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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 310 and 318

[Docket No. 03–025IFA]

Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its interim final rule, ''*Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Cattle,*'' published in the **Federal Register** on January 12, 2004. The amendments permit beef small intestine, excluding the distal ileum, to be used for human food, provided that such product is derived from cattle that were slaughtered in an official establishment in the United States or in a certified foreign establishment from a foreign country that is eligible to export beef products to the United States. Although the distal ileum is the only portion of the small intestine in which BSE infectivity has been confirmed, the January 2004 interim final rule requires that the entire small intestine of all cattle be removed and disposed of as inedible. FSIS is taking this action based on the Agency's evaluation of this issue and of the comments received on the interim final rule, as well as comments received on an advance notice of proposed rulemaking published in July 2004. FSIS has concluded that the distal ileum can be effectively removed from the rest of the small intestine. FSIS has determined that removal of the distal ileum in accordance with the amendments in this document will provide the same level of protection from human exposure to the BSE agent as does the exclusion of the entire small intestine from the human food supply.

DATES: This interim final rule is effective October 7, 2005. Comments on this interim final rule must be received by November 7, 2005.

ADDRESSES: FSIS invites interested persons to submit comments on this amended interim final rule. Comments may be submitted by any of the following methods:

- Mail, including floppy disks or CD–ROM's, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Electronic mail: *fsis.regulationscomments@fsis.usda.gov.* Follow the online instructions at that site for submitting comments.

All submissions received must include the Agency name and docket number 03–025IFA.

All comments submitted in response to this amended interim final rule, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/regulations_&_policies/2005_Interim_&_Final_Rules_Index/index.asp.*

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Engeljohn, Deputy Assistant Administrator, Office of Policy, Program, and Employee Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250–3700, (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

On January 12, 2004, FSIS issued a series of three interim final rules to minimize human exposure to materials that scientific studies have demonstrated contain the BSE agent in cattle infected with the disease. FSIS issued the rules in response to the diagnosis on December 23, 2003, of BSE in an imported dairy cow in Washington State. The animal had been imported from Canada. One of the rules, ''*Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-ambulatory Disabled Cattle*'' (69 FR 1826, January 12, 2004) (also referred to as ''the SRM interim final rule'' or ''the SRM rule''), among other things, designates certain materials from cattle as SRMs, declares that SRMs are inedible, and prohibits the use of these materials for human food (9 CFR 310.22(a) and 9 CFR 310.22(b)). The SRM rule also requires that establishments that slaughter cattle, and establishments that process the carcasses and parts of cattle, incorporate their procedures for the removal, segregation and disposition of SRMs into their HACCP plans or Sanitation SOPs or other prerequisite program (9 CFR 310.22(d)(1)).

The materials identified as SRMs in the FSIS SRM rule are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the distal ileum of the small intestine and tonsils from all cattle (9 CFR 310.22(a)). FSIS designated these materials as SRMs because they have been found to contain BSE infectivity at some point during the disease incubation period. Furthermore, the Agency determined that SRMs should be declared as inedible because, as stated in the preamble to the SRM rule, they present a sufficient risk of exposing humans to the BSE agent so as to render them ''unfit for human food'' within the meaning of section 1(m)(3) of the adulteration provisions of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(m)(3)). For a detailed explanation of FSIS'' rationale for designating these tissues as SRMs, including the supporting scientific studies, refer to the preamble to ''*Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-ambulatory Disabled Cattle.*''

FSIS designated the distal ileum from all cattle as an SRM because, in cattle infected with BSE under experimental conditions, infectivity was confirmed in

the distal ileum in the early stages of the disease. To ensure effective removal of the distal ileum, FSIS requires that the entire small intestine be removed and disposed of as inedible (9 CFR 310.22(a)(3)). However, in the preamble to the SRM rule, FSIS noted that beef processors may be able to effectively remove the distal ileum from the rest of the small intestine and requested comments on this issue (69 FR 1862, 1869).

On July 14, 2004, the Food and Drug Administration (FDA) issued an interim final rule, ''*Use of Materials Derived From Cattle in Human Food and Cosmetics*'' (also referred to as ''the FDA rule'' or ''the prohibited cattle materials rule''), that extends the measures to prevent human exposure to the BSE agent issued by FSIS to FDA-regulated human food and cosmetics (69 FR 42255). In its rule, FDA designates certain materials from cattle as ''prohibited cattle materials'' and prohibits the use of such materials for human food, including dietary supplements, and cosmetics (21 CFR 189.5 and 21 CFR 700.27). Among the materials designated as prohibited cattle materials by the FDA are SRMs, the small intestine from all cattle, and material from cattle not inspected and passed for human consumption. Materials that were designated as SRMs in the FDA rule are the same as the materials designated as SRMs by FSIS.

Although FDA designated the distal ileum of the small intestine from cattle as an SRM, like FSIS, it prohibits the use of the entire small intestine for human food. Consistent with the amendments to the SRM interim final rule that FSIS is issuing in this document, FDA intends to issue an amendment to its prohibited cattle materials rule to permit, under certain circumstances, the manufacture and use of beef casings derived from beef small intestine, excluding the distal ileum, for human food and cosmetics.

Comments Received on Procedures for Removal of the Distal Ileum

In response to the SRM rule, FSIS received several comments from beef processors, the natural casing industry, the beef by-product industry, and importers and exporters of natural casings and beef by-products on the need to exclude the entire small intestine from the human food supply. On July 14, 2004, APHIS, FSIS, and the Food and Drug Administration (FDA) issued an Advance Notice of Proposed Rulemaking (ANPR), ''*Federal Measures To Mitigate BSE Risks: Considerations for Further Action*,'' (also referred to as the APHIS/FSIS/FDA ANPR) that provided another opportunity for interested parties to comment on which portions of the intestine of cattle should be removed to prevent potentially infective material from entering the human food supply (69 FR 42287, 42296). The comment period for the APHIS/FSIS/FDA ANPR closed on September 13, 2004.

Most of the comments submitted to the Agency on this issue requested that FSIS amend the SRM rule to require the removal and disposal of only the distal ileum and allow the remaining portion of the small intestine to be used for human food. As stated by the commenters, infectivity has been confirmed only in the distal ileum of the small intestine of cattle infected with BSE under experimental conditions, and the technology exists to effectively remove the distal ileum from the rest of the small intestine. The commenters noted that, before the issuance of the SRM rule, FSIS had approved a standard operating procedure to certify the removal of the distal ileum from the remaining portions of beef small intestine intended for export to Japan. As stated by the commenters, the procedure approved by FSIS requires the removal of at least 80 inches of the small intestine as measured from the junction of the ileum and the cecum.

To further support their argument, several commenters provided a detailed anatomical description of the small intestine of cattle, along with pictures and diagrams of the anatomy of the small intestine, which they asserted can be used to develop a model of certification of the removal and disposal of the distal ileum. According to the commenters, this description was developed with full scientific oversight and has widespread support within the beef processing, casing, and beef by-product industry.

Many commenters also described, in detail, examples of verifiable procedures for the effective removal of the distal ileum. One procedure described in the comments begins with the removal of the small intestine from the abomasum. Under this procedure, the small intestine is separated from the cecum at the ileocecal orifice, and the ileum is separated from the jejunum at the flange. According to the commenters, the resulting portion that contains the distal ileum would measure 36 to 72 inches in length depending on the age and size of the animal.

Another procedure described in the comments also begins with removal of the small intestine from the abomasum, except that under this procedure the small intestine remains attached to the cecum, and the separation is made at a point 36 to 80 inches from the cecum, leaving behind the remaining edible portions of the small intestine. According to the commenters, leaving the ileum attached to the cecum at this initial stage provides an easily verifiable point of reference for on-line inspectors. The next step in this procedure is to separate the 36 to 80 inch portion of the intestine that contains the ileum from the cecum at the ileocecal orifice, leaving the cecum and the large intestine for edible use.

Another commenter described a procedure that uses a ''Small Intestine Processing Machine'' that was developed in Japan approximately 10 years ago specifically for the harvest of the jejunum of the intestine for export to Japan. As presented by the commenter, the Small Intestine Processing Machine strips the fat from, washes, and then splits the jejunum lengthwise, and cuts the small intestine into sections without leaving any part of the distal ileum attached. The commenter stated that the harvest procedures using the Small Intestine Processing Machine require that the uncoiled and untrimmed jejunum portion of the small intestine be cut at least 72 cm or 30 inches from the cecum end of the small intestine, which is equal to approximately 80 inches of the split, washed, and trimmed small intestine. According to the commenter, this removal procedure exceeds the total length of the distal ileum of the small intestine and includes a portion of the jejunum as a precaution.

This same commenter stated that the harvest procedures for the Small Intestine Processing Machine require that the entire intestinal tract of the digestive system be laid out in full view prior to starting the separation process, which makes accurate identification and removal of the distal ileum possible. The commenter provided pictures depicting the location of the distal ileum, cecum, and jejunum portions of the small intestine and noted that as the distal ileum joins the cecum, it is distinct from the jejunum, duodenum, and colon. The commenter also explained that as the separation of the jejunum (small intestine) is done by the Small Intestine Processing Machine, the harvest is only completed between the initial cut on the cecum end and the final cut adjacent to the duodenal jejunal flexure.

Several commenters indicated that because of the distinct shape of the distal ileum of cattle, FSIS inspection program personnel could easily verify the effective removal of this portion of the small intestine. Furthermore, commenters from the natural casing

industry stated that because of its physical properties, particularly the fact that it has no curve and an irregular thick surface, the distal ileum is not useable as a natural casing for sausage products. Thus, these commenters noted, many slaughter establishments in the United States and Canada had a policy of removing the distal ileum from all cattle at the time of slaughter prior to the effective date of the SRM rule.

Furthermore, as stated by the commenters, prior to the effective date of the SRM rule, slaughter establishments in Brazil, Argentina, and Uruguay, the three countries that are the major exporters of natural casings to the United States, had all been able to certify the removal of the distal ileum using achievable standards when requested to do so by their U.S. customers. One commenter submitted a CD–ROM on ''Details of Beef Casing Production in Brazil: Eliminating the Distal Ileum,'' which, according to the commenter, demonstrates the distinct appearance of the bovine ileum. The commenters also noted that Brazil, Uruguay, and Argentina are countries that are generally recognized as having a negligible BSE risk by the international community.

Other Comments on Removal of the Small Intestine

In addition to the comments that presented procedures for removing the distal ileum, FSIS received other comments on whether the entire small intestine from cattle should be excluded from the human food supply. Some commenters, including members of the natural casing industry, importers and exporters of natural casings and beef by-products, and foreign countries that consider themselves to be ''BSE-free,'' such as Australia, New Zealand, Uruguay, and Argentina, suggested that FSIS consider a country's BSE risk status when determining which portions of the intestine, if any, should be removed and disposed of as inedible. Most of these commenters also requested that FSIS exempt countries recognized as ''BSE-free'' or ''provisionally free'' by the international community from all provisions of the SRM rule.[1]

According to the commenters, a country's BSE-free risk status provides the same level of protection from human exposure to the BSE agent as does exclusion of SRMs and beef small intestine from the human food supply in the United States. In addition, as noted by the commenters, such an approach would be consistent with guidelines established by the World Organization for Animal Health (the OIE), which recommend that countries restrict the importation of beef small intestines and other potentially infective materials on the basis of the BSE risk classification of the region of origin.

FSIS' regulations governing the importation of meat and meat products from foreign countries into the United States prohibit the importation of any product that is adulterated or misbranded, or that does not comply with the regulatory requirements that would apply to it if it were a domestic product (9 CFR 327.3(a)). The FSIS import regulations at 9 CFR 327.4(a) also require that fresh meat or fresh meat by-products consigned to the United States from a foreign country be accompanied by a foreign meat inspection certificate, signed by the official authorized by the national foreign government to issue inspection certificates for meat and meat by-products exported to the Unites States, that certifies, among other things, that such products are not adulterated or misbranded, and that such products have been handled in a sanitary manner and are otherwise in compliance with requirements equivalent to those in the FMIA and its implementing regulations. The regulations, 9 CFR 327.3(a) and 9 CFR 327.4(a), make clear that to be eligible for importation into the United States, meat products from foreign countries must present no greater risk to human health than products that were produced domestically in the United States, and that to achieve the appropriate level of public health protection, such products must comply with regulatory requirements equivalent to those required by FSIS.

Thus, if FSIS were to exempt countries with a BSE-free risk status (or negligible BSE risk under OIE guidelines) from some or all of the provisions of the SRM rule, as requested by some of the commenters, any products eligible for importation into the United States would be required to comply with 9 CFR 327.3(a) and 9 CFR 327.4(a), *i.e.*, they could not be adulterated or misbranded, and would be required to comply with requirements that are equivalent to those in the FSIS SRM rule. As stated above, in response to the confirmation of BSE in the cow in Washington State, FSIS currently considers the distal ileum and all other SRMs from U.S. domestic cattle as adulterated under section 1(m)(3) of the FMIA. The Agency is evaluating whether it is appropriate to consider these materials adulterated if they originate from a country considered to have a BSE-free risk status. Until FSIS has an opportunity to resolve this issue, the Agency has decided that all materials designated as SRMs, including the distal ileum, should be excluded from the human food supply, regardless of their country-of-origin. FSIS will continue to evaluate the issue, and if the Agency determines that an exemption is appropriate for countries considered to have a BSE-free risk status or negligible BSE risk under OIE guidelines, the Agency will take appropriate action.

Other commenters, including a private consultant, consumer advocacy organization, and members of the restaurant industry, recommended that FSIS expand the prohibition on the use of small intestine from cattle for human food to include the entire intestine, both large and small. Some of these comments noted that while certain sections of the intestine were tested with no infectivity, not every section of the intestine was subjected to the bioassay in the pathogenesis studies conducted in the United Kingdom. One comment asserted that instead of assuming that the untested section of the intestine are devoid of infectivity, FSIS should err on the side of caution when it comes to protecting public health.

Some comments, one of them citing an unpublished study, mentioned that positive immunostaining has been identified along the length of the intestine, providing evidence for the entire intestine to be considered SRM under European Union regulations. To better understand the implications of this finding FSIS contacted the commenter to obtain more information on the study. The commenter explained that the statement that positive immunostaining has been identified along the length of the intestine was based on a misunderstanding of a report on a published study.

The commenter clarified that there are published studies in which positive immunostaining has been identified in the distal ileum portion of the enteric nervous system (ENS) of naturally infected and experimentally challenged cattle with BSE. However, the commenter maintained that FSIS should designate the entire intestine, both large and small, as SRM because the ENS runs through the length of the intestinal tract and other areas of the ENS from naturally occurring cases of BSE have not yet been examined for infectious prion staining. Thus, stated the commenter, if other areas of the

[1] The international guidelines established by the OIE have been revised since FSIS issued the SRM interim final rule. The OIE guidelines in the 2005 Terrestrial Animal Health Code provide for a BSE ''negligible risk'' category instead of the ''BSE-free'' and ''provisionally free'' categories.

intestinal tract were subjected to immunostaining, one might expect to find positive immunostaining in portions of the intestinal tract other than the distal ileum. The commenter also noted that, although immunostaining was attempted and found negative on sections of the intestine other than the distal ileum of experimentally challenged cattle, this study was extremely limited with regard to the testing of tissues other than the distal ileum (*i.e.*, tissues from 3 calves sacrificed 6 months post-exposure).

Also, as stated by the comments, according to the E.U. Scientific Steering Committee (SSC), intestine should be SRM because infection from BSE comes from ingesting contaminated feed and slaughterhouse contamination of other intestinal areas with matter from the ileum cannot be avoided. Many of the comments also noted that the International Review Team (IRT) appointed by the Secretary of Agriculture in January 2004 to assess the U.S. Government's response to the detection of BSE in the cow in Washington State recommended that the SRM definition be adjusted to include the entire intestine, from pylorus to anus, of all cattle.

After considering these comments, FSIS has not changed its conclusion that, when the distal ileum is effectively removed, beef small intestine that complies with the requirements of this interim final rule presents no greater risk of introducing the BSE agent into the human food supply than do other beef products permitted for use as human food in the United States. As discussed below, this conclusion is based on the information available to the Agency with regard to BSE infectivity in the intestine of cattle, together with the availability of procedures to effectively remove the distal ileum.

FSIS is not aware of any studies in which BSE infectivity has been confirmed in any portion of the intestinal tract of cattle other than the distal ileum. The animal studies of TSEs that indicate infectivity along the entire intestinal tract that the Agency is aware of involve animal species other than cattle (Ref. 1–6, available for viewing by the public in the FSIS docket room). Although the data on TSEs in other animal species may represent the distribution of infectivity in those species, these data may not represent the distribution of infectivity in cattle as evidenced by the studies discussed below.

The Agency recognizes that, based on the structure and function of cells that make up the gastrointestinal tract of mammals, many areas within the mammalian gastrointestinal tract could theoretically be capable of harboring abnormal prions. TSE infectious agents that enter susceptible animals through oral consumption of infectious material appear to gain access to the CNS through the nerves that innervate the gastrointestinal tract. Infection may involve a first step of presentation to lymphatic tissues and may also occur by direct invasion of nerve endings in the intestinal mucosa (Ref. 7, available for viewing by the public in the FSIS docket room). Both gut-associated lymphoid tissue (GALT) and ENS tissue are present throughout the intestinal tract.

However, despite this theoretical risk, the only bovine GALT found to be positive for BSE infectivity thus far has been in the Peyers Patches of the distal ileum of calves infected with BSE under experimental conditions. Two other GALT tissues from natural field cases, spleen and mesenteric lymph nodes, have been subjected to mouse bioassays and found to be non-infectious (Ref. 8, available for viewing by the public in the FSIS docket room). Spleen and mesenteric lymph node samples from experimentally dosed calves have also been subjected to mouse bioassays with similar results.

A component of the ENS is the myenteric plexus that courses within the length of the intestinal wall (Ref. 9, available for viewing by the public in the FSIS docket room). Distal ileum sections of the intestine from cattle that acquired natural field cases of BSE have been examined for the presence of abnormal prion protien through immunostaining, and the ganglion cells of the myenteric plexus were found to contain abnormal prions in 9 out of 29 samples (Ref. 10, available for viewing by the public in the FSIS docket room). Other areas of the ENS system from naturally occurring cases of BSE have not yet been examined for abnormal prion protein through immunostaining.

Gastrointestinal tissue from BSE field cases were subjected to and found non-infective by mouse bioassay include a sample of the splanchnic nerve, as well as samples of rumen, omasum abomasum, proximal small intestine, distal small intestine, proximal colon, distal colon, and rectum (Ref. 8, available for viewing by the public in the FSIS docket room). From the U.K. pathogenesis studies, in which calves were orally dosed with BSE-infectious materials, samples of rumen, omasum, abomasum, duodenum, and spirial colon were found to be non-infective by mouse bioassay (Ref. 11, available for viewing by the public in the FSIS docket room). None of these samples have been subjected to a cattle bioassay.

FSIS is aware of one small experiment in which immunostaining was attempted on gastrointestinal tissue outside of distal ileum. The study involved three calves that were orally infected with the BSE agent and sacrificed six months later. In the study, immunostaining was negative in all locations tested except for the Peyers Patches of the distal ileum (Ref. 10, available for viewing by the public in the FSIS docket room).

When it issued the SRM interim final rule, FSIS acknowledged that available data on the development and distribution of tissue infectivity in BSE infected cattle are incomplete and that additional studies using cattle bioassays were being conducted to ensure that low levels of infectivity that may not have been detected using mouse bioassays are not missed (69 FR 1862, 1864–1865, January 12, 2005). However, on the basis of the findings described above, FSIS has concluded that bovine intestinal tissues other than the distal ileum are either unlikely to contain BSE infectivity or contain infectivity below the level of detection using the mouse bioassay. Furthermore, FSIS has also concluded that, due to the availability of procedures to remove the distal ileum, the fact that infectivity has been confirmed only in the distal ileum has the most significant implications for human health.

Thus, FSIS has determined that designating the distal ileum as SRM is a prudent and appropriate measure to prevent human exposure to the BSE agent in the United States. The Agency has also determined that it is not necessary to designate the entire small intestine or the large intestine as an SRM.

Future research that has been recommended by the European SSC includes cattle bioassay and more sensitive prion detection testing of many of the cattle tissues described above (Ref. 12, available for viewing by the public in the FSIS docket room). Stored tissue is available for this purpose in the United Kingdom. A pathogenesis study underway in Germany will also provide tissue from cattle incubating BSE for more definitive testing (Ref. 13, available for viewing by the public in the FSIS docket room).

The Agency supports the need for the research being conducted with regard to BSE and other TSEs. On March 18, 2005, the Secretary of Agriculture announced that almost $2 million in funding has been redirected to enhance research on BSE (''Johanns Announces

Expansion of BSE Research Program and Research Initiative to Improve Food Safety,'' USDA press release no. 0097.05, March 18, 2005). The BSE research funds, redirected by USDA's Agricultural Research Service, will be used for newly funded BSE projects and facilities. Many of these newly funded projects involve international collaboration with researchers from the United Kingdom and other European countries. While FSIS believes that the primary tissues of concern for spreading the BSE agent have been identified, the Agency will use the results of futures studies on BSE to further refine this determination and inform its policies with regard to BSE.

FSIS disagrees with the comment that slaughterhouse contamination of other intestinal areas with matter from the ileum cannot be avoided. As discussed earlier in this document, the FSIS SRM interim final rule requires that establishments develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs, and that they incorporate these procedures into their HACCP plans, Sanitation SOPs or other prerequisite programs (9 CFR 310.22(d)(1)). These procedures must ensure that all SRMs, including the distal ileum, are completely removed from the carcass, segregated from edible products, and disposed of in an appropriate manner as prescribed by 9 CFR 314.1 and 9 CFR 314.3 (*i.e.*, used for inedible rendering, incinerated, or denatured). FSIS is responsible for ensuring the adequacy and effectiveness of the establishment's procedures.

As stated throughout this document, FSIS has determined that beef processors have the technology to effectively remove the distal ileum from the intestine of cattle. Thus, the Agency has concluded that when establishments incorporate their technologies for removing the distal ileum into their HAACP plan or Sanitation SOP or other prerequisite program, they will be able to effectively remove the distal ileum in a manner that does not contaminate edible materials.

Amendments to SRM Interim Final Rule

After carefully evaluating this issue and the comments submitted on the removal of the distal ileum, including the anatomical descriptions and diagrams of the bovine small intestine, as well as the detailed descriptions of the procedures for removal of the distal ileum, FSIS has concluded that processors have the technology to effectively remove the distal ileum from the rest of the small intestine. Therefore, FSIS is amending the SRM interim final rule to permit for use as human food beef small intestine, excluding the distal ileum, derived from cattle slaughtered in official U.S. establishments or in certified foreign establishments in countries listed by FSIS in 9 CFR 327.2(b) as eligible to export meat products to the United States.[2] This is a requirement that all meat and meat food products must comply with to be eligible for use as human food in the United States. In addition, FSIS will not permit natural casings derived from beef small intestine, excluding the distal ileum, to be used as containers of meat food products unless the casings are derived from cattle that have been inspected and passed in an official U.S. establishment or in a certified foreign establishment.

9 CFR 327.1(b) of FSIS' import regulations provides that compliance with the conditions of importation under FSIS' regulations does not excuse the need for compliance with applicable requirements under other laws, including the provisions in 9 CFR parts 94, 95, and 96 of APHIS' regulations. Thus, under the amendments to the SRM interim final rule described in this document, beef small intestine derived from cattle that have been in countries listed by APHIS in 9 CFR 94.18(a) as regions that present a risk of introducing BSE into the United States will continue to be subject to importation restrictions established by APHIS. APHIS' regulations at 9 CFR parts 94, 95, and 96 prohibit or restrict the importation of beef products and by-products, as well as casings (except stomachs), from cattle that have been in any of the regions listed by APHIS in 94.18(a). FSIS and APHIS work closely together to ensure that meat and meat products imported into the United States comply with the regulatory requirements of both agencies. FSIS and APHIS will continue to work together to ensure that the agencies maintain a consistent policy with regard to the importation of beef small intestines.

The amendments to the interim final rule also require that establishments that process beef small intestine for human food have in place procedures to ensure that the distal ileum is effectively removed. As provided in 9 CFR 310.22(d)(1), the establishment must incorporate these procedures into its HACCP plan or Sanitation SOPs or other prerequisite program. FSIS has concluded that procedures that require removal of at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum comply with this requirement. The Agency believes that this standard is sufficiently conservative to ensure removal of the distal ileum despite differences in length of the intestinal tract or its segments between breeds or variations from animal to animal of the same breed. However, establishments may propose alternative standards if they can demonstrate that such standards are as effective as the standards described above in ensuring that the entire distal ileum is completely removed.

APHIS' regulations prohibit or restrict the importation of most ruminants and ruminant products, including beef intestines and casings, from countries listed by APHIS as presenting a risk of introducing BSE into the United States. As discussed above, to be eligible for importation under FSIS' regulations, beef small intestine must comply with both FSIS' and APHIS' import regulations.

Jurisdiction

Under section 1(j) of the FMIA, products from cattle that contain meat or other portions of the carcass only in a relatively small proportion or that historically have not been considered by consumers as products of the meat food industry are not considered ''meat food products'' subject to regulation by FSIS (21 U.S.C. 601(j)). Thus, while unprocessed bovine small intestine is regulated by FSIS as a meat food product, stripped and cleaned casings derived from the small intestine of cattle have historically been regulated by FDA.

As discussed above, FSIS has decided to permit for use as human food beef small intestine, excluding the distal ileum, derived from cattle slaughtered in official U.S. establishments or in certified establishments in foreign countries that FSIS considers eligible to export meat and meat products to the United States. However, because the amendments to the SRM interim final rule described in this document are not intended to affect the regulatory authority of either FSIS or FDA, jurisdiction over a product derived from small intestine will continue to depend on whether the product is considered a meat food product as defined in the FMIA. Thus, unprocessed beef small intestine will continue to be regulated

[2] Once a country is listed in 9 CFR 327.2(b) as eligible to export meat and meat products to the United States, it must maintain a meat inspection system that is equivalent to that of the United States. If it does not, FSIS will not permit meat products from that country to be imported into the United States. FSIS conducts audits of eligible foreign countries meat inspection systems at least annually.

by FSIS, and stripped and cleaned natural casing derived from bovine small intestine will continue to be regulated by FDA.

However, although they are regulated by FDA, natural beef casings are used as containers for certain meat food products. Therefore, before FSIS applies the mark of inspection to a meat food product encased in a natural beef casing derived from the small intestine, the Agency will require that the establishment provide documentation that demonstrates that the small intestine from which the casing was derived complies with the requirements in the amendments to the SRM interim final rule.

Small Business Considerations

One of the reasons that FSIS is at this time issuing these amendments to the SRM interim final rule to allow the use of beef small intestine, excluding the distal ileum, for human food is that the Agency has received several comments in response to the SRM rule and the APHIS/FSIS/FDA ANPR from small companies that manufacture sausages and other products encased in natural beef casings, as well as from manufacturers of ethnic foods, that indicate that the prohibition on the use of the entire small intestine for human food is having an adverse economic impact on small and very small businesses. As noted by the commenters, beef round casings, which are derived from the small intestine of cattle, are used in a wide assortment of sausage products, as well as in specialty sausages. The commenters stated that processors can substitute collagen casing for some types of sausage made from natural beef rounds, but this generally results in a lower quality product with a decreased market value.

Although some companies had stocks of natural casings from cattle slaughtered prior to January 12, 2004, the date that the SRM interim final rule went into effect, these companies have informed FSIS that their existing supplies of natural beef casings will soon be exhausted. Permitting the use of beef small intestine, excluding the distal ileum, will relieve some of the economic burden that the prohibition on the use of the entire small intestine for human food has imposed on these small entities.

Summary of the Amendments

As discussed above, FSIS is amending the SRM interim final rule to permit, under certain conditions, the use of beef small intestine, excluding the distal ileum, for human food. As amended, 9 CFR 310.22(a)(3) will no longer require that establishments remove the entire small intestine of all cattle and dispose of it as inedible. Instead, it will specify the conditions under which the small intestine from cattle is permitted to be used for human food. These conditions were described in detail earlier in this document.

The regulations in 9 CFR 318.6(b)(1) provide that casings from cattle may be used as containers of products provided the casings are not derived from the small intestine. FSIS is amending paragraph (b)(1) to permit casings from cattle that are derived from the small intestine to be used as containers if the small intestine complies with the requirements in 9 CFR 310.22(a)(3) as amended. The amendments to paragraph (b)(1) also require that establishments that use casings derived from the small intestine of cattle as containers for products demonstrate, through documentation, that the small intestine from which the casing was derived complies with the requirements in 9 CFR 310.22(a)(3) as amended.

9 CFR 318.6(b)(8) prohibits small intestine from cattle for use in any meat food product or for edible rendering. FSIS is amending paragraph (b)(8) to permit small intestine from cattle to be used in a meat food product or for edible rendering if it complies with the requirements in 9 CFR 310.22(a)(3) as amended.

Effective Date and Opportunity for Public Comment

Because FSIS has already provided the public with opportunities to comment on the issues raised in this document (once in response to the SRM interim final rule published on January 12, 2004 and again in response to the APHIS/FSIS/FDA ANPR published on July 14, 2004), and because the restrictions on the use of the small intestine for human food are adversely affecting small businesses without providing any public health benefits, the amendments to the SRM interim final contained in this document will become effective before the comment period closes. FSIS will consider any comments received during the comment period for this amended interim final rule (see DATES above). After that comment period closes, the Agency will publish another document in the **Federal Register**. The document will include a discussion of all comments received in response to the SRM interim final rule, the APHIS/FSIS/FDA ANPR, and the amendments to the SRM interim final rule described in this document. It will also include any amendments to the SRM interim final rule made as a result of those comments.

Executive Order 12866 and Regulatory Flexibility Act

These amendments to the January 12, 2004 interim final rule have been determined to be significant and therefore, have been reviewed by the Office of Management and Budget.

The interim final rule of January 12, 2004 (69 FR 1862) included a Preliminary Regulatory Impact Analysis (PRIA) that was made available for comment on April 7, 2004 (69 FR 18245). The PRIA indicated that benefits of the SRM interim final rule were primarily those resulting from the reduction in human exposure to BSE infectivity and the restoration of beef exports. The PRIA estimated that designating beef small intestines, including the distal ileum, from cattle of all ages as a specified risk material did not result in a significant reduction in potential human exposure to BSE. As discussed elsewhere in this document, the distal ileum was designated as an SRM because BSE infectivity has been demonstrated in the distal ileum after oral exposure to the BSE agent. Although BSE infectivity was not demonstrated in the remaining part of the small intestine, the interim final rule required the removal of the entire small intestine to ensure effective removal of the distal ileum. Therefore, this action does not change the reduction in human exposure to BSE estimated in the PRIA.

The effect of amending the SRM interim final rule would be to increase the supplies of beef small intestines and beef natural casings manufactured from beef small intestine (beef casings) that do not contain the distal ileum, and that, prior to the implementation of the SRM rule, were used for human food. Although the SRM interim final rule designated the distal ileum of all cattle as an SRM, to ensure effective removal of the distal ileum, it required that the entire small intestine be removed and disposed of as inedible. Thus, as a result of the SRM rule, the supplies of beef small intestine and natural casings derived from beef small intestine produced after the effective date of the SRM rule were prohibited for use as human food.

One of the impacts on consumers of this prohibition of the use of beef small intestine for human food has been the loss of food products in marketplaces where the only suitable casings are beef casings. These types of food products that typically use beef casings include sausages such as salami, hard salami, thuringer, European-type sausages such as braunschweiger, metwurst, and supressa, basterma, and Arabic sausages, some patés, and a variety of

other food products largely sold in ethnic markets. Suitable substitutes for beef casings do not exist or are generally inadequate for some of these types of food products. For example, cellulosic, collagen, fibrous, muslin or synthetic casings, or hog or sheep casings are, in many cases, not adequate substitutes for beef natural casings for use in producing some sausages, or some types of traditional ethnic products. Another impact on consumers of this prohibition has been the loss of food products in ethnic marketplaces where beef small intestines were sold as variety meats, or food products were sold that used beef small intestines as an ingredient of manufactured food products or edible rendered food products. Suitable substitutes for beef small intestines as variety meats do not exist or are generally inadequate for some of these types of products.

The PRIA of the SRM interim final rule estimated that approximately 160 million pounds of small intestines, including the distal ileum, were removed from the human food supply. The net revenue lost by excluding the entire small intestine from the food supply, was estimated to be an average of $27.6 million ($20.6 to $34.5 million) per year for the food industry, after the implementation of the rule. Of the $27.6 million in net annual revenue lost as a result of the interim final rule, the PRIA estimated that an average of $16.6 million ($13.0 to $20.6 million) resulted from exclusion of the distal ileum and an average of $10.9 million from the remaining parts of the small intestine (see page 24 of the analysis). Therefore, this action is estimated to restore an average of $10.9 million ($2.9 to $19.0 million) in net revenues lost as a result of the interim final rule.

In the PRIA, the Agency estimated, by survey, that approximately 47 federally-inspected establishments, that were primarily large establishments, were affected by the value lost of beef small intestines that were used for food products and to manufacture beef casing. The amendment would allow some of these 47 establishments to resume their sales of beef small intestines, beef casing, and food products that use the imported beef casings. Thus, some of the 47 establishments or firms are expected to recover some of the value lost through these new sales because of the amendment. The Agency is unable to estimate the number of establishments that would resume the sales of beef small intestines and their associated food products.

Also, the Agency is unable to estimate the number of establishments that used beef casings in the production of meat products prior to the implementation of the SRM interim final rule in January of 2004. However, it believes that the number of domestic establishments producing such products was small. As discussed elsewhere in this document, the Agency has received comments from small companies that indicate that the prohibition on the use of the entire small intestine for human food is having an adverse economic impact on some small and very small businesses. Most of these commenters are manufactures of meat food products encased in natural beef casing. These amendments will help to relieve some of this economic burden. However, FSIS is unable to determine the number of small entities that will benefit from this action.

The economic impact of the measure on manufacturers of casings produced from other sources is not significant. The availability of natural beef casings may reduce the demand for some cellulosic, collagen, synthetic, or other types of casings. However, the reduction is not expected to be significant, given the long-term trend in the use of these types of non-natural casings.

Therefore, the Agency has determined that these amendments to the interim 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).

The PRIA estimated that the SRM interim final rule would have a minimal impact on U.S. meat production and beef prices paid by consumers, because these products are a very small amount of total beef production. Therefore, allowing the small intestine, excluding the distal ileum, for use as human food as provided in this action will not have a significant impact on the food industry and consumers.

The availability of these types of casing will reduce the demand for some cellulosic, collagen, synthetic, or other types of casings. However, the reduction is not expected to be significant, given the long-term trend in the use of these types of non-natural casings.

Executive Order 12988

This amendment to the SRM interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. In this interim final rule: (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.

Paperwork Requirements

The SRM interim final rule included a paperwork analysis (61 FR 38862) prepared in accordance with the Paperwork Reduction Act. FSIS has determined that the corrections and amendments in this rule do not change any information collection burden hours.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this amended interim final rule, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/2005_Interim_&_Final_Rules_Index/index.asp.* The Regulations.gov Web site is the central online rulemaking portal of the United States government. It is being offered as a public service to increase participation in the Federal government's regulatory activities. FSIS participates in Regulations.gov and will accept comments on documents published on the site. The site allows visitors to search by keyword or Department or Agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at *http://www.regulations.gov/.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

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List of Subjects

9 CFR Part 310

Animal diseases, Disposition of carcasses, Meat inspection, and Post-mortem inspection.

9 CFR Part 318

Entry into official establishments, Food packaging, Meat inspection, Reinspection and preparation of products.

■ For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III as follows:

PART 310—POST-MORTEM INSPECTION

■ 1. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 2. Paragraph (a)(3) of § 310.22 is amended by removing the second sentence and adding the following sentence and paragraphs (a)(3)(i) and (ii) in its place:

§ 310.22 Specified risk materials from cattle and their handling and disposition.

(a) * * *

(3) * * * The small intestine may be used for human food if:

(i) It is derived from cattle that were inspected and passed in an official establishment in the United States or in a certified foreign establishment in a country listed in 9 CFR 327.2(b) as eligible to export meat and meat products to the United States and it is otherwise eligible for importation under 9 CFR 327.1(b), and

(ii) The distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment demonstrates is effective in ensuring complete removal of the distal ileum.

* * * * *

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

■ 3. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 38F, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 4. Section 318.6 is amended to revise paragraphs (b)(1) and (b)(8) to read as follows:

§ 318.6 Requirements concerning ingredients and other articles used in preperation of products.

* * * * *

(b)(1) The only animal casings that may be used as containers of product are those from sheep, swine, or goats. Casings from cattle may be used as containers of products. However, if casings from cattle are derived from the small intestine, the small intestine must comply with the requirements in 9 CFR 310.22(a)(3). Establishments that use casings derived from the small intestine of cattle as containers for products must demonstrate, through documentation, that the small intestine from which the casing was derived complies with the requirements in 9 CFR 310.22(a)(3).

* * * * *

(8) Intestines shall not be used as ingredients in any meat food product for which a standard is prescribed in part 319 of this subchapter and shall not be used in other products unless the products are labeled in accordance with § 317.8(b)(3) of this subchapter. When small intestine from cattle is used in a meat food product or for edible rendering, it must comply with the requirements in 9 CFR 310.22(a)(3).

* * * * *

Done at Washington, DC on: September 1, 2005.

Barbara J. Masters,

Administrator.

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