

veterinary biological products. We carefully considered the comments we received. They are discussed below.

One commenter supported the proposed rule as written.

The second commenter believed that the rule should include a provision to allow treatment for those animals that show certain clinical signs indicative of susceptibility to challenge (defined in an Outline of Production), rather than waiting until such animals have progressed to a point when death is certain to occur without therapeutic intervention.

The Animal and Plant Health Inspection Service (APHIS) cannot accept this recommendation because use of clinical signs as a test endpoint may result in a product that is sufficiently potent to protect against a mild challenge that causes certain disease symptoms, but not sufficiently potent to protect against severe clinical disease or death from natural challenge. APHIS notes that the level of challenge used in animal potency tests may have a significant effect on the results of tests. In order to ensure that a product will have adequate potency to protect animals against severe clinical disease or death resulting from natural challenge, many standard requirements for veterinary biological products currently require a challenge that is strong enough to cause death in the test animals. In such cases, assessment of susceptibility to challenge based solely on clinical signs would not provide an equivalent alternative to one based on death or the expectation of death.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposal as a final rule, without change.

**Executive Order 12866 and Regulatory Flexibility Act**

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

The rule provides that animals used in testing biological products which become ill, accidentally injured, or exhibit unfavorable reactions as a result of factors not due to the test could be removed from the test and be treated or humanely destroyed. The rule also provides for the treatment or humane destruction of animals which are expected to die as a result of the testing of a veterinary biologic. The objective of the rule is to provide humane alternatives when conducting such tests

in order to eliminate any unnecessary testing of animals. It simply provides an option which was not previously available for the treatment of test animals under certain conditions. Therefore, the rule is not anticipated to increase costs to producers of veterinary biological products.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

**Executive Order 12372**

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

**Executive Order 12778**

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

**Paperwork Reduction Act**

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

**List of Subjects in 9 CFR Part 117**

Animal biologics, Animals. Accordingly, 9 CFR part 117 is amended as follows:

**PART 117—ANIMALS AT LICENSED ESTABLISHMENTS**

1. The authority citation for part 117 continues to read as follows:

**Authority:** 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

2. In § 117.4, new paragraphs (d) and (e) are added to read as follows:

**§ 117.4 Test animals.**

\* \* \* \* \*

(d) During the course of a test, animals that are injured or show clinical signs of illness or unfavorable reactions that are not due to the test may be removed from the test and treated or humanely destroyed. If sufficient

animals do not remain for the test to be evaluated, the test shall be declared inconclusive and may be repeated.

(e) Test animals that show clinical signs of illness that are due to the test may be treated or humanely destroyed if the illness has progressed to a point (defined in the filed Outline of Production) when death is certain to occur without therapeutic intervention. When interpreting the results of the test, the animals that were treated or humanely destroyed because of illness due to the test and the animals that have died from illness due to the test prior to being humanely destroyed shall be combined into a common statistic of mortality due to the test.

Done in Washington, DC, this 14th day of August 1995.

**Terry Medley,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 95–20592 Filed 8–18–95; 8:45 am]

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**Food Safety and Inspection Service**

**9 CFR Part 381**

[Docket No. 94–027F]

RIN 0583–AB84

**Transporting Undenatured Poultry Feet to Other Establishments for Processing Prior to Export**

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is amending the poultry products inspection regulations to permit the transportation of undenatured poultry feet from one federally inspected poultry establishment to another establishment for further processing before the feet are exported. Establishments are permitted to ship undenatured poultry feet to another establishment for export provided that the receiving establishment maintains records that identify the incoming undenatured poultry feet, their source, and their location at all times during processing. The receiving establishment is required to certify in writing that the poultry feet have not been, nor will be, commingled with other products intended for human consumption within the United States. This rulemaking was initiated in response to a petition submitted to the Agency by DanD Food Marketing, Inc., Springfield, MO.

**EFFECTIVE DATE:** September 20, 1995.

**FOR FURTHER INFORMATION CONTACT:** Dr. Paula M. Cohen, Director, Regulations Development, Policy, Evaluation and Planning Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700; (202) 720-7164.

**SUPPLEMENTARY INFORMATION:**

**Background**

Section 9 of the Poultry Products Inspection Act (21 U.S.C. 458) prohibits the sale or transportation, from an official establishment, of any slaughtered poultry from which the feet have not been removed, except as may be authorized by regulations of the Secretary. Section 381.147(b) of the poultry products inspection regulations (9 CFR 381.147(b)) permits the processing of poultry feet for use as human food when handled in a manner approved by the [FSIS] Administrator in specific cases. Section 381.190(b) also permits poultry feet collected and handled in an acceptable manner at an official establishment to be shipped from the official establishment and in commerce directly for export for further processing as human food, if they have been examined, found to be suitable for such purpose, and labeled as prescribed.

In 1994, DanD Food Marketing, Inc., Springfield, MO, a poultry slaughterer and processor, petitioned FSIS to amend the poultry products inspection regulations to permit the transportation of undenatured poultry feet from one or more establishments to another establishment, where the feet would be further processed for export. The petitioner provided FSIS with documents that set forth the procedures and safeguards that would be used by the receiving establishment when handling and processing the undenatured poultry feet. FSIS has reviewed the information submitted by the petitioner and has determined that the proposed procedures would ensure that the undenatured poultry feet are neither diverted to nor commingled with any product intended for domestic use.

The foreign demand for poultry feet continues to increase. However, as currently written, 9 CFR 381.190(b) does not permit an exporter of poultry feet to ship undenatured product from one slaughter establishment to a central establishment for processing before export. To prevent the possible commingling of the poultry feet with poultry products intended for domestic consumption, exporters must ship the poultry feet directly overseas from the original slaughter establishment. As a result, it is difficult for the exporters to

keep up with the foreign demand for the poultry feet due to a lack of space and manpower in some slaughter establishments. This final rule allows processing establishments to use a central establishment for pre-export processing of poultry feet provided the establishment official at the receiving processing establishment remains accountable for the identification of the source and the location of the poultry feet at all times prior to their export. When poultry feet are handled in accordance with 9 CFR 381.190(c), sanitary transportation conditions are maintained, and the possibility of the product becoming contaminated or adulterated while en route to another establishment for processing prior to export is minimized. Therefore, we are amending the regulations to allow the transportation of undenatured poultry feet from one or more establishments to another official establishment for further processing before export.

Section 381.175(a) of the poultry products inspection regulations requires that every person, firm, or corporation engaged in certain activities related to poultry production and distribution maintain records which fully and correctly disclose all transactions involved in the business. Section 381.175(b) details the kinds of records that must be maintained, but does not specify the format for such recordkeeping. "Transactions" have been traditionally interpreted by FSIS to be sales, purchases, transportation, receipt, or handling of poultry products that would demonstrate the sources of the poultry products.

This final rule requires those processing establishments that receive undenatured poultry product from slaughter establishments for further processing before export overseas to maintain records that identify the incoming product, i.e., poultry feet, and their source, and identify the location of the product at all times during the processing and preparation for export. In addition, an establishment official must certify that the poultry product has not been and will not be commingled with any products intended for human consumption within the United States.

These recordkeeping requirements enable FSIS and the receiving processing establishments to accurately identify and locate the undenatured poultry product intended for export while still in the central establishment. As a result, FSIS can easily determine that the product has not been commingled with any products intended for domestic consumption.

**Discussion of Comments**

FSIS received one comment in response to the proposed rule. The commenter, a turkey products processor, is in favor of the proposal for the following reason: having the ability to transport products of this nature, specifically turkey feet, between facilities will allow the company to process the product for the ultimate consumer in a safe and sanitary manner, using the most economical means possible.

**Executive Order 12866**

This final rule has been determined to be not significant and therefore has not been reviewed by the Office of Management and Budget.

**Executive Order 12778**

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the Poultry Products Inspection Act (PPIA) from imposing any marking or packaging requirements on federally inspected poultry products that are in addition to, or different than, those imposed under the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over poultry products that are outside official establishments for the purpose of preventing the distribution of poultry products that are misbranded or adulterated under the PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the PPIA, States that maintain poultry inspection programs must impose requirements on State inspected products and establishments that are at least equal to those required under the PPIA. These States may, however, impose more stringent requirements on such State inspected products and establishments.

This final rule is not intended to have retroactive effect.

There are no applicable administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this final rule. However, the administrative procedures specified in 9 CFR § 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the PPIA.

**Effect on Small Entities**

The Administrator has determined that this final rule will not have a significant economic impact on a

substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). This final rule requires establishments that receive undenatured poultry product for processing prior to export to record the source of the incoming product, identify its location at all times during processing and preparation for export, and certify that the product has not been, nor will be, commingled with any product intended for domestic use. While some establishments may have to change their current recordkeeping practices and make changes to their production practices to accommodate the proposed recordkeeping requirements, no significant economic impact will be imposed on the establishments.

**Paperwork Requirements**

Under this final rule, receiving poultry processing establishments are required to maintain records that indicate the source of the incoming undenatured poultry product, and track the poultry product through processing and preparation for export. In addition, an official of the receiving establishment must certify in writing that the product has not been, nor will be, commingled with any product intended for consumption in the United States. Establishments may develop their own systems for gathering and maintaining this information. These recordkeeping requirements have been approved by the Office of Management and Budget under control number 0583-0104.

**List of Subjects in 9 CFR Part 381**

Exports, Poultry and poultry products, Reporting and recordkeeping requirements, Transportation.

For the reasons set forth in the preamble, FSIS is amending 9 CFR part 381 as follows:

**PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS**

1. The authority citation for part 381 continues to read as follows:

**Authority:** 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 451-470; 7 CFR 2.17, 2.55.

(2) Section 381.190(b) is amended by revising the phrase "in subpart C or T" in the first sentence to read "in this paragraph (b) and subpart C or T" and designating that sentence as paragraph (b)(1); by designating the second, third, and fourth sentences as paragraphs (b)(2)(i) through (iii); by revising new paragraph (b)(2)(i); in new paragraph (b)(2)(ii) by redesignating the subparagraphs formerly designated as (1) through (3) as (A) through (C); and

by adding a new paragraph (b)(3) to read as follows:

**§ 381.190 Transactions in slaughtered poultry and other poultry products restricted; vehicle sanitation requirements.**

\* \* \* \* \*

(b)(1) \* \* \*, except as otherwise provided in this paragraph (b) and subpart C or T.

(2)(i) Poultry heads and feet that are collected and handled at an official establishment in an acceptable manner may be shipped from the official establishment directly for export as human food, if they have been examined and found to be suitable for such purpose, by an inspector and are labeled as prescribed in this paragraph.

\* \* \* \* \*

(3)(i) Poultry heads and feet that are collected and handled at an official establishment in an acceptable manner may be shipped from the official establishment and in commerce directly to another official establishment for processing before export, provided the receiving establishment maintains records that:

(A) Identify the source of the incoming undenatured poultry product;

(B) Identify the location of the product at all times during processing and preparation for export; and

(C) Contain a written certification from an official of the receiving establishment that the undenatured poultry product intended for export has not been, and will not be, commingled with any product intended for consumption in the United States.

(ii) The receiving establishment may only ship the undenatured poultry product intended for export in accordance with the inspection and labeling requirements of paragraph (b)(2) of this section.

\* \* \* \* \*

Dated: August 11, 1995.

**Michael R. Taylor,**

*Acting Under Secretary for Food Safety.*

[FR Doc. 95-20471 Filed 8-18-95; 8:45 am]

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**NUCLEAR REGULATORY COMMISSION**

**10 CFR Part 55**

**Public Meeting on the Pilot Operator Licensing Initial Examination Process**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Announcement of meeting.

**SUMMARY:** The United States Nuclear Regulatory Commission (USNRC) will

hold a public information workshop with industry to discuss the pilot Operator Licensing Initial Examination Process and to discuss NRC expectations regarding industry participation and implementation. The workshop is open to the public as observers. The workshop will provide the participants an opportunity to be informed on the pilot process, ask questions of the staff, make comments during the discussions, or submit written comments for NRC consideration. Written comments received from interested parties unable to attend the workshop will also be considered.

**DATES:** The meeting will be held on Tuesday, September 26, 1995, from 9:00 am to 5:00 pm. Submit registration by September 15, 1995.

**ADDRESSES:** The meeting will be held at the NRC's Two White Flint North building in the auditorium, 11545 Rockville Pike, Rockville, Maryland 20852-2738. Forward the attached registration form to the **FOR FURTHER INFORMATION CONTACT.**

Written comments should be mailed to: Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, M/S T-6-D-59, USNRC, Washington, DC, 20555.

**FOR FURTHER INFORMATION CONTACT:** Lawrence Vick, M/S O-10-D-22, U.S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, Washington, DC 20555, Telephone (301) 415-3181; FAX 301-415-2260; INTERNET:LXV@NRC.GOV

**SUPPLEMENTARY INFORMATION:** In SECY-95-075, dated March 24, 1995, the Commissioners were briefed on the proposed changes to the NRC Operator Licensing Program. The briefing described the staff's intent to revise the process for examining candidates applying for reactor operator (RO) or senior reactor operator (SRO) licenses at power reactor facilities and to adjust the degree of NRC involvement in facility requalification examinations. These changes are part of NRC's continuing efforts to streamline the functions of the Federal government consistent with Administration initiatives and to accommodate anticipated resource reductions.

To ensure that adequate seating is available, persons planning to attend the workshop are requested to either call the contact designated below or complete and forward the attached registration form to the same contact by September 15, 1995.