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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Chapter III

[Docket No. 99–060N]

Recent Developments Regarding Beef Products Contaminated With *Escherichia coli* O157:H7; Public Meeting

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that it will hold a public meeting on February 29, 2000, to discuss FSIS' policy regarding *Escherichia coli* (*E. coli*) O157:H7 and new information concerning the pathogen and its relation to human health. At this meeting, FSIS and other groups will present new data concerning the pathogen and new developments that may affect the Agency's policy. The purpose of this meeting is not to debate the policy that the Agency announced in January of 1999 (64 FR 2803) on the status of certain beef products contaminated with *E. coli* O157:H7 but to ensure that that policy is implemented based on the best available information and in a manner that will best protect public health. In addition, FSIS will allow time for comments and discussion regarding FSIS' testing procedures and other issues on *E. coli* O157:H7.

DATES: The meeting will be held February 29, 2000, from 9:00 a.m. to 5:00 p.m. Written comments must be received by April 11, 2000.

ADDRESSES: The meeting will be held at the Holiday Inn Rosslyn Westpark Hotel, 1900 North Fort Myer Drive, Arlington, Virginia, telephone number: (703) 807–2000. To register for the meeting, contact Ms. Mary Gioglio by telephone at (202) 501–7244 or by FAX at (202) 501–7642. If a sign language interpreter or other special accommodation is necessary, contact Ms. Gioglio at the above numbers by February 18, 2000. If you are planning to present an oral comment at the meeting, please submit one original and two copies of the prepared comment to the FSIS Docket Clerk, Docket No. 99–060N, Room 102 Cotton Annex, 300 12th Street, SW, Washington, DC 20250–3700. Send one original and two copies of all other comments to the Docket Clerk at the address listed above. All comments received in response to this notice will be considered part of the public record and will be available for viewing in the Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel Engeljohn, Ph.D., Director, Regulations Development and Analysis Division, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, Room 112 Cotton Annex, 300 12th Street, SW, Washington, DC 20250. Telephone number (202) 720–5627, fax number (202) 690–0486.

SUPPLEMENTARY INFORMATION:

Background

1. January 1999 Federal Register Notice

On January 19, 1999, FSIS published a policy statement, ''Beef Products Contaminated with *E. coli* O157:H7'' (64 FR 2803). This statement explained the Agency's policy governing beef products that contain *E. coli* O157:H7. The Agency stated that, in evaluating beef products contaminated with *E. coli* O157:H7, it would distinguish intact cuts of muscle (*e.g.,* steaks and roasts) distributed for consumption from non-intact products (*e.g.,* beef that has been mechanically tenderized by needling or cubing) and from intact cuts of muscle that are to be further processed into non-intact product prior to distribution for consumption. The Agency stated that, if the latter two types of products are found to be contaminated with *E. coli* O157:H7, they must be processed into ready-to-eat product, or they would be deemed to be adulterated. FSIS explained that pathogens, including *E. coli* O157:H7, may be introduced below the surfaces of non-intact products as the result of the processes by which they are made. As a result, customary cooking of these products may not be adequate to kill the pathogens. In contrast, the meat interior of intact products remains essentially protected from pathogens migrating below the exterior surfaces. Consequently, customary cooking of these products will destroy any *E. coli* O157:H7. FSIS requested comments and recommendations relevant to the Agency's policy and to any regulatory requirements appropriate to prevent the distribution of beef products adulterated with this pathogen.

On March 8, 1999, FSIS held a public meeting to discuss the policies addressed in its January 19, 1999, policy statement. The meeting provided the public with an additional opportunity to comment and discuss the policy announced in this statement and the public health risks associated with beef products contaminated with *E. coli* O157:H7. The meeting also provided an opportunity for participants to discuss a set of questions and answers that FSIS had developed regarding the *E. coli* O157:H7 policy. At this meeting, a group of companies described a plan for testing carcasses for *E. coli* O157:H7. The group stated that they would submit their testing protocol to FSIS. In addition, individuals from Kansas State University presented preliminary findings of research on *E. coli* O157:H7 in blade tenderized beef steaks.

In its March 15, 1999, Constituent Update, FSIS explained that the Agency would not act on its January 19, 1999, policy statement until it had an opportunity to consider the comments received. On April 5, the American Meat Institute (AMI) submitted a protocol on behalf of the group of companies participating in the study on carcass testing for *E. coli* O157:H7 discussed above. The protocol called for testing 1 in 300 carcasses slaughtered by approximately 12 plants, before and after hide removal, as well as after processing interventions and at the trimmings stage, for *E. coli* O157:H7. In its May 14, 1999, Constituent Update, FSIS announced the availability of the protocol and the Agency's response to it and invited comments on these documents.

2. Draft White Paper

FSIS recently developed a draft White Paper on *Escherichia coli* O157:H7. FSIS announced the availability of this document in its November 5, 1999,

Constituent Update. The document is currently available over the Internet (URL: http://www.fsis.usda.gov/OA/update/110599__att.htm).

The White Paper discusses new information and developments that will have a bearing on the Agency's *E. coli* O157:H7 policy. The paper explains that new information indicates that *E. coli* O157:H7 is not as rare as previously thought. In September 1999, FSIS began using a method for analyzing samples of products for *E. coli* O157:H7 that is four times more sensitive than the previous method. Of the total number of positive samples found by FSIS since the testing program began in 1994, 40 percent (21 out of 53) have been found using the new test method. The recent increase in positive samples suggests that the low rate of positive findings in the past may have had more to do with the sensitivity of the method being used than with the rarity of the pathogen.

In addition to the FSIS testing data, the White Paper explains that the Centers for Disease Control and Prevention (CDC) recently released estimates of foodborne illness that show a much higher rate of illness from *E. coli* O157:H7 than the CDC had previously reported. The CDC increased its estimates for illnesses associated with *E. coli* O157:H7 because recent surveillance data allowed a more detailed estimation of mild illnesses not resulting in physician consultation (Mead, Paul S., *et al.*, ''Food-Related Illness and Death in the United States,'' *Journal of Emerging Infectious Diseases*, Vol. 5, No. 5, 1999). Although not all of these illnesses are attributable to beef, the increase in illnesses associated with *E. coli* O157:H7 indicates that this pathogen occurs more frequently than was previously thought.

The White Paper also discusses recent research and studies concerning *E. coli* O157:H7. The paper explains that the data from the industry study discussed above are being analyzed and should soon be available. This study should provide further insight into whether *E. coli* O157:H7 is a rare pathogen and whether it occurs on hides and freshly slaughtered carcasses of beef with some regularity. Under the study's protocol, 1 in 300 carcasses were tested for *E. coli* O157:H7 before hide removal, after hide removal, and after pathogen reduction interventions have been applied. The study was to run for 30 days, starting in early September. Twelve plants were involved in the study.

The White Paper also notes that the Agricultural Research Service (ARS), in Clay Center, Nebraska, is conducting research related to prevalence, and that FSIS plans to conduct some sampling to assess the feasibility of identifying *E. coli* O157:H7 on carcasses and of establishing a routine, Agency-directed sampling program to supplement or replace FSIS' ongoing ground beef testing.

The White Paper explains that FSIS' risk assessment for *E. coli* O157:H7 in ground beef will better enable both the Agency and industry to identify interventions that can lead to public health improvements and to weigh available options. The Agency hopes that the risk assessment will be completed by spring 2000. When the risk assessment on ground beef is complete, FSIS expects to expand it to cover all meat products, as well as other products that may be affected by *E. coli* O157:H7.

The White Paper also addresses data concerning blade tenderized roasts and steaks. As discussed above, during the March 8, 1999, public meeting, individuals from Kansas State University presented preliminary findings of research on *E. coli* O157:H7 in blade tenderized beef steaks. The researchers stated that the blade tenderization process transfers approximately three to four percent of surface contamination to the interior of the muscle. The researchers pointed out that proper cooking to a specified time/temperature combination resulting in rare steaks could reliably result in safe product. In addition, industry members have stated that muscle systems from which steaks are derived could be removed from larger primal or sub-primal cuts hygienically. The beef industry has been persistent in encouraging FSIS to exempt blade tenderized product, especially when derived hygienically or with reduced possibilities for becoming contaminated, from the scope of products considered adulterated when contaminated with *E. coli* O157:H7.

As of fall 1999, FSIS has tentatively determined that there is insufficient information regarding the hygienic processing of muscle systems to narrow the scope of products affected by the *E. coli* O157:H7 policy. FSIS expects its planned effort to broaden the risk assessment will address some of the issues raised by the industry. Meanwhile, FSIS has encouraged industry to label their intact and non-intact primal and sub-primal cuts with appropriate cooking statements. The 1999 Food Code (section 3–401.11) prescribes appropriate cooking instructions for intact versus non-intact steaks for destruction of organisms of public health concern.

The White Paper recognizes that interventions other than cooking may be available to address *E. coli* O157:H7 in product under FSIS control. For example, irradiation offers the possibility of treating raw meat products to eliminate *E. coli* O157:H7. The final rule on irradiation published on December 23, 1999, and will become effective on February 22, 2000. In addition to irradiation, FSIS is willing to consider whether other alternatives to cooking product within an FSIS-inspected establishment could be used to address a positive finding.

The paper notes that several other considerations are likely to be important as the Agency reviews its policy on *E. coli* O157:H7. For example, since January 25, 2000, all meat and poultry plants have been operating under the pathogen reduction and hazard analysis and critical control point (PR/HACCP) systems rule. This will likely improve food safety and may affect the Agency's *E. coli* O157:H7 policy. In reviewing this policy, FSIS will also consider the meat industry's efforts to reduce the pathogen at the production level.

Finally, the White Paper lists areas for consideration concerning FSIS' *E. coli* O157:H7 policy. FSIS has revised the questions in the White Paper to read as follows:

1. If FSIS finds that *E. coli* O157:H7 occurs with some regularity on hides and carcasses of cattle raised using certain production practices (*e.g.*, feedlot cattle) but not on cattle raised under different production practices (*e.g.*, cull dairy cows), should the pathogen be considered a hazard ''reasonably likely to occur'' only in slaughter and processing operations that use the former types of cattle? Should *E. coli* O157:H7 be addressed in the HACCP plans of those operations? Is *E. coli* O157:H7 a hazard that is reasonably likely to occur in the production of beef products? If so, what is the best HACCP-related guidance that FSIS can provide to such plants for use in their reassessment of their HACCP plans, and what actions should be taken by the Agency?

2. Should FSIS re-design its testing program? Specifically:

- Are any changes needed in the proportion of samples taken in-plant and at retail?
- Should FSIS alter its policy that 15 consecutive samples be negative after a positive finding?
- Should FSIS continue selecting a sample if a plant has a positive finding within the last 6 months, or should the Agency defer to plant routine testing completely and remove the 6-month restriction? If FSIS sampling is continued under these circumstances,

should the rules for the random selection of samples be changed?

• Should FSIS sampling of carcasses replace or supplement ground beef sampling at slaughter plants?

• Should FSIS develop additional sampling schemes, including increasing its testing of ground beef and other beef products (*e.g.*, carcasses, trimmings, and non-intact cuts)?

• What alternatives to the FSIS testing program would best encourage the regulated industry to better ensure that pathogen reduction interventions specifically for *E. coli* O157:H7 are instituted?

3. Should FSIS consider a plant's generic *E. coli* and *Salmonella* results in making its decision on whether to target a plant's products for *E. coli* O157:H7 sampling?

4. What effect should a plant's testing or verification program have on whether and how FSIS targets its testing in that plant? Should the plant's testing or verification program only be considered sufficient if included as part of HACCP validation?

5. How should FSIS treat non-intact product? Specifically, should blade-tenderized beef steaks and roasts—with specific cooking instructions for destroying the pathogen and handling instructions for preventing cross-contamination and temperature abuse—be treated the same as other non-intact beef with regard to the FSIS policy?

6. How effective are voluntary producer actions in providing animals with reduced levels of E. coli O157:H7 to plants, and should these voluntary activities, if effective, affect slaughter plants' strategies and FSIS' policy?

3. FSIS Plans

The Agency intends to consider all information that is ultimately developed from the sources of information discussed in the White Paper, as well as all information presented in response to this notice, the January 1999 notice, and the May 1999 Constituent Update, and to use that information in deciding how best to address *E. coli* O157:H7. At the February 29, 2000, public meeting, FSIS plans to discuss the issues raised in its White Paper, including the significance of the findings with its new testing method that the Agency is using to detect *E. coli* O157:H7, of the final regulations on irradiation, and of the FSIS risk assessment for *E. coli* O157:H7. ARS will present the results of a survey it performed to estimate the frequency of *E. coli* O157:H7 in feces and on hides within lots of fed cattle and the frequency of carcass contamination during processing from cattle within the same lots. The industry group will present the results of the industry study, and Kansas State University will present data concerning *E. coli* O157:H7 in blade tenderized steaks. There will be presentations on interventions available to industry and on new technology. Finally, consumer groups will present information. The public meeting also will provide an opportunity for comments and discussion regarding FSIS' *E. coli* O157:H7 policy and the course it should take, the Agency's testing and sampling methods, new issues related to the pathogen, and issues that arise during the public meeting.

The purpose of the meeting is to move forward with the January 1999 policy. The Agency has accumulated some information that suggests that a hazard resulting from *E. coli* O157:H7 in the production of beef may be more likely to occur than previously thought and that the regulated industry may not be reassessing its HACCP plans accordingly. Since all Federally inspected meat and poultry establishments are now operating under HACCP, and since a yearly reassessment of the HACCP plans (9 CFR 417.4(a)(3)) is required, FSIS hopes to use this public meeting as a means to ensure that the most current information is available to interested persons as the Agency arrives at a policy that will best protect the public health.

4. Comments Received

FSIS received a total of 81 comments in response to requests for comments in the January 19, 1999, **Federal Register** (64 FR 2803) and in the May 14, 1999, Constituent Update. FSIS received one comment in response to the March 8, 1999, public meeting notice. Comments addressed issues including the policy discussed in the January 19, 1999, policy statement, related documents, testing for *E. coli* O157:H7, and the industry's protocol. A summary of comments and the Agency's responses to these comments follow.

Consumer Support

Several consumers supported the policy and suggested that it be expanded to include *Listeria monocytogenes* and *Campylobacter jejuni*. Several consumer groups also supported the policy. Several groups argued that the policy should be expanded to include intermediate products, such as those produced from advanced meat recovery systems and other products that are added to raw ground beef. One animal welfare organization stated that even intact steaks and roasts and other cuts of muscle with surface contamination should not be distributed.

At this time, FSIS does not intend to expand its *E. coli* O157:H7 policy to cover additional products. Once FSIS' risk assessment on ground beef is completed, FSIS intends to expand the risk assessment to cover all meat products and other products that may be affected by *E. coli* O157:H7. Depending upon the results of the risk assessment for *E. coli* in these products, FSIS may consider expanding the policy to cover additional products. Also at this time, FSIS does not believe that raw product contaminated with *Listeria monocytogenes* or *Campylobacter* is adulterated within the meaning of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) or Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*). *E. coli* O157:H7 is a particularly virulent pathogen. Based on epidemiological data, low numbers of *E. coli* O157:H7 may be injurious to health, especially among vulnerable consumers. FSIS is not aware of any data that suggest that customary cooking of these beef products does not reduce *Listeria monocytogenes* and *Campylobacter* to levels that are not injurious to health, even among vulnerable consumers.

Products Covered by the Policy

Numerous industry commenters did not support the policy that non-intact products contaminated with *E. coli* O157:H7 must either be processed into ready-to-eat product or deemed adulterated. Several industry commenters supported the policy with regard to beef trimmings. Several other industry commenters stated that trimmings contaminated with *E. coli* O157:H7 should not be considered adulterated. One of these commenters stated that the policy should only be applied to trimmings that will be used in raw ground products.

Numerous industry commenters also stated that FSIS has no data to support the policy that products other than ground beef that are contaminated with *E. coli* O157:H7 should be considered adulterated. Specifically, many of these commenters discussed the lack of data concerning non-intact products and the risk associated with blade tenderized steaks. One commenter from an academic institution stated that its study demonstrated that there is no difference in risk between intact and non-intact steaks cooked at temperatures resulting in rare to well-done levels of doneness.

Several industry commenters suggested that FSIS should not implement its new policy until after completion of a risk assessment or the

industry pilot program for carcass testing, or until available data show that there is a need for the policy, especially with regard to non-intact product.

In evaluating the public health risk presented by *E. coli* O157:H7-contaminated beef products, FSIS carefully considered the deliberations of the National Advisory Committee on Microbiological Criteria for Foods and its Meat and Poultry Subcommittee. As noted in the January 19, 1999, policy statement, in 1998, this Committee concluded that intact muscle should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change and additional heat to effect a complete sear across the cut surfaces (64 FR 2803–2804). The Committee's definition of ''Intact Beef Steak'' limited the applicability of this conclusion to muscle that has not been injected, mechanically tenderized, or reconstructed.

FSIS has tentatively determined that there is insufficient information regarding the processing of muscle systems to narrow the scope of products affected by the *E. coli* O157:H7 policy. When the risk assessment on ground beef is complete (see 63 FR 44232), FSIS expects to expand it to cover all meat products, as well as other products that may be affected by *E. coli* O157:H7. The Agency's efforts to broaden its risk assessment for *E. coli* O157:H7 may also address some of the issues raised by the industry with regard to non-intact product. Meanwhile, FSIS has encouraged industry to label their intact and non-intact primal and sub-primal cuts with appropriate cooking statements. The 1999 Food Code (section 3–401.11) prescribes appropriate cooking instructions for intact versus non-intact steaks for destruction of organisms of public health concern. The 1999 Food Code recommends these products be cooked to 145 °F for 15 seconds.

FSIS has received the results of the study referred to in the comments. The study confirmed that *E. coli* O157:H7 can be translocated to the interior of a non-intact steak. Therefore, FSIS will continue to recommend that non-intact product be cooked to 145 °F for 15 seconds, consistent with the Food Code.

Procedural Questions

Several commenters, including industry groups and a government Agency, stated that FSIS should have issued a proposed rule, and that FSIS' policy change should be subject to the requirements of the Administrative Procedures Act (APA).

The January 19, 1999, policy statement was an interpretive rule and therefore was not subject to the notice-and-comment rulemaking requirements in section 553(b) of the APA. It was intended to elucidate the policy that FSIS announced in 1994. Under section 552 of the APA, FSIS is required to publish interpretive rules in the **Federal Register**. FSIS complied with that requirement.

Effect on Industry

Several industry commenters stated that the new policy could put companies out of business and could be disproportionately burdensome on small businesses. Two industry commenters stated that the new policy could result in less voluntary testing by industry.

Experience has shown that these predictions were wrong, at least for the short-term. The policy resulted in the important carcass testing that the industry is currently conducting. FSIS' future direction in testing will be determined in large measure based on the information that FSIS has gathered since the publication of the January 19, 1999, policy statement and on the information that FSIS receives in response to this notice.

Consumer Responsibility

Several industry commenters stated that consumers should assume more responsibility for their safety and expressed the need for consumer awareness programs regarding the importance of cooking beef products thoroughly.

Industry can reduce or eliminate risk associated with *E. coli* O157:H7 through various controls and interventions, such as steam pasteurization and irradiation, that can be incorporated into HACCP systems. Because industry has the means to reduce or eliminate the hazard, consumers should not be expected to assume all the responsibility for preventing foodborne illness associated with *E. coli* O157:H7.

FSIS has informed consumers of the risk of foodborne illness from products contaminated with *E. coli* O157:H7. For example, on May 27, 1998, FSIS held a public meeting to discuss safe handling measures consumers should take in cooking hamburgers. During the meeting, participants discussed the food safety issues presented by premature browning, including the question of whether color is an appropriate indicator that ground beef is cooked to a safe internal temperature.

In addition, the Food Safety Education and Communications Staff within FSIS provides information to the public concerning numerous food safety issues, including information on cooking beef products. This office provides food safety education information through USDA's Toll-Free Meat and Poultry Hotline (1–800–535–4555), through public service announcements, printed materials, and a variety of communication channels. In addition, FSIS makes this information available over the Internet (URL: http://www.fsis.usda.gov/). Industry and consumers are invited to present information on how best to communicate the need for proper handling of non-intact products that are contaminated with *E. coli* O157:H7 at the public meeting.

Definition of Adulteration

Several commenters, including industry groups, an academic organization, and an inspection association, were opposed to the concept that beef that tests positive for *E. coli* O157:H7 be considered adulterated because the organism may be inherent in raw meat and poultry when produced under current technology.

Under the FMIA, a product is ''adulterated'' if ''it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health * * *.'' (21 U.S.C. § 601(m)(1)). Because beef products contaminated with *E. coli* O157:H7 are often cooked in a manner that may not prevent illness, this pathogen is a substance that renders ''injurious to health'' even products that many consumers consider to be properly cooked (see *Texas Food Industry Association, et. al.* v. *Espy, et. al.*, Civ. No. A–94–CA–748 JN.)

Testing for E. coli O157:H7

Several industry commenters recommended carcass sampling rather than end-product testing or combo bin sampling. In contrast, one industry organization and one consumer group opined that carcass testing would not ensure the safety of a carcass that tests positive for *E. coli* O157:H7. One consumer group specifically supported testing raw product, rather than carcasses, at both the processing and retail levels.

Several industry commenters expressed general concerns regarding testing for *E. coli* O157:H7. Several commenters noted that testing is not a means of eliminating or reducing pathogens. Other commenters noted that the likelihood of finding a pathogen

such as *E. coli* O157:H7 through testing is minimal.

Numerous industry commenters stated that FSIS should not expand its sampling and testing program. Numerous commenters that submitted the same letter stated that rather than expand the program, the Agency should refocus the program on verifying that processes are in control. Several consumer groups stated that the Agency should expand the sampling and testing program.

Effective system controls, such as through HACCP, are the appropriate means of preventing *E. coli* O157:H7 in ground beef from entering commerce. FSIS is interested in encouraging industry to conduct sampling and testing for *E. coli* O157:H7, as well as microbiological testing for appropriate non-pathogenic organisms, to allow verification and validation of HACCP systems. Microbiological sampling, as part of HACCP systems monitoring, verification, and validation, is an effective operational indicator. FSIS agrees that end-product testing alone is ineffective for ensuring process control. However, FSIS began its testing program for ground beef, an end-product testing program, as a means of spurring establishments into taking more aggressive action to control their processes. Establishments can incorporate sampling and testing for *E. coli* O157:H7 and appropriate non-pathogenic organisms into their HACCP plans to reduce risk and can ensure that they are effectively controlling the pathogen through their monitoring, verification, and validation activities. The safety of ground products will likely improve as a result of these activities at Federal establishments.

Guidance is available to industry for developing sampling and testing programs for beef. The American Meat Science Association report entitled, ''The Role of Microbiological Testing in Beef Food Safety Programs,'' published in 1999, provides guidance for microbiological testing within a HACCP system. At this time, FSIS believes that some of the assumptions concerning the prevalence and distribution of *E. coli* O157:H7 in this report may not reflect recent data; however, the guidance for sampling and testing for appropriate organisms within a HACCP system continues to be useful to industry.

FSIS considers its end-product testing as one means of preventing adulterated product from reaching consumers. Currently, FSIS is scheduling more sampling at Federal establishments than at retail stores because more product is accessible for testing.

Control at Farm

Several commenters, including industry organizations and an animal welfare organization, stated that FSIS or another entity within the Department of Agriculture should promote efforts to control the incidence of *E. coli* O157:H7 on the farm.

FSIS agrees that there should be a farm-to-table approach to reducing or preventing the risk of *E. coli* O157:H7. At the animal production level, FSIS encourages research, applied studies, and educational activities to enhance adoption of food safety practices. FSIS' Animal Production Food Safety Staff supports research to develop voluntary, science-based food safety practices and verification procedures for food animal production that will reduce the risk of microbial hazards, such as *E. coli* O157:H7, entering the food chain. This staff also provides information to the animal production community to assist them in meeting reasonable, science-based requirements for animals at the receiving stage of processing. Finally, this staff works with outside organizations to promote adoption of food production practices by producers and suppliers that result in safe and high quality animals being presented to meat and poultry slaughtering establishments.

Interventions

Several industry commenters emphasized the importance of microbial interventions, such as thermal carcass washing and irradiation, in producing safe product. Several industry commenters urged FSIS to publish its final regulations on irradiation, noting that irradiation should ensure the elimination of *E. coli* O157:H7.

FSIS agrees with commenters that interventions are integral features of any process for reducing or eliminating *E. coli* O157:H7 in beef products. However, FSIS has data that show that not all interventions are effective, and that interventions must be implemented properly to be effective. Establishments using interventions to prevent or reduce the risk of *E. coli* O157:H7 should incorporate these interventions into their HACCP plans and validate the effectiveness of the interventions.

The final rule on irradiation published on December 23, 1999, and will become effective on February 22, 2000. Therefore, this intervention will soon be available to establishments producing raw beef products.

Other Meat and Poultry Products

One industry commenter stated that this policy discriminates against beef processors, because the pork and poultry industries are similarly faced with pathogens that contribute to foodborne illnesses, but this broadened policy interpretation would not apply to them.

FSIS does not consider raw pork or poultry products to be adulterated when they are contaminated with bacteria, because these products are customarily cooked in a manner that will ensure that any pathogenic microorganisms are eliminated.

Exporting Countries

Two government organizations representing countries that export meat to the United States did not support the policy with regard to non-intact beef products. One commenter stated that any testing required of product shipped to the U.S. would cause numerous problems. The commenter explained that producers do not know whether beef cuts will be used for making non-intact product, such as reformed steaks, at the time of shipment.

The other commenter did not believe that end-product testing is the best means to ensure consumer protection against *E. coli* O157:H7 because of its low prevalence. This commenter also stated that the policy explained in the January 19, 1999, policy statement would be difficult to implement. As an alternative, the commenter recommended that any beef used to manufacture ground beef should be subject to compliance action if it is contaminated with *E. coli* O157:H7. Further, the commenter stated that appropriate compliance action should be determined based on the level of generic *E. coli* in the contaminated product.

One FSIS bargaining unit employee stated that millions of pounds of block frozen beef enter the United States daily from countries such as Australia. This commenter further stated that Australia has practically eliminated its government inspection program, and that U.S. import inspectors are allowed to sample only an insignificant amount of the product.

In response to the first comment discussed above, FSIS notes that product testing is not mandatory. With regard to the statement that exporting producers do not know whether beef cuts will be used for making non-intact product at the time of shipment, the HACCP regulations require that establishments identify the intended use or consumers of the finished product (§ 417.2(a)(2)). Countries exporting product to the United States are required to operate according to HACCP systems (§ 327.2(a)(2)(ii)(H)). Therefore,

the exporting producer should make an effort to determine whether the beef will be used to produce intact or non-intact product. If the shipping company does, and it conducts any testing and finds *E. coli* O157:H7 on the beef, that company could ensure that the beef is handled appropriately once it is shipped.

In response to the second commenter above, as discussed under *Testing for E. coli O157:H7,* FSIS agrees that end-product testing alone is ineffective for ensuring process control. However, FSIS began its testing program for ground beef, an end-product testing program, as a means of spurring establishments into taking more aggressive action to control their processes. Also, at this point, FSIS does not intend to narrow the scope of products affected by the *E. coli* O157:H7 policy. With regard to this commenter's suggestion that appropriate compliance action should be determined based on the level of generic *E. coli* in the contaminated product, data show that levels of generic *E. coli* are not necessarily indicative of the levels of *E. coli* O157:H7 in product.

In response to the comments from the FSIS bargaining unit employee, FSIS ensures that products exported to the United States are produced under inspection requirements equivalent to those in the Federal meat inspection regulations. In addition, FSIS schedules sample collection for imported ground beef product. These samples are collected and tested for *E. coli* O157:H7 according to the same procedures as are used for domestic product.

Comments on Related Documents

FSIS received comments recommending changes to FSIS Directive 10,010.1, ''Microbiological Testing Program For *Escherichia coli* O157:H7 in Raw Ground Beef.'' FSIS also received comments regarding the questions and answers it developed shortly before the March 8, 1999, public meeting.

FSIS is currently considering whether and how to revise these documents. In considering revisions to these documents, FSIS will take into account the comments submitted and information from the risk assessment on ground beef. Further, FSIS soon expects to receive the results from the industry carcass testing study and will consider modifying the directive based on its review of the results of the study.

Industry Protocol

Two consumer groups objected to FSIS' decision to delay implementation of the policy discussed in the January 19, 1999, policy statement. One of these commenters stated that FSIS should not await the results of the industry study before implementing the policy. The other expressed concerns with regard to FSIS' interest in comments to the industry protocol. For example, the commenter questioned what bearing comments from the public will have on the study. In addition, this commenter expressed doubt that the industry study would be carried out in an unbiased manner.

Another consumer group stated that data from the industry's study could offer valuable insight into both the prevalence of the pathogen and the ability of existing intervention technologies to eliminate it from beef carcasses. However, the commenter suggested that certain changes should be made to the protocol. For example, the commenter stated that FSIS' recommended changes should be incorporated into the study, and that industry should ensure that the plants involved in the study are representative of the variations that exist among plants that produce raw ground and non-intact beef products.

FSIS delayed implementation of the policy discussed in the January 19, 1999, policy statement because it was waiting for the results of the risk assessment for *E. coli* O157:H7 in ground beef and needed time to consider comments received concerning the policy, not because of the industry study. With regard to the industry study, FSIS reviewed the protocol and provided suggested changes to the industry. In addition, FSIS made the comments discussed above available to the industry through the FSIS docket room. Although FSIS reviewed and provided suggested changes to the industry, this study is an industry study; therefore, the industry was not required to revise its protocol based on comments from FSIS or from the public. FSIS has not yet received the results of the study. When reviewing the results, FSIS will take into account any short-comings in the protocol.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development are important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice of public meeting, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at http://www.fsis.usda.gov. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720–5704.

Done at Washington, DC, on: February 7, 2000.

Thomas J. Billy,

Administrator.

[FR Doc. 00–3197 Filed 2–10–00; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. 99–059DF]

Termination of Designation of the State of Minnesota with Respect to the Inspection of Poultry and Poultry Products

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 by terminating the designation of the State of Minnesota under sections 1 through 4, 6 through 11, and 12 through 22 of the Poultry Products Inspection Act.

DATES: This final rule is effective February 11, 2000.

ADDRESSES: Authorizing letters from Minnesota State officials are on file in the FSIS Docket Room, Room 102, Cotton Annex Building, 300 12th Street, SW, Washington, DC 20250–3700. The Docket Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. William F. Leese, Director, Federal-State Relations Staff, Food Safety and Inspection Service; telephone (202) 418–8900 or fax (202) 418–8834.

SUPPLEMENTARY INFORMATION: