sup>Conditions for the approval of any defrost facility by the Food Safety and Inspection Service, United States Department of Agriculture, may be

(ii) The Administrator may deny approval of any defrost facility if the Administrator determines that the defrost facility does not meet the conditions for approval. If approval is denied, the operator of the defrost facility will be informed of the reasons for denial and be given an opportunity to respond. The operator will be afforded an opportunity for a hearing with respect to any disputed issues of fact. The hearing will be conducted in accordance with rules of practice that will be adopted for the proceeding.

(iii) The Administrator may withdraw approval of any defrost facility as follows:

(A) When the operator of the defrost facility notifies the Administrator in writing that the defrost facility no longer performs the required services; or

(B) When the Administrator determines that the defrost facility does not meet the conditions for approval. Before the Administrator withdraws approval from any defrost facility, the operator of the defrost facility will be informed of the reasons for the proposed withdrawal and given an opportunity to respond. The operator will be afforded a hearing with respect to any disputed issues of fact. The hearing will be conducted in accordance with rules of practice that will be adopted for the proceeding. If approval of a defrost facility is withdrawn, the Administrator will remove its name from the list of approved defrost facilities.

(d) *Meat processing establishment; standards.* (1) Before the Administrator will approve a meat processing establishment for export shipment of cooked meat to the United States, the Administrator must determine:

(i) That the meat processing establishment has furnished APHIS with a description of the process used to inactivate rinderpest or foot-and-mouth disease virus that may be present in meat intended for export to the United States, and with blueprints of the facilities where this meat is cooked and packaged;

(ii) That an APHIS representative has inspected the establishment and found that it meets the standards set forth in paragraph (d)(2) of this section;

(iii) That the operator of the establishment has signed a cooperative service agreement with APHIS, stating:

(A) That all cooked meat processed for importation into the United States will be processed in accordance with the requirements of this part;

obtained from the Import Inspection Division, International Programs, Food Safety and Inspection Service, United States Department of Agriculture, Washington, DC 20250.

(B) That a full-time, salaried meat inspection official of the National Government of the exporting country will supervise the processing (including certification of the cold spot) and examination of the product, and certify that it has been processed in accordance with this section; and

(C) That APHIS personnel or other persons authorized by the Administrator may enter the establishment, unannounced, and will be given full access to inspect the establishment and its records; and

(iv) That the operator of the establishment has entered into a trust fund agreement with APHIS and is current in paying all costs for an APHIS representative to inspect the establishment for initial evaluation, and periodically thereafter, including travel, salary, subsistence, administrative overhead, and other incidental expenses (including an excess baggage provision up to 150 pounds). In accordance with the terms of the trust fund agreement, before the APHIS representative's site inspection, the operator of the processing establishment must deposit with the Administrator an amount equal to the approximate cost of one inspection by an APHIS representative, including travel, salary, subsistence, administrative overhead, and other incidental expenses (including an excess baggage provision up to 150 pounds). As funds from that amount are obligated, a bill for costs incurred based on official accounting records will be issued to restore the deposit to the original level, revised as necessary to allow for inflation or other changes in estimated costs. To be current, bills must be paid within 14 days of receipt.

(2) *Establishment.* An APHIS representative will conduct an on-site evaluation, and subsequent inspections, as provided in § 94.5(d)(1), to determine whether the following conditions are met:

(i) The facilities used for processing cooked meat in the meat processing establishment are separate from the facilities used for processing raw meat (precooking, boning, preparation, and curing), with only the through-the-wall cooking system through which the meat product is delivered at the end of the cooking cycle connecting them; and there is at all times a positive air flow from the cooked to the raw product side;

(ii) The cooking equipment has the capacity to cook all meat pieces in accordance with § 94.5(c)(4) or (c)(5);

(iii) Workers who process cooked meat are at all times kept separate from workers who process raw meat, and have for their exclusive use: A separate entrance, dining area, toilets, lavatories

with cold and hot water, soap, disinfectants, paper towels, clothes hampers and waste baskets for disposal, and changing rooms stocked with the clean clothing and rubber boots into which all persons must change upon entering the establishment. Workers and all other persons entering the establishment must wash their hands and change into the clean clothing and boots provided in the changing rooms before entering the cooking facilities, and must leave this clothing for laundering and disinfecting before exiting from the establishment, regardless of the amount of time spent inside or away from the establishment; and

(iv) Original records identifying the slaughtering facility from which the meat was obtained and the date the meat entered the meat processing establishment, and original certification (including temperature recording charts and graphs), must be kept for all cooked meat by the full-time salaried meat inspection official of the National Government of the exporting country assigned to the establishment, and must be retained for 2 years.

(e) Importation of cured meats derived from swine from any region of origin that is classified as Risk Class R3, R4, or RU for hog cholera is prohibited, unless the requirements of paragraph (a) of this section and the following conditions have been met and are certified to by the authorized official of the exporting country on the foreign meat inspection certificate:<sup>6</sup>

(1) All bones have been completely removed in the region of origin;

(2) The meat has been held in an unfrozen, fresh condition for at least 3 days immediately following the slaughter of the animals from which it was derived; and

(3) The meat has been thoroughly cured and fully dried for a period of not less than 90 days so that the product is shelf stable without refrigeration:

*Provided, That* the period of curing and drying may be 45 days if the pork or pork product is accompanied to the processing establishment by a certificate of an official of the national government of a Risk Class RN, R1, or R2 region that specifies that:

(i) The pork involved originated in a region that is classified as Risk Class RN, R1, or R2, and the pork or pork product was consigned to a processing establishment in \_\_\_\_\_ (name of a region classified as Risk Class R3, R4,

<sup>6</sup>The certification required may be placed on the foreign meat inspection certificate prescribed by § 327.4 of this title, or may be contained in a separate document.

or RU for hog cholera), in a closed container sealed by the national veterinary authorities of the region classified as Risk Class RN, R1, or R2 for hog cholera by seals of a serially numbered type approved by the Administrator; and

(ii) The numbers of the seals used were entered on the meat inspection certificate of the region that is classified as Risk Class RN, R1, or R2 for hog cholera that accompanied the shipment from such region: And, *provided further*, that the certification<sup>7</sup> required by paragraph (e) of this section also states that: The container seals specified in paragraph (e)(3)(i) of this section were found intact and free of any evidence of tampering, by a national veterinary inspector upon arrival at the processing establishment; and the processing establishment from which the pork or pork product is shipped to the United States does not receive or process any live swine; and uses only pork or pork products that originate in regions that are classified as Risk Class RN, R1 or R2 for hog cholera; and processes all such pork or pork products in accordance with this section.

(f) Importation of cured meats derived from swine from any region of origin that is classified as Risk Class R3, R4, or RU for swine vesicular disease is prohibited, unless the requirements of paragraph (a) of this section and the following conditions have been met and are certified to by the authorized official of the exporting country on the foreign meat inspection certificate:<sup>8</sup>

(1) All bones have been completely removed in the region of origin; and

(2) Such pork or pork products either are consigned directly from the port of entry in the United States to a meat processing establishment operating under Federal meat inspection and approved by the Administrator,<sup>9</sup> for heating to an internal temperature of 166 °F (74.4 °C); or

(3) Such pork or pork product, if it is from a region of origin designated as a Risk Class RN, R1, or R2 for swine

<sup>7</sup> See footnote 6 in § 94.5(e).

<sup>8</sup> See footnote 6 § 94.5(e).

<sup>9</sup> The names and addresses of approved establishments may be obtained from, and request for approval of any establishment may be made to the National Center for Import and Export, Veterinary Services, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231. Establishments will be approved only if the Administrator determines that the imported articles will be so handled at the establishments as to prevent the introduction and dissemination of livestock or poultry diseases into the United States. Approval of any establishment may be refused, suspended, or withdrawn only after the operator thereof has been given notice of the proposed action and has had an opportunity to present his or her views thereon, in accordance with rules of practice adopted by the Administrator.

vesicular disease has been cured and dried and is in compliance with the following requirements:

(i) Such pork or pork product is accompanied from the Risk Class RN, R1 or R2 region of origin to the Risk Class R3, R4 or RU region by a certificate signed by an official of the National Government of the Risk Class RN, R1 or R2 region of origin specifying that the pork or pork product involved originated in that region and that the pork or pork product was consigned to a processing establishment in \_\_\_\_\_ (name of a region listed as a Risk Class R3, R4 or RU region for swine vesicular disease), in a closed container sealed by the national veterinary authorities of the Risk Class RN, R1, or R2 region of origin by seals of a serially numbered type approved by the Administrator. The numbers of these seals must be entered on this certificate; and

(ii) The certification required by paragraph (f)(3)(i) of this section must also state that:

(A) The container seals were found intact and free of any evidence of tampering upon arrival at the processing establishment in the Risk Class R3, R4 or RU region, by a national veterinary inspector of the country in which the region is located;

(B) The processing establishment from which the pork or pork product was shipped to the United States does not receive or process any live swine, and uses only pork or pork products that are from regions of origin that are classified as Risk Class RN, R1, or R2 for swine vesicular disease; and

(C) Such establishment processes all such pork or pork products in accordance with this section.

(g) Small amounts of pork or pork products subject to the restrictions of this section, may, in specific cases, be imported for purposes of examination, testing, or analysis, if the importer applies for and receives written approval for such importation from the Administrator, authorizing such importation. Approval will be granted only when the Administrator determines that the articles have been processed by heat in a manner so that such importation will not endanger the livestock of the United States.

(h) Importation of cooked meat from swine from any region of origin that is classified as Risk Class R3, R4, or RU for hog cholera and/or swine vesicular disease is prohibited unless the requirements of paragraph (a) of this section and the following conditions have been met and are certified to by the authorized official of the exporting

country on the foreign meat inspection certificate<sup>10</sup>:

(1) Such pork and pork product has been fully cooked by a commercial method in a container hermetically sealed promptly after filling but before such cooking, so that such cooking and sealing produced a fully sterilized product that is shelf-stable without refrigeration; or

(2) Such pork or pork product is in compliance with the following requirements:

(i) All bones have been completely removed in the region of origin; and

(ii) Such pork or pork product has received heat treatment in a commercially accepted manner used for perishable canned pork products that produces an internal temperature of 156° F.

(i) Importation of cooked meat from swine originating in any region that is classified as Risk Class R3, R4, or RU for African swine fever is prohibited, unless the requirements of paragraph (a) of this section and the following conditions have been met and are certified to by the authorized official of the exporting country on the foreign meat inspection certificate:

(1) Such pork or pork product has been fully cooked by a commercial method in a container hermetically sealed promptly after filling but before such cooking, so that such cooking and sealing produced a fully-sterilized product that is shelf-stable without refrigeration; or

(2) Such pork or pork product is not otherwise prohibited importation under this part and is consigned directly from the port of arrival in the United States to a meat processing establishment operating under Federal meat inspection, and approved by the Administrator, for further processing of such pork or pork product by heat; or

(3) Such pork or pork product meets the following conditions:

(i) It was derived from pork or pork products that originated from swine raised and slaughtered in a region that is classified as Risk Class RN, R1 or R2 for African swine fever, which were handled in the following manner:

(A) The swine were shipped from the region of origin to a processing establishment<sup>11</sup> in region that is classified as Risk Class RN, R1 or R2 for African swine fever, and were shipped

in a closed container sealed with serially numbered seals applied by an official of the national government of the country of origin;

(B) The swine were accompanied from the foreign region of origin to such processing establishment by a certificate signed by an official of the national government of the country of origin specifying the region of origin, the processing establishment to which the pork was consigned, and the numbers of the seals applied;

(C) The swine were taken out of the container at such processing establishment only after an official of the national government of the country where such processing establishment is located determined that the seals were intact and free of any evidence of tampering, and had so stated by the certification referred to in paragraph (i)(3)(i)(B) of this section;

(D) All bones were completely removed from the pork or pork product;

(E) The pork or pork product was heated by other than a flash-heating method at the foreign processing establishment referred to in paragraph (i)(3)(i)(A) of this section, to an internal temperature of at least 69° C. (156° F.) throughout (this must have occurred after the bones had been removed); and

(F) The processing establishment referred to in paragraph (i)(3)(i)(A) of this section:

(1) Does not receive or process any live swine, uses only pork or pork products that originate in regions that are classified as Risk Class RN, R1 or R2 for African swine fever, and processes pork or pork products only in accordance with paragraphs (i)(3)(i) and (i)(3)(ii) of this section;

(2) Is operated by persons who have entered into a valid written compliance agreement with APHIS whereby such persons have agreed to maintain on file at the establishment for at least 2 years copies of the certifications referred to in paragraph (i)(3)(i)(B) of this section, and to allow APHIS personnel to make unannounced inspections as necessary to monitor compliance with the provisions of this section, and have agreed to otherwise comply with the provisions of this section; and

(3) Is operated by persons who have entered into a trust fund agreement executed by such persons and APHIS; pursuant to the trust fund agreement the establishment is current in paying the cost for APHIS personnel to inspect the establishment (it is anticipated that such inspections will occur once per year), including travel, salary, subsistence, administrative overhead, and other incidental expenses (including excess baggage provisions up to 150 pounds);

<sup>10</sup> See footnote 6 in § 94.5(e).

<sup>11</sup> As a condition of entry into the United States, pork or pork products must also meet all of the requirements of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and regulations thereunder (9 CFR part 301), including requirements that the pork or pork products be prepared only in approved establishments.

and, in addition, the establishment has on deposit with APHIS, an unobligated amount equal to the cost for APHIS personnel to conduct one inspection; and

(ii) The pork or pork product was processed at only one processing establishment in a region classified as Risk Class R3, R4, or RU.

#### § 94.6 Regulation of certain garbage.

(a) *Garbage.* For purposes of this section, garbage means all waste material derived in whole or in part from fruits, vegetables, meats, or other plant or animal (including poultry) material, and other refuse of any character whatsoever that has been associated with any such material on board any means of conveyance, and including food scraps, table refuse, galley refuse, food wrappers or packaging materials, and other waste material from stores, food preparation areas, passengers' or crews' quarters, dining rooms, or any other areas on the means of conveyance. For purposes of this subpart, garbage also means meals and other food that were available for consumption by passengers and crew on an aircraft but were not consumed. Not all garbage is regulated for the purposes of this section. Garbage regulated for the purposes of this section is defined as "regulated garbage" in paragraphs (b), (c), and (d) of this section.

(b) *Garbage regulated because of movements outside the United States or Canada.* For purposes of this section, garbage on or removed from a means of conveyance is regulated garbage, if, when the garbage is on or removed from the means of conveyance, the means of conveyance has been in any port or area outside the United States and Canada within the previous 2-year period. There are, however, two exceptions to this provision. These exceptions are as follows:

(1) *Exception 1.* Garbage on or removed from a means of conveyance other than an aircraft is exempt from requirements under paragraph (b) of this section if the following conditions are met when the garbage is on or removed from the means of conveyance:

(i) The means of conveyance is accompanied by a certificate from an APHIS inspector stating the following:

(A) That the means of conveyance had first been cleared of all garbage and of the following: All meats and meat products, whatever the region of origin, except meats that are shelf-stable; all fresh and condensed milk and cream from regions classified as Risk Class R3, R4, or RU for foot-and-mouth-disease; all fresh fruits and vegetables; and all eggs; and the items cleared from the

means of conveyance as prescribed by this paragraph (b)(1)(i)(A) have been disposed of according to the procedures for disposing of regulated garbage, as specified in paragraph (f)(1) of this section.

(B) That the means of conveyance had been cleaned and disinfected in the presence of the inspector; and

(ii) Since being cleaned and disinfected, the means of conveyance has not been in a country other than the United States or Canada.

(2) *Exception 2.* Garbage on or removed from an aircraft is exempt from requirements under paragraph (b) of this section if the following two conditions are met:

(i) The aircraft had been cleared of all garbage and all stores; and the items cleared from the aircraft as prescribed by this paragraph (b)(2)(i) have been disposed of according to the procedures for disposing of regulated garbage, as specified in paragraph (f)(1) of this section.

(ii) After the garbage and stores referred to in paragraph (b)(2)(i) of this section were removed, the aircraft has not been in a country other than the United States or Canada.

(c) *Garbage regulated because of certain movements to or from Hawaii, territories, or possessions.* For purposes of this section, garbage on or removed from a means of conveyance is regulated garbage, if the means of conveyance has moved during the previous one-year period, either directly or indirectly, to the continental United States from any territory or possession or from Hawaii; to any territory or possession from any other territory or possession or from Hawaii; or to Hawaii from any territory or possession. There are, however, two exceptions to this provision. These exceptions are as follows:

(1) *Exception 1.* Garbage on or removed from a means of conveyance other than an aircraft is exempt from requirements under paragraph (c) of this section if the following two conditions are met when the garbage is on or removed from the means of conveyance:

(i) The means of conveyance is accompanied by a certificate from an APHIS inspector, stating that the means of conveyance has been cleared of all garbage and all fresh fruits and vegetables; and the items cleared from the means of conveyance as prescribed by this paragraph (c)(1)(i) have been disposed of according to the procedures for disposing of regulated garbage, as specified in paragraph (f)(1) of this section; and

(ii) After being cleared of the garbage and stores referred to in paragraph (c)(1)(i) of this section, the means of

conveyance has not moved to the continental United States from any territory or possession or from Hawaii; to any territory or possession from any other territory or possession or from Hawaii; or to Hawaii from any territory or possession.

(2) *Exception 2.* Garbage on or removed from an aircraft is exempt from requirements under paragraph (c) of this section if the following two conditions are met when the garbage is on or removed from the means of conveyance:

(i) The aircraft had been cleared of all garbage and all fresh fruits and vegetables; and the items cleared from the aircraft as prescribed by this paragraph (c)(2)(i) have been disposed of according to the procedures for disposing of regulated garbage, as specified in paragraph (f)(1) of this section; and

(ii) After the garbage and stores referred to in paragraph (c)(2)(i) of this section were removed, the aircraft has not moved to the continental United States from any territory or possession or from Hawaii; to any territory or possession from any other territory or possession or from Hawaii; or to Hawaii from any territory or possession.

(d) Garbage that is commingled with regulated garbage is also regulated garbage.

(e) *Restrictions on regulated garbage.* (1) Regulated garbage may not be on or removed from a means of conveyance, or be disposed of, unless in accordance with the provisions of this part.

(2) Regulated garbage is subject to general surveillance for compliance with this section by APHIS inspectors, and to such disposal measures as authorized by section 105 of the Federal Plant Pest Act (7 U.S.C. 150dd), section 10 of the Plant Quarantine Act of 1912, as amended (7 U.S.C. 164a), section 2 of the Act of February 2, 1903, as amended (21 U.S.C. 111), and section 306 of the Act of July 17, 1930, as amended (19 U.S.C. 1306), to prevent the dissemination of plant pests and livestock or poultry diseases.

(f)(1) All regulated garbage must be contained in tight, leak-proof covered receptacles during storage on board a means of conveyance while in the territorial waters, or while otherwise within the territory of the United States. All such receptacles must be contained inside the guard rail if on a watercraft. Such regulated garbage shall not be unloaded from such means of conveyance in the United States unless such regulated garbage is removed in tight, leak-proof receptacles under the direction of an APHIS inspector to an approved facility for incineration, sterilization, or grinding into an



approved sewage system, under supervision by such an inspector, or such regulated garbage is removed for other handling in such manner and under such supervision as may, upon request in specific cases, be approved by the Administrator as complying with the applicable laws for environmental protection and as adequate to prevent the dissemination into or within the United States of plant pests and livestock or poultry diseases.

(2) Application for approval of a facility or sewage system may be made in writing by the authorized representative of any carrier or by the official having jurisdiction over the port or place of arrival of the means of conveyance, to the Administrator, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. The application must be endorsed by the operator of the facility or sewage system. Approval will be granted if the Administrator determines that the requirements set forth in this section are met. Approval may be denied or withdrawn at any time, if the Administrator determines that such requirements are not met, after notice of the proposed denial or withdrawal of the approval and the reasons therefor, and an opportunity to demonstrate or achieve compliance with such requirements, has been afforded to the operator of the facility or sewage system and to the applicant for approval. However, approval may also be withdrawn without such prior procedure in any case in which the public health, interest or safety requires immediate action, and in such case, the operator of the facility or sewage system and the applicant for approval shall promptly thereafter be given notice of the withdrawal and the reasons therefor and an opportunity to show cause why the approval should be reinstated.

(g) APHIS will cooperate with other Federal, State, and local agencies responsible for enforcing other statutes and regulations governing disposal of regulated garbage to the end that such disposal shall be adequate to prevent the dissemination of plant pests and livestock or poultry diseases and comply with applicable laws for environmental protection. The inspectors, in maintaining surveillance over regulated garbage movements and disposal, shall coordinate their activities with the activities of representatives of the Environmental Protection Agency and other Federal, State, and local agencies also having jurisdiction over such regulated garbage.

(h) *Compliance agreement and cancellation.* (1) Any person engaged in the business of handling or disposing of

regulated garbage must first enter into an agreement with APHIS. Compliance agreement forms (PPQ Form 519) are available without charge from local USDA, APHIS, Plant Protection and Quarantine Offices, which are listed in telephone directories.

(2) A person who enters into a compliance agreement, and employees or agents of that person, must comply with the following conditions and any supplemental conditions that shall be listed in the compliance agreement, as deemed by the Administrator to be necessary to prevent the dissemination into or within the United States of plant pests and livestock or poultry diseases:

(i) Comply with the provisions of this section;

(ii) Allow APHIS inspectors access to all records maintained by the person regarding handling or disposal of regulated garbage, and to all areas where handling or disposal of regulated garbage occurs;

(iii) Remove regulated garbage from a means of conveyance only in tight, leak-proof receptacles;

(iv) Move the receptacles of regulated garbage only to a facility approved in accordance with paragraph (f)(2) of this section; and

(v) At the approved facility, dispose of the regulated garbage only through incineration, sterilization, grinding into a sewage system approved in accordance with paragraph (f)(2) of this section, or in any other manner approved by the Administrator and described in the compliance agreement.

(3) Approval for a compliance agreement may be denied at any time if the Administrator determines that the requirements set forth in this section are not met, after notice of, and the reasons for, the proposed denial of the approval, and an opportunity to demonstrate or achieve compliance with such requirements, has been afforded to the compliance agreement applicant.

(4) Any compliance agreement may be canceled in writing by the Administrator whenever it is found that the person who has entered into the compliance agreement has failed to comply with this section. Any person whose compliance agreement has been canceled may appeal the decision, in writing, within 10 days after receiving written notification of the cancellation. The appeal must state all of the facts and reasons upon which the person relies to show that the compliance agreement was wrongfully canceled. As promptly as circumstances allow, the Administrator will grant or deny the appeal, in writing, stating the reasons for the decision. A hearing will be held to resolve any conflicts as to any

material fact. Rules of practice concerning a hearing will be adopted by the Administrator. This administrative remedy must be exhausted before a person can file suit in court challenging the cancellation of a compliance agreement.

(5) Where a compliance agreement is denied or canceled, an APHIS inspector may allow the regulated garbage to be unloaded from a means of conveyance and disposed of at an approved facility in accordance with paragraph (f)(1) of this section.

(Approved by the Office of Management and Budget under control number 0579-0015)

**§ 94.7 Carcasses, or parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds; importations from countries where Exotic Newcastle disease (VVND) or *S. enteritidis* is considered to exist.**

(a) *Countries where Exotic Newcastle disease (VVND) is considered to exist.*

(1) Exotic Newcastle disease (VVND) is considered to exist in all countries of the world except those listed in paragraph (a)(2) of this section.

(2) The following countries are considered to be free of Exotic Newcastle disease (VVND): Australia, Canada, Chile, Denmark, Fiji, Finland, Great Britain (England, Scotland, Wales, and the Isle of Man), Iceland, New Zealand, Northern Ireland, Norway, Republic of Ireland, Sweden, and Switzerland.

(b) *Countries where *S. enteritidis*, phage-type 4, is considered to exist.* (1) *S. enteritidis*, phage-type 4, is considered to exist in all countries of the world except those listed in paragraph (b)(2) of this section.

(2) The following countries are considered to be free of *S. enteritidis*, phage-type 4: Canada.

(c) *Carcasses, and parts or products of carcasses, from countries where VVND is considered to exist.* Carcasses, and parts or products of carcasses, of poultry, game birds, or other birds may be imported only in accordance with this section if they: are of poultry, game birds, or other birds that were raised or slaughtered in any country where VVND is considered to exist (see paragraph (a) of this section); are imported from any country where VVND is considered to exist; or are moved into or through any country where VVND is considered to exist at any time before importation or during shipment to the United States.

(1) Carcasses of game birds may be imported if eviscerated, with heads and feet removed. Viscera, heads, and feet removed from game birds are ineligible for entry into the United States.



(2) Carcasses, or parts or products of carcasses, of poultry, game birds, and other birds may be imported for consignment to any museum, educational institution or other establishment that has provided the Administrator with evidence that it has the equipment, facilities, and capabilities to store, handle, process, or disinfect such articles so as to prevent the introduction or dissemination of viscerotropic velogenic Newcastle disease into the United States, and that is approved by the Administrator.<sup>12</sup>

(3) Carcasses, or parts or products of carcasses, of poultry, game birds, and other birds, may be imported if packed in hermetically sealed containers and if cooked by a commercial method after such packing to produce articles that are shelf-stable without refrigeration.

(4) Carcasses, or parts or products of carcasses, of poultry, game birds, and other birds may be imported if thoroughly cooked, and if, upon inspection by a representative of the United States Department of Agriculture at the port of arrival, the carcasses or parts or products thereof have a thoroughly cooked appearance throughout.

(5) Carcasses or parts or products of carcasses, of poultry, game birds, and other birds that do not otherwise qualify for importation under paragraph (c) of this section may be imported only if the importer applies to, and is granted a permit by the Administrator authorizing such importation. Permission will be given only when the Administrator determines that such importation will not constitute a risk of introduction or dissemination of viscerotropic velogenic Newcastle disease into the United States. Application for a permit may be made in accordance with paragraph (e) of this section.

(d) *Eggs (other than hatching eggs) from countries where VVND or S. enteritidis is considered to exist.* Eggs (other than hatching eggs<sup>13</sup>) from poultry, game birds, or other birds may be imported only in accordance with this section if they: Are laid by poultry, game birds, or other birds that were raised in any country where VVND or *S. enteritidis*, phage-type 4, is considered to exist (see paragraphs (a) and (b) of this section); are imported from any country where VVND or *S. enteritidis*, phage-type 4, is considered to exist; or are moved into or through any country

where VVND or *S. enteritidis*, phage-type 4, is considered to exist at any time before importation or during shipment to the United States.

(1) *With a certificate.* The eggs may be imported if they are accompanied by a certificate signed by a salaried veterinarian of the national government of the country of origin and:

(i) The eggs are imported in cases marked with the identity of the flock of origin and sealed with the seal of the national government of the country of origin.

(ii) The certificate accompanying the eggs is presented to an authorized inspector when the eggs reach the port of arrival in the United States.

(iii) The certificate identifies the flock of origin and shows the country of origin, the port of embarkation, the port of arrival, the name and address of the exporter and importer, the total number of eggs, and cases of eggs, shipped with the certificate, and the date the certificate was signed.

(iv) The certificate states that the eggs qualify for importation in accordance with this section.

(v) No more than 90 days before the certificate was signed, a salaried veterinary officer of the national government of the country of origin inspected the flock of origin and found no evidence of communicable diseases of poultry.

(vi) The eggs were washed, to remove foreign material from the surface of the shells, and sanitized on the premises of origin with a hypochlorite solution of from 100 ppm to 200 ppm available chlorine.

(vii) The eggs were packed on the premises of origin in previously unused cases.

(viii) Before leaving the premises of origin, the cases in which the eggs were packed were sealed with a seal of the national government of the country of origin by the salaried veterinarian who signed the certificate.

(ix) And, if the eggs were laid in any country where VVND is considered to exist (see paragraph (a) of this section):

(A) No VVND occurred on the premises of origin or on adjoining premises during the 90 days before the certificate was signed.

(B) There is no evidence that the flock of origin was exposed to VVND during the 90 days before the certificate was signed.

(C) The eggs are from a flock of origin found free of VVND in one of the following ways:

(1) Sentinel birds<sup>14</sup> were present in the flock of origin for at least 60 days

before the certificate was signed. There was at least 1 sentinel bird per 1,000 poultry, with at least 30 sentinel birds per house. The sentinel birds remained free of clinical and immunological evidence of VVND as demonstrated by negative hemagglutination inhibition tests conducted on blood samples drawn at 10-day intervals by a salaried veterinary officer of the national government of the country of origin. The tests were conducted in a laboratory located in the country of origin, and the laboratory was approved to conduct the tests by the national government of that country; or

(2) Once every week, beginning at least 60 days before the certificate was signed, a salaried veterinary officer of the national government of the country of origin collected carcasses of all poultry that died during that week, and the carcasses were examined for VVND using the embryonated egg inoculation technique. Once a month, beginning at least 60 days before the certificate was signed, a salaried veterinary officer of the national government of the country of origin collected tracheal and cloacal swabs from not less than 10 percent of the poultry in the flock, and the swabs were tested for VVND. All examinations and tests were conducted in a laboratory located in the country of origin, and the laboratory was approved to conduct the tests and examinations by the national government of that country. All results were negative for VVND.

(x) And, if the eggs were laid in any country where *S. enteritidis*, phage-type 4 is considered to exist (see paragraph (b) of this section):

(A) No salmonellosis caused by *S. enteritidis* occurred on the premises of origin or on adjoining premises during the 90 days before the certificate was signed.

(B) There is no evidence that the flock of origin was exposed to *S. enteritidis* during the 90 days before the certificate was signed.

(C) The eggs are from a flock of origin found free of *S. enteritidis* as follows:

(1) At least 60 days before the certificate was signed, a veterinary medical officer of the national government of the country of origin took a blood specimen from a representative sample of at least 300 poultry in each house, or, if any house contained fewer than 300 poultry, from all the poultry in that house. The blood specimens were tested for *S. enteritidis* with *Salmonella pullorum* or *S. enteritidis* antigen using a tube or plate test. The tests were

Services, Animal and Plant Health Inspection Service, 4700 River Road Unit 33, Riverdale, MD 20737-1228.

<sup>12</sup> The names and addresses of approved establishments may be obtained from, and requests for approval may be made to the National Center for Import and Export, 4700 River Road Unit 39, Riverdale, Maryland 20737-1231.

<sup>13</sup> The requirements for importing hatching eggs are contained in part 93 of this chapter.

<sup>14</sup> For information on sources of sentinel birds, contact the Operational Support Staff, Veterinary

conducted in a laboratory located in the country of origin, and the laboratory was approved to conduct the tests by the national government of that country.

(2) Beginning the week after the flock was tested and found negative as required in paragraph (d)(1)(x)(C)(I) of this section, and continuing once a week thereafter, a salaried veterinarian of the national government of the country of origin collected 25 carcasses, or 10 percent of the carcasses, whichever was greater, of all the poultry that died in each house during the previous week. The carcasses were bacteriologically examined and found negative for *S. enteritidis*. The examinations were conducted in a laboratory located in the country of origin, and the laboratory was approved to conduct the examinations by the national government of that country.

(3) After the blood specimens were drawn as required in paragraph (d)(1)(x)(C)(I) of this section, no poultry were added to the flock of origin until a blood specimen from each was tested for *S. enteritidis* with *Salmonella pullorum* or *S. enteritidis* antigen using a plate or tube test, and the specimen was found negative. The tests were conducted in a laboratory located in the country of origin, and the laboratory was approved to conduct the tests by the national government of that country.

(2) *To an approved establishment for breaking and pasteurization.* The eggs may be imported if they are moved from the port of arrival in the United States, under seal of the United States Department of Agriculture, to an approved establishment<sup>15</sup> for breaking and pasteurization. Establishments will be approved when the Administrator determines that pasteurization and sanitation procedures for handling the eggs, and for disposing of egg shells, cases, and packing materials, are adequate to prevent the introduction of VVND or *S. enteritidis*, phage-type 4, into the United States.

(3) *For scientific, educational, or research purposes.* The eggs may be imported if they are imported for scientific, educational, or research purposes and the Administrator has determined that the importation can be made under conditions that will prevent the introduction of VVND or *S. enteritidis*, phage-type 4, into the United States. The eggs must be accompanied by a permit obtained from APHIS prior to the importation in accordance with paragraph (e) of this section, and they

must be moved and handled as specified on the permit to prevent the introduction of VVND or *S. enteritidis*, phage-type 4, into the United States.

(4) *Other.* The eggs may be imported when the Administrator determines that the eggs have been cooked or processed or will be handled in a manner that will prevent the introduction of VVND or *S. enteritidis*, phage-type 4, into the United States. The eggs must be accompanied by a permit obtained from APHIS prior to the importation in accordance with paragraph (e) of this section, and they must be moved and handled as specified on the permit to prevent the introduction of VVND or *S. enteritidis*, phage-type 4, into the United States.

(e) To apply for a permit, contact the Administrator, c/o National Center for Import and Export, 4700 River Road, Unit 39, Riverdale, 20737-1231.

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#### § 94.8 Disposal of meats ineligible for importation.

(a) Fresh, chilled, or frozen meats, prohibited importation under §§ 94.1 and 94.2, that come into the United States by ocean vessel and are offered for entry and refused admission into this country, shall be destroyed or otherwise disposed of as the Administrator may direct pursuant to section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), unless they are exported by the consignee within 48 hours, and meanwhile are retained under such isolation and other safeguards as the Administrator may require to prevent the introduction or dissemination of livestock or poultry diseases into the United States.

(b) Fresh, chilled, or frozen meats prohibited importation under §§ 94.1 and 94.2, that come into the United States aboard an airplane or railroad car and are refused entry into this country, shall be destroyed or otherwise disposed of as the Administrator may direct pursuant to section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), unless they are exported by the consignee within 24 hours, and meanwhile are retained under such isolation and other safeguards as the Administrator may require to prevent the introduction or dissemination of livestock or poultry diseases into the United States.

(c) Fresh, chilled, or frozen meats prohibited importation under §§ 94.1 and 94.2 that come into the United States by any means other than ocean vessel, airplane, or railroad car and are refused entry into this country, shall be destroyed or otherwise disposed of as the Administrator may direct pursuant

to section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), unless they are exported by the consignee within 8 hours on the same means of conveyance and meanwhile are retained under such isolation and other safeguards as the Administrator may require to prevent the introduction or dissemination of livestock or poultry diseases into the United States.

(d) Fresh, chilled, or frozen meats, prohibited importation under §§ 94.1 and 94.2, that come into the United States by any means but are not offered for entry into this country; and other animals, meats, and other articles prohibited importation under other sections of this part that come into the United States by any means, whether they are offered for entry into this country or not, shall be immediately detained, removed, destroyed or otherwise disposed of as the Administrator may direct at any time in accordance with section 2 of the Act of February 2, 1903, as amended, or section 2 of the Act of July 2, 1962 (21 U.S.C. 111, 134a).

#### § 94.9 Meat and other animal products; in-transit movement and handling.

(a) Any meat or other animal product that would be eligible for entry into the United States, as specified in the regulations in this part, may transit through the United States for immediate export if the following conditions are met:

(1) Notification of the transiting of such meat or other animal product is made by the importer to the Plant Protection and Quarantine Officer at the United States port of arrival prior to such transiting; and

(2) The meat or other animal product transited is contained in a sealed, leakproof carrier or container that must remain sealed while aboard the transporting carrier or other means of conveyance, or if the container or carrier in which the meat or other animal product is transported is offloaded in the United States for reshipment, it must remain sealed at all times.

(b) Meat or other animal products that are not otherwise eligible for entry into the United States in accordance with the regulations in this part may enter the United States through land border ports for transit through the United States and immediate export if the following conditions are met:

(1) The person desiring to move the meat or other animal products through the United States obtains a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors (VS Form 16-6). (An application for the

<sup>15</sup> The names and addresses of approved establishments may be obtained from, and requests for approval may be made to National Center for Import and Export, 4700 River Road Unit 39, Riverdale, MD 20737-1231.

permit may be obtained from the Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, Maryland 20737-1231.)

(2) The meat or other animal products are sealed in the region of origin in a leakproof container with serially numbered seals approved by APHIS, and the container remains sealed during the entire time that it is in transit across the United States, from the point of arrival to its exportation.

(3) The person moving the meat or other animal products through the United States notifies, in writing, the Plant Protection and Quarantine Officer at the United States port of arrival prior to such transiting. The notification must include the following information regarding the meat or other animal products:

- (i) Permit number;
- (ii) Times and dates of arrival in the United States;
- (iii) Time schedule and route to be followed through the United States; and
- (iv) Serial numbers of the seals on the containers.

(4) The meat and other animal products transit the United States under Customs bond and are exported from the United States within the time limit specified on the permit. Any meat and other animal products that have not been exported within the time limit specified on the permit or that have not been transited in accordance with the permit or applicable requirements of this part will be destroyed or otherwise disposed of as the Administrator may direct pursuant to section 2 of the Act of February 2, 1903, as amended (21 U.S.C. 111).

(c) Meat and other animal products from regions listed as R1 or R2 regions for restricted agents of ruminants or swine, that are not otherwise eligible for importation, may transit the United States for immediate export, provided the requirements of paragraph (a) of this section are met.

(d) Any meat or other animal products not otherwise eligible for entry into the United States, as provided in this part and part 95 of this chapter, may transit the United States for immediate export if the following conditions are met:

(1) Notification of the transiting of such meat or other animal product is made by the importer to the Plant Protection and Quarantine officer at the United States port of arrival prior to such transiting;

(2) The meat or other animal product is contained in a sealed, leakproof carrier or container, which remains sealed while aboard the transporting

carrier or other means of conveyance, or, if the container or carrier in which the meat or other animal product is transported is offloaded in the United States for reshipment, it remains sealed at all times;

(3) Such transit is limited to the maritime or airport port of arrival only, with no overland movement outside the airport terminal area or dock area of the maritime port; and

(4) The meat or other animal product is not held or stored for more than 24 hours at the maritime or airport port of arrival.

#### **§ 94.10 Milk and milk products.**

(a) The following milk products are exempt from the provisions of this part:

(1) Cheese, but not including cheese with liquid and not including cheese made with unpasteurized milk, and not including cheese containing any item that is regulated by other sections of this part, unless such item is independently eligible for importation into the United States under this part;

(2) Butter; and

(3) Butteroil.

(b) Milk and milk products originating in, or shipped from, any region classified as Risk Class R3, R4 or RU for rinderpest or foot-and-mouth disease may be imported into the United States if they are certified as having met the requirements of paragraphs (b) (1), (2), or (3) of this section:

(1) They are in a concentrated liquid form and have been processed by heat by a commercial method in a container hermetically sealed promptly after filling but before such heating, so as to be shelf stable without refrigeration.

(2) They are dry milk or dry milk products, including dry whole milk, nonfat dry milk, dried whey, dried buttermilk, and formulations that contain any such dry milk products, and are consigned directly to an approved establishment<sup>16</sup> for further processing

<sup>16</sup>The names and addresses of approved establishments or warehouses or information as to approved manner of processing, and request for approval of any such establishment, warehouse, or manner of processing may be made to the National Center for Import and Export Unit 40, 4700 River Road, Riverdale, MD 20737-1231. Any establishment or warehouse will be approved for the purpose of this section only if the operator has provided the Administrator with satisfactory evidence that the establishment or warehouse has the equipment, facilities, and capability to store, handle and process the imported dry milk or dry milk product subject to § 94.9(b)(2) in a manner which will prevent the introduction or dissemination of livestock diseases into the United States. Similarly, processing methods will be approved only if the Administrator determines they are adequate to prevent the introduction or dissemination of such diseases into the United States. Approval of any establishment or warehouse or processing method may be refused or withdrawn

in a manner approved by the Administrator as adequate to prevent the introduction or dissemination of livestock diseases into the United States. However, in specific cases, upon request by the importer to the Administrator, and with approval by the Administrator, they may be stored for a temporary period in an approved warehouse<sup>16</sup> under the supervision of an APHIS inspector pending movement to an approved establishment. Such products must be transported from the United States port of first arrival to an approved establishment or an approved warehouse, and from an approved warehouse to an approved establishment only under Department seals or seals of the U.S. Customs Service. Such seals may be broken only by such an inspector or other person authorized to do so by the Administrator. Such products may not be removed from the approved warehouse or approved establishment except upon special permission by the Administrator, and upon compliance with all the conditions and requirements specified by him or her for such movement in each specific case.

(3) Milk and milk products not exempted under paragraph (a) of this section and not of classes included within the provisions of paragraphs (b) (1) or (2) of this section may be imported if the importer first applies to and receives written permission from the Administrator authorizing such importation. Permission will be granted only when the Administrator determines that such action will not endanger the health of the livestock of the United States. Products subject to this provision include but are not limited to condensed milk, long-life milks such as sterilized milk, casein and caseinates, lactose, and lactalbumin.

(4) Small amounts of milk and milk products subject to the restrictions of this part may in specific cases be imported for purposes of examination, testing, or analysis, if the importer applies to and receives written approval for such importation from the Administrator. Approval will be granted only when the Administrator determines that such action will not

by the Administrator only after the operator thereof has been given notice of the proposed action and has had an opportunity to present his views thereon, and upon a determination by the Administrator that the conditions for approval are not met. Approval of an establishment or warehouse may also be withdrawn after such notice and opportunity if the Administrator determines that such imported dry milk or milk products have been stored, handled, or processed by the operator thereof other than at an approved establishment or warehouse or other than in an approved manner.

endanger the health of the livestock of the United States.

(c) Milk and milk products originating in and shipped from regions that are classified as Risk Class RN, R1, or R2 for rinderpest and foot-and-mouth disease, but that have entered a port or otherwise transited any region that is classified as Risk Class R3, R4 or RU for rinderpest or foot-and-mouth disease shall not be imported into the United States unless:

(1) The product was transported under serially numbered official seals applied at the point of origin of the shipment by an authorized representative of the country of such origin; except that, if any seal applied at the point of origin was broken by any foreign official to inspect the shipment, an authorized representative of that country applied a new serially numbered official seal to the hold, compartment, or container in which the milk or milk products were transported; and if any member of a ship's crew broke a seal, the serial number of the seal, the location of the seal, and the reason for breaking the seal were recorded in the ship's log.

(2) The numbers of such seals are listed on, or are on a list attached to, the bill of lading or similar document accompanying the shipment.

(3) Upon arrival of the carrier at the first United States port, an APHIS inspector determines that the seals are intact and that their numbers are in agreement with the numbers appearing on the accompanying document; Provided that, if the representative finds that any seal has been broken or has a different number than is recorded on the accompanying document, the milk or milk products may remain eligible for entry into the United States only if APHIS personnel are available to inspect the hold, compartment, or container, the cartons or other containers of milk or milk products, and all accompanying documentation; and also provided that the representative determines that such products meet all of the importation requirements, and the importer furnishes additional documentation (either copies of pages from the ship's log signed by the officer-in-charge, or certification from a foreign government that the original seal was removed and the new seal applied by officials of the government) that demonstrates to the satisfaction of the Administrator that the milk or milk products were not contaminated or exposed to contamination during movement from the region of origin to the United States.

(d) Milk and milk products from regions that are classified as Risk Class RN for disease agents affecting

ruminants may be imported into the United States if accompanied by documentation indicating the region of origin of the milk or milk product, and if they are not otherwise prohibited importation under paragraph (c) of this section.

(e) Milk or milk products imported from a region classified as R1 or R2 for rinderpest and foot-and-mouth disease must be accompanied by a certificate endorsed by a full-time, salaried veterinarian employed by the country of export. The certificate must state that the milk was produced and processed in a region that is classified as RN, R1 or R2 for rinderpest and foot-and-mouth disease, or that the milk product was processed in a foreign region that is classified as RN, R1, or R2 for rinderpest and foot-and-mouth disease, from milk produced in a region classified as RN, R1, or R2 for rinderpest and foot-and-mouth disease. The certificate must name the region in which the milk was produced and the foreign region in which the milk or milk product was processed. Further, the certificate must state that, except for movement under seal as described in § 94.10(c), the milk or milk product has never been in a region that is classified as R3, R4, or RU for rinderpest or foot-and-mouth disease. Milk or milk products from a region that is classified as RN, R1, or R2 for rinderpest and foot-and-mouth disease, that were processed in whole or in part from milk or milk products from a foreign region classified as R3, R4, or RU, may be imported into the United States in accordance with § 94.10(b)(3).

(f) Milk or milk products from regions listed that are classified as Risk Class R3, R4 or RU for *Brucella melitensis* shall enter the United States only under the following conditions:

(1) The milk must be pasteurized according to the Food and Drug Administration requirements of 21 CFR 131.3;

(2) Milk and milk products, including cheese, must meet the Food and Drug Administration requirements of 21 CFR part 1210 and any other applicable regulations for imported milk;

(3) Milk products, including cheese, must be prepared from milk treated as described in paragraph (f)(1) of this section before being used to manufacture milk products; and

(4) Milk or milk products must be processed in a facility where only milk or milk products are processed as described in paragraph (f)(1) of this section.

**§ 94.11 Dry-cured pork products from regions classified as Risk Class R3, R4, or RU for foot-and-mouth disease, rinderpest, African swine fever, hog cholera, or swine vesicular disease.**

A dry-cured ham, pork shoulder, or pork loin shall not be permitted importation into the United States from a region that is classified as Risk Class R3, R4, or RU for foot-and-mouth disease, rinderpest, African swine fever, hog cholera, or swine vesicular disease unless it meets the following conditions:

(a) The ham, pork shoulder, or pork loin came from a region determined by the Administrator to have and to enforce laws requiring the immediate reporting to the national veterinary services of that region any premises found to have any animal infected with foot-and-mouth disease, rinderpest, African swine fever, hog cholera, or swine vesicular disease;

(b) The ham, pork shoulder, or pork loin came from a swine that was not on any premises where foot-and-mouth disease, rinderpest, African swine fever, hog cholera, or swine vesicular disease exists or had existed within 60 days prior to slaughter;

(c) The ham, pork shoulder, or pork loin was accompanied from the slaughtering facility to the processing establishment by a numbered certificate issued by a person authorized by the government of the country of origin stating that the provisions of paragraph (b) of this section have been met;

(d) The ham, pork shoulder, or pork loin was processed as set forth in paragraph (h) of this section in only one processing establishment;<sup>17</sup>

(e) The ham, pork shoulder, or pork loin was processed in a processing establishment that, prior to the processing of any hams, pork shoulders, or pork loins in accordance with this section, was inspected by a veterinarian of APHIS and determined by the Administrator to be capable of meeting the provisions of this section for processing hams, pork shoulders, or pork loins for importation into the United States;

(f) The ham, pork shoulder, or pork loin was processed in a processing establishment for which the operator of the establishment has signed an agreement with APHIS within 12 months prior to receipt of the hams, pork shoulders, or pork loins for processing, stating that all hams, pork

<sup>17</sup> As a condition of entry into the United States, pork and pork products must also meet all of the requirements of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and the regulations thereunder (9 CFR part 301), including requirements that the pork or pork products be prepared only in approved establishments.

shoulders, or pork loins processed for importation into the United States will be processed only in accordance with the provisions of this part;

(g) Workers who handle fresh pork in the processing establishment where the dry-cured ham, pork shoulder, or pork loin was processed are required to shower and put on a full set of clean clothes, or to wait 24 hours after handling fresh pork, before handling hams, pork shoulders, or pork loins that have progressed in the aging/curing process as follows:

(1) In the case of Italian-type hams processed in accordance with paragraph (h)(1) of this section, those that have progressed beyond the final wash stage;

(2) In the case of Serrano hams or Iberian hams or pork shoulders processed in accordance with paragraphs (h)(2), (h)(3), or (h)(4) of this section, those that have progressed beyond salting; and

(3) In the case of Iberian pork loins processed in accordance with paragraph (h)(5) of this section, those that have progressed beyond being placed in a casing; and

(h) The dry-cured ham, pork shoulder, or pork loin was processed in accordance with this paragraph. Except for pork fat treated to at least 76 °C. (168.8 °F.), which may have been placed over the meat during curing, the dry-cured pork product must have had no contact with any other meat or animal product during processing:

(1) *Italian-type hams.* The ham was processed for a period of not less than 400 days in accordance with the following conditions: after slaughter the ham was held at a temperature of 0 to 3 °C. (3 to 34.7 °F.) for a minimum of 72 hours, during which time the "aitch" bone and the foot was removed and the blood vessels at the end of the femur were massaged to remove any remaining blood; thereafter the ham was covered with an amount of salt equal to 4 to 6 percent of the weight of the ham, with a sufficient amount of water added to ensure that the salt had adhered to the ham; thereafter the ham was placed for 5 to 7 days on racks in a chamber maintained at a temperature of 0 to 4 °C. (32 to 39.2 °F.) and at a relative humidity of 70 to 85 percent; thereafter the ham was covered with an amount of salt equal to 4 to 6 percent of the weight of the ham, with a sufficient amount of water added to ensure that the salt had adhered to the ham; thereafter the ham was placed for 21 days in a chamber maintained at a temperature of 0 to 4 °C. (32 to 39.2 °F.) and at a relative humidity of 70 to 85 percent; thereafter the salt was brushed off the ham; thereafter the ham was placed in a

chamber maintained at a temperature of 1 to 6 °C. (33.8 to 42.8 °F.) and at a relative humidity of 65–80 percent for between 52 and 72 days; thereafter the ham was brushed and rinsed with water; thereafter the ham was placed in a chamber for 5–7 days at a temperature of 15 to 23 °C. (59 to 73.4 °F.) and a relative humidity of 55–85 percent; thereafter the ham was placed for curing in a chamber maintained for a minimum of 314 days at a temperature of 15 to 20 °C. (59 to 68 °F.) and at a relative humidity of 65–80 percent at the beginning and increased by 5 percent every 2½ months until a relative humidity of 85 percent was reached.

(2) *Serrano hams.* Serrano hams were processed as follows (190-day minimum curing process):

(i) If the ham is received frozen, it was thawed in a chamber with relative humidity between 70 and 80 percent, with room temperature maintained at 12 to 13 °C. (53.6 to 55.4 °F.) for the first 24 hours, then at 13 to 14 °C. (55.4 to 57.2 °F.) until the internal temperature of the ham reached 3 to 4 °C. (37.4 to 39.2 °F.), at which point the blood vessels at the end of the femur were massaged to remove any remaining blood.

(ii) The ham was covered in salt and placed in a chamber maintained at a temperature from 0 to 4 °C. (32 to 39.2 °F.), with relative humidity between 75 and 95 percent, for a period no less than 0.65 days per kg., and no more than 2 days per kg., of the weight of the ham.

(iii) The ham was rinsed with water and/or brushed to remove any remaining surface salt.

(iv) The ham was placed in a chamber maintained at a temperature of 0 to 6 °C. (32 to 42.8 °F.), with a relative humidity of 70 to 95 percent, for no less than 40 and no more than 60 days.

(v) The ham was placed for curing in a chamber with a relative humidity of 60 to 80 percent and a temperature gradually raised in 3 phases, as follows:

(A) A temperature of 6 to 16 °C. (42.8 to 60.8 °F.), maintained for a minimum of 45 days;

(B) A temperature of 16 to 24 °C. (60.8 to 75.2 °F.), maintained for a minimum of 35 days; and

(C) A temperature of 24 to 34 °C. (75.2 to 93.2 °F.), maintained for a minimum of 30 days.

(vi) Finally, with the relative humidity unchanged at 60 to 80 percent, the temperature was lowered to 12 to 20 °C. (53.6 to 68 °F.) and maintained at that level for a minimum of 35 days, until at least 190 days after the start of the curing process; Except that: In a region that is classified as R3, R4, or RU for swine vesicular disease, the ham

must be maintained at that level an additional 370 days, until at least 560 days after the start of the curing process.

(3) *Iberian hams.* Iberian hams were processed as follows (365-day minimum curing process):

(i) If the ham was received frozen, it was thawed in a chamber with relative humidity between 70 and 80 percent, with room temperature maintained at 5.5 to 6.5 °C. (41.9 to 43.7 °F.) for the first 24 hours, then at 9.5 to 10.5 °C. (49.1 to 50.9 °F.) until the internal temperature of the ham reached 3 to 4 °C. (37.4 to 39.2 °F.), at which point the blood vessels at the end of the femur were massaged to remove any remaining blood.

(ii) The ham was covered in salt and placed in a chamber maintained at a temperature from 0 to 4 °C. (32 to 39.2 °F.), with relative humidity between 75 and 95 percent, and kept in the chamber for a period no less than 0.65 days per kg., and no more than 2 days per kg., of the weight of the ham.

(iii) The ham was rinsed with water and/or brushed to remove any remaining surface salt.

(iv) The ham was placed in a chamber maintained at a temperature of 0 to 6 °C. (32 to 42.8 °F.), with relative humidity of 70 to 95 percent, for no less than 40 and no more than 60 days.

(v) The ham was placed for curing in a chamber with a temperature of 6 to 16 °C. (42.8 to 60.8 °F.) and relative humidity of 60 to 80 percent for a minimum of 90 days.

(vi) The temperature was raised to 16 to 26 °C. (60.8 to 78.8 °F.) and the relative humidity reduced to 55 to 85 percent, for a minimum of 90 days.

(vii) Finally, with the relative humidity raised to 60 to 90 percent, the temperature was lowered to 12 to 22 °C. (53.6 to 71.6 °F.) and maintained at that level for a minimum of 115 days, until at least 365 days after the start of the curing process; Except that: In a region that is classified as R3, R4, or RU for swine vesicular disease, the ham must be maintained at that level an additional 195 days, until at least 560 days after the start of the curing process.

(4) *Iberian pork shoulders.* Iberian pork shoulders were processed as follows (240-day minimum curing process):

(i) If the pork shoulder was received frozen, it was thawed at a room temperature of 12 to 13 °C. (53.6 to 55.4 °F.), with the relative humidity between 75 and 85 percent, for approximately 24 hours, until the internal temperature reached 3 to 4 °C. (37.4 to 39.2 °F.), at which point the blood vessels in the scapular region were massaged to remove any remaining blood.

(ii) The pork shoulder was covered in salt and placed in a chamber maintained at a temperature of 0 to 4 °C. (32 to 39.2 °F.) with the relative humidity between 75 and 95 percent, for a period of no less than 0.65 days per kg., and no more than 2 days per kg., of the weight of the pork shoulder.

(iii) The pork shoulder was rinsed with water and/or brushed to remove any remaining surface salt.

(iv) The pork shoulder was placed in a chamber maintained at a temperature of 0 to 6 °C. (32 to 42.8 °F.) and a relative humidity of 70 to 95 percent for not less than 40 days and not more than 60 days.

(v) The pork shoulder was placed for curing in a chamber at a temperature of 6 to 16 °C. (42.8 to 60.8 °F.) and a relative humidity of 60 to 80 percent for a minimum of 90 days.

(vi) The temperature was raised to 16 to 26 °C. (60.8 to 78.8 °F.) and the relative humidity was changed to 55 to 85 percent, and those levels were maintained for a minimum of 90 days.

(vii) Finally, the temperature was reduced to 12 to 22 °C. (53.6 to 71.6 °F.) and the relative humidity was raised to 60 to 90 percent for a minimum of 45 days, until at least 240 days after the start of the curing process.

(5) *Iberian pork loins.* Iberian pork loins were processed as follows (130-day minimum curing process):

(i) If the pork loin was received frozen, it was thawed at a room temperature maintained at 11 to 12 °C. (51.8 to 53.6 °F.), with the relative humidity between 70 and 80 percent for the first 24 hours, then between 75 and 85 percent, until the loin's internal temperature reached 3 to 4 °C. (37.4 to 39.2 °F.), at which point the external fat, aponeurosis, and tendons were cleaned from the loin.

(ii) The pork loin was covered in a pickle preparation (25–30 grams of salt for each kilogram of pork loin) and placed in a chamber where it was maintained at a relative humidity of 75 to 95 percent and a temperature of 3 to 4 °C. (37.4 to 39.2 °F.) for 72 hours.

(iii) The pork loin was removed from the pickle preparation (25–30 grams of salt for each kilogram of pork loin), externally cleaned (brushed or rinsed), placed in an artificial casing, and fastened shut with a metal clip.

(iv) The pork loin was placed for curing in a chamber with a relative humidity of 60 to 90 percent and a temperature gradually raised in 3 phases, as follows:

(A) A temperature of 2 to 6 °C. (35.6 to 42.8 °F.), maintained for a minimum of 20 days;

(B) A temperature of 6 to 15 °C. (42.8 to 59.0 °F.), maintained for a minimum of 20 days;

(C) A temperature of 15 to 25 °C. (59.0 to 77.0 °F.), maintained for a minimum of 40 days;

(v) Finally, with the relative humidity unchanged at 60 to 80 percent and the temperature lowered to 0 to 5 °C. (32.0 to 41.0 °F.), the pork loin was vacuum-packed and maintained under those conditions for a minimum of 15 days, until at least 130 days after the start of the curing process.

(i)(1) The ham, if it is Italian-type ham processed in accordance with paragraph (h)(1) of this section, bears a hot iron brand or an ink seal (with the identifying number of the slaughtering establishment) that was placed thereon at the slaughtering establishment under the direct supervision of a person authorized to supervise such activity by the veterinary services of the national government of the country in which the region of origin is located bears a button seal (approved by the Administrator as being tamper-proof) on the hock that states the month and year the ham entered the processing establishment and a hot iron brand (with the identifying number of the processing establishment and the date salting began) that were placed thereon at the processing establishment immediately prior to salting, under the supervision of a person authorized to supervise such activity by the veterinary services of the national government of the country of origin;

(2) The dry-cured ham, if it is processed in accordance with paragraphs (h)(2) or (h)(3) of this section, or the dry-cured pork shoulder, if it is processed in accordance with paragraph (h)(4) of this section, bears an ink seal (with the identifying number of the slaughtering establishment) that was placed thereon at the slaughtering establishment under the direct supervision of a person authorized to supervise such activity by the veterinary services of the national government of the country of origin, and an ink seal (with the identifying number of the processing establishment and the date the salting began) that was placed thereon at the processing establishment, immediately prior to salting, under the supervision of a person authorized to supervise such activity by the veterinary services of the national government of the country of origin; or

(3) The dry-cured pork loin, if it is processed in accordance with paragraph (h)(5) of this section, is packaged with material that bears a seal of the government of the country of origin that was placed thereon at the slaughtering

establishment under the direct supervision of a person authorized to supervise such activity by the veterinary services of the national government of the country of origin, and bears a tamper-proof plastic tag, securely attached to the pork loin itself, that states the identifying number of the slaughtering establishment and the date the pork loin was placed in the pickle preparation under the supervision of a person authorized to supervise such activity by the veterinary service of the national government of the country of origin.

(j) The dry-cured ham, pork shoulder, or pork loin came from an establishment where a person authorized by the veterinary services of the national government of the country of origin to conduct activities under this paragraph maintained original records (which shall be kept for a minimum of 2 years) identifying the dry-cured ham, pork shoulder, or pork loin by the date it entered the processing establishment, by the slaughtering facility from which it came, and by the number of the certificate that accompanied the dry-cured ham, pork shoulder, or pork loin from the slaughtering facility to the processing establishment, and where such original records are maintained under lock and key by such person, with access to such original records restricted to officials of the government of the country of origin, officials of the United States government, and such person maintaining the records.

(k) The dry-cured ham, pork shoulder, or pork loin came from a processing establishment that allows the unannounced entry into the establishment of APHIS personnel, or other persons authorized by the Administrator, for the purpose of inspecting the establishment and records of the establishment.

(l) The dry-cured ham, pork shoulder, or pork loin was processed in accordance with one of the following criteria:

(1) The ham, if it is an Italian-type ham processed in accordance with paragraph (h)(1) of this section, was processed in a region that is classified as either an RN, R1, or R2 region for rinderpest, and which has, through the veterinary services of the country in which it is located, submitted to the Administrator a written statement stating that it conducts a program to authorize persons to supervise activities specified under this section;

(2) The Serrano ham, processed in accordance with paragraph (h)(2) of this section, and came from any breed of large, white swine, including but not limited to Landrace, Pietrain, Duroc,

Jersey, Hampshire, and Yorkshire breeds, and crosses of such breeds;

(3) The Iberian ham, processed in accordance with paragraph (h)(3) of this section, and came from a swine of the Iberico breed of pigs;

(4) The Iberian pork shoulder, processed in accordance with paragraph (h)(4) of this section, and came from a swine of the Iberico breed of pigs;

(5) The Iberian pork loin, if processed in accordance with paragraph (h)(5) of this section, and came from a swine of the Iberico breed of pigs.

(m) The dry-cured ham, pork shoulder, or pork loin came from a processing establishment that has entered into a trust fund agreement executed by the operator of the establishment or a representative of the establishment and APHIS, and that pursuant to the trust fund agreement is current in paying all costs for a veterinarian of APHIS to inspect the establishment (it is anticipated that such inspections will occur up to four times per year), including travel, salary, subsistence, administrative overhead, and other incidental expenses (including an excess baggage provision up to 150 pounds). In accordance with the terms of the trust fund agreement, the operator of the processing establishment must deposit with the Administrator an amount equal to the approximate costs for a veterinarian to inspect the establishment one time, including travel, salary, subsistence, administrative overhead and other incidental expenses (including an excess baggage provision up to 150 pounds), and as funds from that amount are obligated, bills for costs incurred based on official accounting records will be issued to restore the deposit to its original level. Amounts to restore the deposit to its original level must be paid within 14 days of receipt of such bills.

(n) The dry-cured ham, pork shoulder, or pork loin is accompanied at the time of importation into the United States by a certificate issued by a person authorized to issue such certificates by the veterinary services of the national government of the country of origin, stating:

(1) That all the provisions of this section have been complied with, including paragraphs (h) and (l) of this section; and

(2) The paragraph of this section under which the dry-cured ham, pork shoulder, or pork loin was processed; and stating further that, if the product covered by the certificate:

(i) Is an Italian-type ham processed under paragraph (h)(1) of this section, it was processed for a minimum of 400 days;

(ii) Is a Serrano ham processed under paragraph (h)(2) of this section, it was:

(A) Processed for a minimum of 190 days in a region that is classified as either RN, R1, or R2 for swine vesicular disease, in a facility authorized by the veterinary services of the national government of the country in which the region of origin is located to process meat only from regions classified as either RN, R1, or R2 for swine vesicular disease; or

(B) Processed for a minimum of 560 days in any region, in a facility that may also process meat from regions that are classified as R3, R4, or RU for swine vesicular disease;

(iii) Is an Iberian ham processed under paragraph (h)(3) of this section, it was:

(A) Processed for a minimum of 365 days in a region that is classified as RN, R1, or R2 for swine vesicular disease, in a facility authorized by the veterinary services of the national government of the country in which the region is located to process only meat from countries that are classified as RN, R1, or R2 for swine vesicular disease; or

(B) Processed for a minimum of 560 days in any region, in a facility that may also process meat from regions that are classified as R3, R4, or RU for swine vesicular disease;

(iv) Is a dry-cured pork shoulder, it was processed in accordance with paragraph (h)(4) of this section for a minimum of 240 days; or

(v) Is a dry-cured pork loin, it was processed in accordance with paragraph (h)(5) of this section for a minimum of 130 days.

(Approved by the Office of Management and Budget under control number 0579-0015)

**§ 94.12 Ruminant meat and edible products from ruminants that have been in regions classified as Risk Class R3, R4, or RU for bovine spongiform encephalopathy.**

(a) *Gelatin*. The importation of gelatin derived from ruminants that have been in any region that is classified as Risk Class R3, R4 or RU for bovine spongiform encephalopathy is prohibited unless the following conditions have been met:

(1) The gelatin must be imported for use in human food, human pharmaceutical products, photography, or some other use that will not result in the gelatin coming in contact with ruminants in the United States.

(2) The person importing the gelatin must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials

and Organisms and Vectors by filing a permit application on VS form 16-3.<sup>18</sup>

(3) The permit application must state the intended use of the gelatin and the name and address of the consignee in the United States.

(b) *Transit shipment of articles*. Fresh, chilled, or frozen meat, and edible products other than meat, that are prohibited importation into the United States from regions that are classified as Risk Class R3, R4 or RU for bovine spongiform encephalopathy may transit the United States for immediate export if the following conditions are met:

(1) The person moving the articles obtains a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16-3.

(2) The articles are sealed in leakproof containers bearing serial numbers during transit. Each container must remain sealed during the entire time that it is in the United States.

(3) The person moving the articles notifies, in writing, the Plant Protection and Quarantine Officer at both the place in the United States where the articles will arrive and the port of export prior to such transit. The notification must include the:

(i) United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors permit number;

(ii) Times and dates of arrival in the United States;

(iii) Times and dates of exportation from the United States;

(iv) Mode of transportation; and

(v) Serial numbers of the sealed containers.

(4) The articles transit the United States in Customs bond.

(Approved by the Office of Management and Budget under control number 0579-0015)

**§ 94.13 Movement of meat and meat products.**

Meat or meat products consigned from the port of arrival to an approved establishment under the provisions of this part (e.g., § 94.5 (f) and (i)) must be moved from the port of arrival to the approved establishment under Customs seals or seals of the Administrator, and must be otherwise handled as the Administrator may direct in order to guard against the introduction and dissemination of contagious diseases of livestock. Seals applied under this section may not be broken except by persons authorized to do so by the Administrator.

<sup>18</sup> VS form 16-3 may be obtained from National Center for Import and Export, 4700 River Road Unit 40, Riverdale, MD 20737-1231.



**§ 94.14 Seizure, quarantine, and disposal of meat and meat products.**

Meat or meat products imported into the United States from a region that is classified as Risk Class R3, R4, or RU for foot-and-mouth disease, rinderpest, African swine fever, bovine spongiform encephalopathy, hog cholera, and/or swine vesicular disease that do not meet the requirements specified in this part shall be seized, quarantined, and disposed of as the Administrator may direct in order to guard against the introduction and dissemination of the contagion of the disease.

**§ 94.15 Cancellation of compliance agreements.**

Any compliance agreement may be canceled orally or in writing by the inspector who is supervising its enforcement whenever the inspector finds that such person has failed to comply with the provisions of this section or any conditions imposed pursuant to such provisions. If the cancellation is oral, the decision and the reasons therefor shall be confirmed in writing, as promptly as circumstances allow. Any person whose compliance agreement has been canceled may appeal the decision, in writing, within ten (10) days after receiving written notification of the cancellation. The appeal shall state all of the facts and reasons upon which the person relies to show that the compliance agreement was wrongfully canceled. The Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator.

52. Part 95 would be revised to read as follows:

**PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES**

Sec.

- 95.1 Definitions.
- 95.2 Region of origin.
- 95.3 Prohibited animal byproducts.
- 95.4 Bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants in regions classified as Risk Class R3, R4, or RU for bovine spongiform encephalopathy according to criteria in § 92.3 of this chapter.
- 95.5 Untanned hides and skins; requirements for unrestricted entry.
- 95.6 Untanned hides and skins; importations permitted subject to restrictions.

- 95.7 Wool, hair, and bristles; requirements for unrestricted entry.
- 95.8 Wool, hair, and bristles; importations permitted subject to restrictions.
- 95.9 Glue stock; requirements for unrestricted entry.
- 95.10 Glue stock; importations permitted subject to restrictions.
- 95.11 Bones, horns, and hoofs for trophies or museum; disinfected hoofs.
- 95.12 Bones, horns, and hoofs; importations permitted subject to restrictions.
- 95.13 Bone meal for use as fertilizer or as feed for domestic animals; requirements for entry.
- 95.14 Blood meal, tankage, meat meal, and similar products, for use as fertilizer or animal feed; requirements for entry.
- 95.15 Blood meal, blood albumin, intestines, and other animal byproducts for industrial use; requirements for unrestricted entry.
- 95.16 Blood meal, blood albumin, intestines, and other animal byproducts for industrial use; importations permitted subject to restrictions.
- 95.17 Glands, organs, ox gall, and like materials; requirements for unrestricted entry.
- 95.18 Glands, organs, ox gall, and like materials; importations permitted subject to restrictions.
- 95.19 Animal stomachs.
- 95.20 Animal manure.
- 95.21 Hay and straw; requirements for unrestricted entry.
- 95.22 Hay and straw; importations permitted subject to restrictions.
- 95.23 Previously used meat covers; importations permitted subject to restrictions.
- 95.24 Methods for disinfection of hides, skins, and other materials.
- 95.25 Transportation of restricted import products; placarding cars and marking billing; unloading enroute.
- 95.26 Railroad cars, trucks, boats, aircraft and other means of conveyance, equipment or containers, yards, and premises; cleaning and disinfection.
- 95.27 Regulations applicable to products from territorial possessions.
- 95.28 Hay or straw and similar material from tick-infested regions.

Authority: 21 U.S.C. 111, 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d).

**§ 95.1 Definitions.**

Whenever in the regulations in this part the following words, names, or terms are used they shall be construed, respectively, to mean:

**Administrator.** The Administrator of the Animal and Plant Health Inspection Service, or any other employee of the Animal and Plant Health Inspection Service, United States Department of Agriculture, delegated to act in the Administrator's stead.

**Animal and Plant Health Inspection Service.** The Animal and Plant Health Inspection Service of the United States Department of Agriculture (APHIS).

**Animal byproducts.** Hides, skins, hair, wool, glue stock, bones, hoofs, horns, bone meal, hoof meal, horn meal, blood meal, meat meal, tankage, glands, organs, or other parts or products of ruminants and swine unsuitable for human consumption.

**Approved chlorinating equipment.** Equipment approved by the Administrator as effective for the disinfection of effluents against the contagions of foot-and-mouth disease, rinderpest, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease.

**Approved establishment.** An establishment approved by the Administrator for the receipt and handling of restricted import animal byproducts.

**Approved sewerage system.** A drainage system equipped and operated so as to carry and dispose of sewage without endangering livestock through the contamination of streams or fields and approved by the Administrator.

**Approved warehouse.** A warehouse having facilities approved by the Administrator for the handling and storage, apart from other merchandise, of restricted import products.

**Blood meal.** Dried blood of animals.

**Bone meal.** Ground animal bones and hoof meal and horn meal.

**Department.** The United States Department of Agriculture.

**Glue stock.** Fleshings, hide cuttings and parings, tendons, or other collagenous parts of animal carcasses.

**Hay and straw.** Dried grasses, clovers, legumes, and similar materials or stalks or stems of various grains, such as barley, oats, rice, rye, and wheat.

**Inspector.** An employee of the Animal and Plant Health Inspection Service authorized to perform duties required under this part.

**Meat meal or tankage.** The rendered and dried carcasses or parts of the carcasses of animals.

**Region.** Any defined geographic land region identifiable by geological, political or surveyed boundaries.

**Risk Class Regions.** Foreign exporting regions designated by APHIS according to the results of a risk assessment as defined in § 92.1 of this chapter, and determined by criteria as set forth in § 92.3 of this chapter are incorporated herein and are applicable to this part.

**Shipped directly.** Shipped (moved, transported, or otherwise shipped) without unloading and without stopping except for refueling, or for traffic conditions such as traffic lights or stop signs.

**United States.** All of the States of the United States, the District of Columbia,



Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other territories and possessions of the United States.

#### § 95.2 Region of origin.

No products or materials specified in the regulations in this part may be imported into the United States unless there be shown upon the commercial invoice, or in some other manner satisfactory to the Administrator, the name of the region of origin of such product or material: *Provided*, That the region of origin shall be construed to mean:

(a) In the case of an animal byproduct, the region in which such product was taken from an animal or animals; and

(b) In the case of other materials, the region in which such materials were produced.

#### § 95.3 Prohibited animal byproducts.

The importation of any animal byproduct taken or removed from an animal affected with anthrax, foot-and-mouth disease, rinderpest, bovine spongiform encephalopathy, Lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, or swine vesicular disease is prohibited.

#### § 95.4 Bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants in regions classified as Risk Class R3, R4 or RU for bovine spongiform encephalopathy according to criteria in § 92.3 of this chapter.

(a) Except as provided in paragraphs (c) and (d) of this section, the importation of bone meal, blood meal, meat meal or tankage, offal, fat, and glands from ruminants that have been in any region classified as a Risk Class R3, R4, or RU region for bovine spongiform encephalopathy is prohibited.

(b) Except as provided in paragraphs (c) and (d) of this section, the importation of serum from ruminants that have been in any region classified as a Risk Class R3, R4, or RU region for bovine spongiform encephalopathy is prohibited, except that serum from ruminants may be imported for scientific, educational, or research purposes if the Administrator determines that the importation can be made under conditions that will prevent the introduction of bovine spongiform encephalopathy into the United States. Serum from ruminants imported in accordance with this paragraph must be accompanied by a permit issued by APHIS in accordance with § 104.3 of this chapter, and must be moved and handled as specified on the permit.

(c) *Articles for cosmetics.* The importation of collagen, collagen

products, amniotic liquids or extracts, placental liquids or extracts, serum albumin, and serocolostrum, derived from ruminants that have been in any region classified as Risk Class R3, R4, or RU region bovine spongiform encephalopathy is prohibited unless the following conditions are met:

(1) The article is imported for use as an ingredient in cosmetics.

(2) The person importing the article obtains a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16-3.<sup>1</sup>

(3) The permit application states the intended use of the article and the name and address of the consignee in the United States.

(d) *Transit shipment of articles.* Articles that are prohibited importation into the United States in accordance with this section may transit the United States for immediate export if the following conditions are met:

(1) The person moving the articles obtains a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16-3.<sup>1</sup>

(2) The articles must be sealed in leakproof containers bearing serial numbers during transit. Each container must remain sealed with a Customs seal or seal of the Administrator during the entire time that it is in the United States, and must be otherwise handled as the Administrator may direct in order to guard against the introduction and dissemination of contagious diseases of livestock.

(3) The person moving the articles must notify, in writing, the Plant Protection and Quarantine Officer at both the place in the United States where the articles will arrive and the port of export prior to such transit. The notification must include the:

(i) United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors permit number;

(ii) Times and dates of arrival in the United States;

(iii) Times and dates of exportation from the United States;

(iv) Mode of transportation; and

(v) Serial numbers of the sealed containers.

(4) The articles must transit the United States in Customs bond.

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<sup>1</sup> VS form 16-3 may be obtained from the National Center for Import and Export, Veterinary Services, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231.

#### § 95.5 Untanned hides and skins; requirements for unrestricted entry.

Untanned hides and/or skins of cattle, buffalo, sheep, goats, other ruminants, and swine that do not meet the conditions of requirements specified in any one of paragraphs (a) to (e) of this section may not be imported except subject to handling and treatment in accordance with § 95.6 after arrival at the port of entry:

(a) Hides or skins originating in and shipped directly from a region classified as a Risk Class RN, R1, or R2 region for foot-and-mouth disease, rinderpest, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, or swine vesicular disease may be imported without further restriction.

(b) Hides or skins may be imported without other restriction if found upon inspection by an inspector, or by certificate of the shipper or importer satisfactory to said inspector, to be hard dried hides or skins.

(c) Abattoir hides or skins taken from animals slaughtered under national government inspection in a region<sup>2</sup> and in an abattoir in which is maintained an inspection service determined by the Administrator to be adequate to assure that they have been removed from animals found at time of slaughter to be free from anthrax, foot-and-mouth disease, rinderpest, bovine spongiform encephalopathy, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease, and to assure further the identity of such materials until loaded upon the transporting vessel, may be imported into the United States without other restriction if accompanied by a certificate bearing the seal of the proper department of such national government and signed by an official veterinary inspector of such region showing that the therein described hides or skins were taken from animals slaughtered in such specified abattoir and found free from anthrax, foot-and-mouth, rinderpest, bovine spongiform encephalopathy, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease.

(d) Hides or skins may be imported without other restriction if shown upon inspection by an inspector, or by certificate of the shipper or importer satisfactory to said inspector, to have been pickled in a solution of salt

<sup>2</sup> Names of regions of this character will be furnished upon request made to the National Center for Import and Export, Veterinary Services, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231.

containing mineral acid and packed in barrels, casks, or tight cases while still wet with such solution.

(e) Hides or skins may be imported without other restriction if shown upon inspection by an inspector, or by certificate of the shipper or importer satisfactory to said inspector, to have been treated with lime in such manner and for such period as to have become dehaired and to have reached the stage of preparation for immediate manufacture into products ordinarily made from rawhide.

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**§ 95.6 Untanned hides and skins; importations permitted subject to restrictions.**

Hides or skins imported or offered for importation into the United States that do not meet the conditions or requirements of § 95.5 shall be handled and treated in the following manner after arrival at the port of entry:

(a) They shall be consigned from the coast or border port of arrival to an approved establishment and shall be subject to disinfection by such method or methods as the Administrator may prescribe unless the said establishment discharges drainage into an approved sewerage system or has approved chlorinating equipment adequate for the proper disinfection of effluents: *provided, however*, that, upon permission of the Administrator, such hides or skins may be stored for a temporary period in approved warehouses under bond, and under the supervision of an inspector: *and provided further*, that in-transit or in-bond shipments of hides or skins may go forward under customs seals from a coast or border port of arrival, with the approval of an inspector at said port, to another port in the United States for consumption entry subject to the other provisions of this section.

(b) They must be moved from the coast or border port of arrival or, in case of in-transit or in-bond shipments, from the interior port to the approved establishment in cars or trucks or in vessel compartments with no other materials contained therein, sealed with seals of the Department, that may not be broken except by inspectors or other persons authorized by the Administrator to do so, or without sealing as aforesaid and with other freight when packed in tight cases or casks acceptable to the inspector in charge at the port of entry.

(c) They must be handled at the approved establishment under the direction of an inspector in a manner approved by the Administrator to guard against the dissemination of foot-and-

mouth disease, rinderpest, bovine spongiform encephalopathy, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease. They may not be removed therefrom except upon special permission of the Administrator, and upon compliance with all the conditions and requirements of this section relative to the movement of the said hides and skins from the port of arrival to the said establishment.

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**§ 95.7 Wool, hair, and bristles; requirements for unrestricted entry.**

Wool, hair, or bristles derived from ruminants and/or swine that do not meet the conditions or requirements specified in any one of paragraphs (a) to (d) of this section may not be imported except subject to handling and treatment in accordance with § 95.8 after their arrival at the port of entry: *provided, however*, that no bloodstained wool, hair, or bristles may be imported under any condition:

(a) Such wool, hair, or bristles may be imported without other restriction if originating in and shipped directly from a region classified as a Risk Class RN, R1, or R2 region for foot-and-mouth disease, rinderpest, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease.

(b) Wool or hair clipped from live animals or pulled wool or hair may be imported without other restriction if the said wool or hair is reasonably free from animal manure in the form of dung locks or otherwise.

(c) Wool, hair, or bristles taken from sheep, goats, cattle, or swine, when such animals have been slaughtered under national government inspection in a region<sup>3</sup> and in an abattoir in which is maintained an inspection service determined by the Secretary of Agriculture to be adequate to assure that such materials have been removed from animals found at time of slaughter to be free from anthrax, foot-and-mouth disease, rinderpest, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease, and to assure further the identity of such materials until loaded upon the transporting vessel, may be imported without other restriction if accompanied by a certificate bearing the seal of the proper department of said national government and signed by an official veterinary inspector of such region showing that

the therein described wool, hair, or bristles were taken from animals slaughtered in such specified abattoir and found free from anthrax, foot-and-mouth disease, rinderpest, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease.

(d) Wool, hair, or bristles that have been scoured, thoroughly washed, or dyed may be imported without other restriction.

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**§ 95.8 Wool, hair, and bristles; importations permitted subject to restrictions.**

Wool, hair, or bristles imported into the United States that do not meet the conditions or requirements of § 95.7 must be handled and treated in the following manner after arrival at the port of entry:

(a) Such wool, hair, or bristles must be consigned from the coast or border port of arrival to an approved establishment: *provided, however*, that upon permission by the Administrator, such wool, hair, or bristles may be stored for a temporary period in approved warehouses under bond and under the supervision of an inspector: and *provided further*, that in-transit or in-bond shipments of wool, hair, or bristles may go forward under customs seals from a coast or border port of arrival, with the approval of an inspector at said port, to another port for consumption entry, subject to the other provisions of this section.

(b) Such wool, hair, or bristles must be moved from the coast or border port of arrival or, in the case of in-transit or in-bond shipments, from the interior port to the approved establishment in cars or trucks or in vessel compartments with no other materials contained therein, sealed with seals of the Department, that may not be broken except by inspectors or other persons authorized by the Administrator to do so, or without sealing as aforesaid and with other freight when packed in tight cases acceptable to an inspector.

(c) Such wool, hair, or bristles must be handled at the approved establishment under the direction of an inspector, in a manner approved by the Administrator to guard against the dissemination of foot-and-mouth disease, rinderpest, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease. Such products may not be removed therefrom except upon special permission of the Administrator, and upon compliance with all the conditions and

<sup>3</sup> See footnote 2 in § 95.5.

requirements of this section relative to the movement of the said wool, hair, or bristles from the port of arrival to the said establishment.

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**§ 95.9 Glue stock; requirements for unrestricted entry.**

Glue stock that does not meet the conditions or requirements specified in any one of paragraphs (a) to (c) of this section may not be imported into the United States, except subject to handling and treatment in accordance with § 95.10 after arrival at the port of entry:

(a) Glue stock originating in and shipped directly from a region classified as a Risk Class RN, R1, or R2 region for foot-and-mouth disease, rinderpest, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease may be imported without other restriction.

(b) Glue stock may be imported without other restriction if found upon inspection by an inspector, or by certificate of the shipper or importer satisfactory to said inspector, to have been properly treated by acidulation or by soaking in milk of lime or a lime paste; or to have been dried so as to render each piece of the hardness of a sun-dried hide.

(c) Glue stock taken from cattle, sheep, goats, or swine slaughtered under national government inspection in a region and in an abattoir in which is maintained an inspection service determined by the Secretary of Agriculture to be adequate to assure that such materials have been removed from animals found at time of slaughter to be free from anthrax, foot-and-mouth disease, rinderpest, bovine spongiform encephalopathy, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease, and to assure further the identity of such materials until loaded upon the transporting vessel, may be imported without other restriction if accompanied by a certificate bearing the seal of the proper department of said national government and signed by an official veterinary inspector of such country showing that the therein described glue stock was taken from animals slaughtered in such specified abattoir and found free from anthrax, foot-and-mouth disease, rinderpest, bovine spongiform encephalopathy, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease.

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**§ 95.10 Glue stock; importations permitted subject to restrictions.**

Glue stock imported into the United States that does not meet the conditions or requirements of § 95.9 must be handled and treated in the following manner after arrival at the port of entry:

(a) It must be consigned from the coast or border port of arrival to an approved establishment and shall be subject to disinfection by such method or methods as the Administrator may prescribe, unless the said establishment discharges drainage into an approved sewerage system or has an approved chlorinating equipment adequate for the proper disinfection of effluents:

*Provided, however,* that upon permission by the Administrator, glue stock may be stored for a temporary period in approved warehouses under bond and under the supervision of an inspector: And provided further, that in-transit or in-bond shipments of glue stock may go forward under customs seals from a coast or border port of arrival with the approval of an inspector at said port to another port for consumption entry, subject, after arrival at the latter port, to the other provisions of this section.

(b) It must be moved from the coast or border port of arrival or, in case of in-transit or in-bond shipments, from the interior port to the approved establishment in cars or trucks or in vessel compartments with no other materials contained therein, sealed with seals of the Department, that may not be broken except by inspectors or other persons authorized by the Administrator to do so, or without sealing as aforesaid and with other freight when packed in tight cases or casks acceptable to an inspector at the port of entry.

(c) It must be handled at the approved establishment under the direction of an inspector in a manner approved by the Administrator to guard against the dissemination of foot-and-mouth disease and rinderpest. It may not be removed therefrom except upon special permission of the Administrator, and upon compliance with all the conditions and requirements of this section relative to the movement of the said glue stock from the port of arrival to the said establishment.

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**§ 95.11 Bones, horns, and hoofs for trophies or museum; disinfected hoofs.**

(a) Clean, dry bones, horns, and hoofs, that are free from undried pieces of hide, flesh, and sinew and are imported

as trophies or for consignment to museums may be imported without other restrictions.

(b) Clean, dry, hoofs disinfected in the country of origin may be imported without other restrictions if the following conditions are met:

(1) The hoofs have been disinfected using one of the following methods:

(i) Dry heat at 180 °F (82.3 °C) for 30 minutes;

(ii) Soaking in boiling water for 20 minutes;

(iii) Soaking in a 0.1 percent chlorine bleach solution for 2 hours;

(iv) Soaking in a 5 percent acetic acid solution for 2 hours; or

(v) Soaking in a 5 percent hydrogen peroxide solution for 2 hours.

(2) The hoofs are accompanied by a certificate issued by the national government of the country of origin and signed by an official veterinary inspector of that country stating that the hoofs have been disinfected and describing the manner in which the disinfection was accomplished.

**§ 95.12 Bones, horns, and hoofs; importations permitted subject to restrictions.**

Bones, horns, and hoofs, imported into the United States, that do not meet the conditions or requirements of § 95.11 must be handled and treated in the following manner after arrival at the port of entry:

(a) They must be consigned from the coast or border port of arrival to an approved establishment having facilities for their disinfection or their conversion into products customarily made from bones, horns, or hoofs: provided, however, that in-transit or in-bond shipments of bones, horns, or hoofs may go forward under customs seals from a coast or border port of arrival, with the approval of an inspector at said port, to another port for consumption entry subject to the other provisions of this section.

(b) They must be moved from the coast or border port of arrival or, in the case of in-transit or in-bond shipments, from the interior port to the approved establishment in cars or trucks with no other materials contained therein, sealed with seals of the Department, that may not be broken except by inspectors or other persons authorized by the Administrator to do so, or without sealing as aforesaid and with other freight when packed in tight cases or casks acceptable to an inspector at the port of entry.

(c) They must be handled at the approved establishment under the direction of an inspector, in a manner to guard against the dissemination of

anthrax, foot-and-mouth disease, rinderpest, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease, and the bags, burlap, or other containers thereof, before leaving the establishment, must be disinfected by heat or otherwise, as directed by the Administrator, or burned at the establishment. They may not be removed therefrom except upon special permission of the Administrator, and upon compliance with all the conditions and requirements of this section relative to the movement of the said bones, horns, and hoofs.

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**§ 95.13 Bone meal for use as fertilizer or as feed for domestic animals; requirements for entry.**

Steamed or degelatinized or special steamed bone meal, that, in the normal process of manufacture, has been prepared by heating bone under a minimum of 20 pounds steam pressure for at least one hour at a temperature of not less than 250 °F (121 °C), may be imported into the United States without further restrictions for use as fertilizer or as feed for domestic animals if such products are free from pieces of bone, hide, flesh, and sinew and contain no more than traces of hair and wool. Bone meal for use as fertilizer or as feed for domestic animals that does not meet these requirements will not be eligible for entry.

**§ 95.14 Blood meal, tankage, meat meal, and similar products, for use as fertilizer or animal feed; requirements for entry.**

Dried blood or blood meal, lungs or other organs, tankage, meat meal, wool waste, wool manure, and similar products, for use as fertilizer or as feed for domestic animals, may not be imported into the United States except subject to handling and treatment in accordance with paragraphs (a), (b), and (c) of § 95.16, unless:

(a) Such products originated in and were shipped directly from a region classified as a Risk Class RN, R1, or R2 region for foot-and-mouth disease, rinderpest, bovine spongiform encephalopathy, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease; or

(b) The inspector at the port of entry finds that such products have been fully processed by tanking under live steam or by dry rendering.

**§ 95.15 Blood meal, blood albumin, intestines, and other animal byproducts for industrial use; requirements for unrestricted entry.**

Blood meal, blood albumin, bone meal, intestines, or other animal materials intended for use in the industrial arts may not be imported into the United States except subject to handling and treatment in accordance with § 95.16, unless such products originated in and were shipped directly from a region classified as Risk Class RN, R1, or R2 region for foot-and-mouth disease, rinderpest, bovine spongiform encephalopathy, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease.

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**§ 95.16 Blood meal, blood albumin, intestines, and other animal byproducts for industrial use; importations permitted subject to restrictions.**

Blood meal, blood albumin, bone meal, intestines, or other animal materials intended for use in the industrial arts, that do not meet the conditions or requirements of § 95.15 must be handled and treated in the following manner after arrival at the port of entry:

(a) They must be consigned from the coast or border port of arrival to an approved establishment: *provided, however*, that upon permission by the Administrator, they may be stored for a temporary period in approved warehouses under bond and under the supervision of an inspector: *and provided further*, that in-transit or in-bond shipments of such products may go forward under customs seals from a coast or border port of arrival, with the approval of an inspector at said port, to another port of consumption entry, subject after arrival at the latter port to the other provisions of this section.

(b) They must be moved from the coast or border port of arrival or, in the case of in-transit or in-bond shipments, from the interior port to the approved establishment in cars or trucks or in vessel compartments with no other materials contained therein, sealed with seals of the Department, that may not be broken except by inspectors or other persons authorized by the Administrator to do so, or without sealing as aforesaid and with other freight when packed in tight cases or casks acceptable to an inspector at the port of entry.

(c) They must be handled at the approved establishment under the direction of an inspector in a manner to guard against the dissemination of foot-and-mouth disease, rinderpest, bovine

spongiform encephalopathy, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease. They may not be removed therefrom except upon special permission of the Administrator, and upon compliance with all the conditions and requirements of this section relative to the movement of the said products from the port of arrival to the said establishment.

(Approved by the Office of Management and Budget under control number 0579-0015)

**§ 95.17 Glands, organs, ox gall, and like materials; requirements for unrestricted entry.**

Glands, organs, ox gall or bile, bone marrow, and various like materials derived from domestic ruminants or swine, intended for use in the manufacture of pharmaceutical products may not be imported except subject to handling and treatment in accordance with § 95.18, unless such glands, organs, or materials originated in and were shipped directly from a region classified as a Risk Class RN, R1, or R2 region for foot-and-mouth disease, rinderpest, bovine spongiform encephalopathy, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease.

**§ 95.18 Glands, organs, ox gall, and like materials; importations permitted subject to restrictions.**

Glands, organs, ox gall or bile, bone marrow, and various like materials derived from domestic ruminants or swine, that do not meet the requirements of § 95.17 may be imported for pharmaceutical purposes only if they are in tight containers and consigned to an approved establishment: *provided, however*, that upon special permission of the Administrator, they may be stored for a temporary period in approved warehouses under bond and under the supervision of an inspector. They must be handled and processed at the said establishment in a manner approved by the Administrator, and the containers must be destroyed or disinfected as prescribed by him or her. They shall not be removed therefrom except upon special permission of the Administrator, and upon compliance with all the conditions and requirements of this section relative to the movement of the said glands, organs, ox gall, and like materials from the port of arrival to the said establishment.

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**§ 95.19 Animal stomachs.**

Stomachs or portions of the stomachs of ruminants or swine, other than those imported for food purposes under the meat-inspection regulations of the Department, may not be imported into the United States without permission from the Administrator. Importations permitted shall be subject to such restrictions as the Administrator may deem necessary in each instance.

(Approved by the Office of Management and Budget under control number 0579-0015)

**§ 95.20 Animal manure.**

Manure of horses, cattle, sheep, other ruminants, and swine may not be imported except upon permission from the Administrator. Importations permitted shall be subject to such restrictions as the Administrator may deem necessary in each instance: *Provided, however,* That manure produced by animals while in transit to the United States shall be subject only to the requirements of the Department regulations governing the importation of livestock and other animals.

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**§ 95.21 Hay and straw; requirements for unrestricted entry.**

Except as provided in § 95.28, hay or straw may not be imported into the United States except subject to handling and treatment in accordance with § 95.22 after arrival at the port of entry, unless such hay or straw originated in and was shipped directly from a region classified as a Risk Class RN, R1, or R2 region for foot-and-mouth disease, rinderpest, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, swine vesicular disease, and restricted ectoparasites.

**§ 95.22 Hay and straw; importations permitted subject to restrictions.**

Except as provided in § 95.28, hay or straw that does not meet the conditions or requirements of § 95.21 must be handled and treated in the following manner upon arrival at the port of entry:

(a) Hay or straw packing materials must be burned or disinfected at the expense of the importer or consignee in the manner and within the time directed by the Administrator to prevent the introduction of disease.

(b) Hay or straw for use as feeding material, bedding, or similar purposes must be stored and held in quarantine for a period of not less than 90 days in an approved warehouse at the port of entry and must be otherwise handled as directed by the Administrator to prevent the introduction of disease.

**§ 95.23 Previously used meat covers; importations permitted subject to restrictions.**

Cloth or burlap that has been used to cover fresh or frozen meats originating in any region classified as a Risk Class R3, R4, or RU region for rinderpest, foot-and-mouth disease, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease may not be imported into the United States except under the following conditions:

(b) The cloth or burlap must be consigned from the coast or border port of arrival to an establishment specifically approved for the purpose by the Administrator.

(c) The cloth or burlap must be immediately moved from the coast or border port of arrival, or in the case of in-transit or in-bond shipments from the interior port, to the approved establishment, in railroad cars or trucks, or in vessel compartments, with no other material contained therein, sealed with seals of the Department, that may not be broken, except by inspectors or other persons authorized by the Administrator: *provided, however,* that upon permission of the Administrator, such cloth or burlap may be stored for a temporary period in approved warehouses at the port of arrival under bond and under the supervision of an inspector. The material must be disinfected and otherwise handled at the establishment under the direction of an inspector in a manner approved by the Administrator to guard against the dissemination of foot-and-mouth disease, rinderpest, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease, and the material may not be removed therefrom, except upon special permission of the Administrator, until all of the conditions and requirements of this section have been complied with.

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**§ 95.24 Methods for disinfection of hides, skins, and other materials.**

Hides, skins, and other materials required by the regulations in this part to be disinfected must be subjected to disinfection by methods found satisfactory and approved by the Administrator.

**§ 95.25 Transportation of restricted import products; placarding cars and marking billing; unloading enroute.**

(a) Transportation companies or other operators of cars, trucks or other vehicles carrying import products or materials moving under restriction,

other than those in tight cases or casks, must affix to and maintain on both sides of all such vehicles durable placards not less than 5½ by 6 inches in size, on which must be printed with permanent black ink and in boldface letters not less than 1½ inches in height the words "Restricted import product." These placards must also bear the words "Clean and disinfect this car or truck." Each of the waybills, conductors' manifests, memoranda, and bills of lading pertaining to such shipments must have the words "Restricted import product, clean and disinfect car or truck," plainly written or stamped upon its face. If for any reason the placards required by this section have not been affixed to each car, or the billing has not been marked by the initial or the connecting carrier, or the placards have been removed, destroyed, or rendered illegible, the placards must be immediately affixed or replaced and the billing marked by the initial or connecting carrier, the intention being that the billing accompanying the shipment must be marked and each car, truck or other vehicle placarded as specified in this section from the time such shipment leaves the port of entry until it is unloaded at final destination and the cars, trucks or other vehicles are cleaned and disinfected as required by § 95.26.

(b) If it is necessary to unload enroute any of the materials or products transported in a placarded car, truck or other vehicle as provided in this section, the car, truck or other vehicle from which the transfer is made and any part of the premises in or upon which the product or material may have been placed in the course of unloading or reloading must be cleaned and disinfected by the carrier, in accordance with the provisions of § 95.26, and the said carrier must immediately report the matter, by telephone or FAX, to the Import/Export Products Staff, National Center for Import Export, APHIS, USDA, Telephone: 301-734-3294. Such report must include the following information: Nature of emergency; place where product or material was unloaded; original points of shipment and destination; number and materials of the original car or truck; and number and initials of the car, truck or other vehicle into which the product or material is reloaded in case the original car or truck is not used.

(Approved by the Office of Management and Budget under control number 0579-0015)

**§ 95.26 Railroad cars, trucks, boats, aircraft and other means of conveyance, equipment or containers, yards, and premises; cleaning and disinfection.**

Railroad cars, trucks, boats, aircraft and other means of conveyance, equipment or containers, yards, and premises that have been used in the transportation, handling, or storing of restricted import products or materials, other than those contained in leakproof cases or casks, must be cleaned and disinfected with a disinfectant approved for use in this part under the supervision of an inspector within the time and in the manner provided in this section. Except as provided in paragraph (a) of this section, such railroad cars, trucks, boats, aircraft and other means of conveyance, equipment or containers, may not be moved in interstate or foreign commerce until they have been so treated.

(a) *Cars to be cleaned and disinfected by final carrier at destination.* Cars required by this part to be cleaned and disinfected must be so treated by the final carrier at destination as soon as possible after unloading and before the same are moved from such final destination for any purpose: Provided, however, That when the products or materials are destined to points at which an inspector or other authorized representative of APHIS is not maintained or present or where proper facilities cannot be provided, the transportation company must seal, bill, and forward the cars in which the products or materials were transported to a point to be agreed upon between the transportation company and APHIS, and the transportation company must there clean and disinfect the said cars under the supervision of an inspector.

(b) *Methods of cleaning and disinfecting.* (1) Railroad cars, trucks, aircraft and means of conveyance other than boats, equipment or containers, required by this part to be cleaned and disinfected must be treated in the following manner: Collect all litter and other refuse therefrom and destroy by burning or other method approved by the Administrator; clean the exterior and interior of the cars or trucks, and the areas of the aircraft or other means of conveyance, equipment or containers that may have been contaminated; and saturate the entire surface with a permitted disinfectant approved for use in this part.

(2) Boats required by this part to be cleaned and disinfected must be treated in the following manner: Collect all litter and other refuse from the decks, compartments, and all other parts of the boat used for the transportation of the products or materials covered by this

part, and from the portable chutes or other appliances, fixtures or areas used in loading and unloading same, and destroy the litter and other refuse by burning or by other methods approved by the Administrator, and saturate the entire surface of the said decks, compartments, and other parts of the boat with a permitted disinfectant approved for use in this part.

(3) Buildings, sheds, and premises required by this part to be disinfected must be treated in the following manner: Collect all litter and other refuse therefrom and destroy the same by burning or other approved methods, and saturate the entire surface of the fencing, chutes, floors, walls, and other parts with a permitted disinfectant approved for use in this part.

(c) *Permitted disinfectants.* The disinfectants permitted for use in disinfecting railroad cars, trucks, boats, aircraft and other means of conveyance, equipment or containers, yards, and premises against infection of foot-and-mouth disease, rinderpest, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease are freshly prepared solutions of:

(1) Sodium carbonate (4 percent) in the proportion of 1 pound to 3 gallons of water;

(2) Sodium carbonate (4 percent) plus sodium silicate (0.1 percent) in the proportion of 1 pound of sodium carbonate plus sodium silicate to 3 gallons of water; or

(3) Sodium hydroxide (Lye) prepared in a fresh solution in the proportion of not less than 1 pound avoirdupois of sodium hydroxide of not less than 95 percent purity to 6 gallons of water, or one 13½-ounce can to 5 gallons of water.<sup>4</sup>

(d) *Permitted disinfectants against ticks.* The disinfectants permitted for use against tick infestation are liquefied phenol (U. S. P. strength 87 percent phenol) in the proportion of at least 6 fluid ounces to one gallon of water; or chlorinated lime (U. S. P. strength 30 percent available chlorine) in the proportion of one pound to three gallons of water; or any one of the cresylic disinfectants permitted by APHIS in §§ 71.10 and 71.11 of this chapter, in the proportion of at least four fluid ounces to one gallon of water; or through application of boiling water if the treatment is against rinderpest, or foot-

<sup>4</sup> Due to the extreme caustic nature of sodium hydroxide solution, precautionary measures such as the wearing of rubber gloves, boots, raincoat and goggles should be observed. An acid solution such as vinegar shall be kept readily available in case any of the sodium hydroxide should come in contact with the body.

and-mouth disease, lumpy skin disease (Neethling virus), Sheep pox, goat pox, African swine fever, hog cholera, and swine vesicular disease and tick infestation; or other disinfectants or treatments approved by the Administrator.

**§ 95.27 Regulations applicable to products from Territorial possessions.**

The regulations in this part shall be applicable to all the products and materials specified in this part that are imported into the United States from any place under the jurisdiction of the United States to which the animal-quarantine laws of this country do not apply.

**§ 95.28 Hay or straw and similar material from tick-infested regions.**

Hay or straw, grass, or similar material from tick-infested pastures, ranges, or premises may disseminate the contagion of splenic, Southern or Texas fever when imported for animal feed or bedding; therefore, such hay or straw, grass, or similar materials may not be imported into the United States from regions classified as Risk Class R3, R4, or RU regions for restricted ticks, unless such material is first disinfected with a disinfectant specified in § 95.26(d).

**PART 96—RESTRICTION OF IMPORTATIONS OF FOREIGN ANIMAL CASINGS OFFERED FOR ENTRY INTO THE UNITED STATES**

53. The authority citation for part 96 would continue to read as follows:

Authority: 21 U.S.C. 111, 136, 136a; 7 CFR 2.22, 2.80, and 371.2(d).

54. In § 96.1, the definition of *Administrator* would be revised to read as follows:

**§ 96.1 Definitions.**

*Administrator.* The Administrator of the Animal and Plant Health Inspection Service or any other employee of the Animal and Plant Health Inspection Service, United States Department of Agriculture, delegated to act in the Administrator's stead.

\* \* \* \* \*

55. Section 96.2 would be revised to read as follows:

**§ 96.2 Casings from regions classified as Risk Class R3, R4, or RU for African swine fever or bovine spongiform encephalopathy.**

(a) The importation of swine casings that originated in or were processed in a region that is classified as Risk Class R3, R4, or R4 for African swine fever is prohibited, with the following exception: Swine casings that originated

in a region designated as Risk Class RN, R1, or R2 for African swine fever may be processed in a region classified as R3, R4, or RU for African swine fever, if processed in an establishment that meets the criteria set forth in § 94.5(d) of this chapter.

(b) The importation of ruminant casings that originated in or were processed in any region that is classified as Risk Class R3, R4, or RU for bovine spongiform encephalopathy is prohibited, except for bovine stomachs.

**§ 96.3 [Amended]**

56. Section 96.3, paragraph (a), would be amended by removing the words "foreign country" and adding in their place the words "foreign region".

57. Section 96.10 would be amended by revising the introductory text of paragraph (a) to read as follows:

**§ 96.10 Uncertified casings; transportation for disinfection; original shipping containers; disposition of salt.**

(a) Foreign animal casings imported into the United States without certification may be forwarded in customs custody to a USDA-approved facility for disinfection under APHIS supervision and release by the United States Customs authorities, provided that before being transported over land in the United States each and every container of such casings shall be disinfected by the application of a solution of sodium hydroxide prepared as follows:

\* \* \* \* \*

58. Sections 96.15 and 96.16 would be removed.

**PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND ANIMAL SEMEN**

59. The authority citation for part 98 would continue to read as follows:

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 103–105, 111, 134a, 134b, 134c, 134d, 134f, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d).

60. In part 98, the heading for subpart A would be revised to read:

**Subpart A—Ruminant and Swine Embryos from Regions Classified as Risk Class RN, R1, or R2 for Rinderpest and Foot-and-Mouth Disease; and Embryos of Horses and Asses**

61. In § 98.3, the introductory text, paragraph (a), and paragraph (f) would be revised to read as follows:

**§ 98.3 General conditions.**

Except as provided in subpart B of this part, an animal embryo shall not be

imported into the United States unless it is from a region that is classified as Risk Class RN, R1, or R2 for rinderpest and foot-and-mouth disease, and:

(a) The embryo is exported to the United States from the region in which it was conceived;

\* \* \* \* \*

(f) There is no basis for denying an import permit for the donor sire or donor dam under § 93.304(a)(2) of this chapter for horses, § 93.404(a)(2) of this chapter for ruminants, and § 93.504(a)(2) of this chapter for swine;

\* \* \* \* \*

**§ 98.4 [Amended]**

62. In § 98.4, paragraphs (c)(1) and (c)(5), the word "country" would be removed and the word "region" would be added in its place.

63. Section 98.6 would be revised to read as follows:

**§ 98.6 Ports of entry.**

An embryo shall not be imported into the United States unless at a port of entry listed in § 93.303 of this chapter for horses, § 93.403 of this chapter for ruminants, or § 92.503 of this chapter for swine.

**§ 98.7 [Amended]**

64. In § 98.7, paragraph (g) would be amended by removing the word "country" and adding the word "region" in its place.

65. In part 98, the heading for subpart B would be revised to read:

**Subpart B—Ruminant and Swine Embryos from Regions Classified as Risk Class R3, R4, or RU for Rinderpest or Foot-and-Mouth Disease**

66. Section 98.12, paragraph (a), would be revised to read as follows:

**§ 98.12 General prohibitions.**

(a) Ruminant and swine embryos may not be imported from regions that are classified as Risk Class R3, R4, or RU for rinderpest or foot-and-mouth disease, except in accordance with this subpart.

\* \* \* \* \*

67. Section 98.13, paragraph (a), would be revised to read as follows:

**§ 98.13 Import permit.**

(a) Ruminant and swine embryos and all test samples required by this subpart may be imported into the United States from regions that are classified as Risk Class R3, R4, or RU for rinderpest or foot-and-mouth disease only if accompanied by import permits issued by the Animal and Plant Health Inspection Service (APHIS).

\* \* \* \* \*

68. In § 98.14, the introductory text to paragraph (a) would be revised to read as follows:

**§ 98.14 Health certificate.**

(a) Ruminant and swine embryos may be imported into the United States from a region that is classified as R3, R4, or RU for rinderpest or foot-and-mouth disease only if accompanied by a health certificate issued by:

\* \* \* \* \*

69. In § 98.15, paragraph (a)(5)(ii) would be amended by removing the word "country" and replacing it with the word "region" and the introductory text of the section would be revised to read as follows:

**§ 98.15 Health requirements.**

Ruminant and swine embryos may be imported from a region that is classified as Risk Class R3, R4, or RU for rinderpest or foot-and-mouth disease only if all of the following conditions are met:

\* \* \* \* \*

70. In § 98.16, the introductory text, the first sentence would be revised to read as follows:

**§ 98.16 The embryo collection unit.**

Ruminant and swine embryos may be imported into the United States from a region that is classified as R3, R4, or RU for rinderpest or foot-and-mouth disease only if they were conceived, collected, processed, and stored prior to importation at an embryo collection unit.

\* \* \* \* \*

**§ 98.17 [Amended]**

71. In § 98.17, paragraphs (f)(6)(i) and (f)(6)(ii) would be amended by removing the word "country" each time it appears, and adding in its place the word "region."

72. Section 98.34 would be amended as follows:

a. The word "country" would be removed and the word "region" would be added in its place in the following places:

i. Paragraph (a)(1), each time it appears;

ii. Paragraph (a)(3), each time it appears;

iii. Paragraph (c)(1)(ii);

iv. Paragraph (c)(3);

v. Paragraph (c)(4); and

vi. Paragraph (c)(5).

b. Paragraph (a)(2) would be revised to read as set forth below.

c. Paragraph (c), the heading and introductory text, would be revised to read as set forth below:

**§ 98.34 Import permits for poultry semen and animal semen.**

(a) \* \* \*

(2) An application for permit to import animal semen will be denied for semen from ruminants or swine from any region that is classified as Risk Class R3, R4, or RU for foot-and-mouth disease or rinderpest, except as provided in paragraph (c) of this section.

\* \* \* \* \*

(c) *Animal semen from regions classified as Risk Class R3, R4, or RU for foot-and-mouth disease or rinderpest.* Importation of semen of ruminants or swine, originating in any region that is classified as Risk Class R3, R4, or RU for foot-and-mouth disease or rinderpest is prohibited, except that semen from ruminants or swine originating in such a region may only be imported into the United States at the port of New York and later released from such port, provided the following conditions have been fulfilled:

\* \* \* \* \*

Done in Washington, DC, this 26th day of March 1996.

Lonnie J. King,

*Administrator, Animal and Plant Health Inspection Service.*

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