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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 189 and 700

[Docket No. 2004N-0081]
RIN 0910-AF47

Use of Materials Derived From Cattle in Human Food and Cosmetics

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule and request for comments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on the use of materials derived from cattle in human food and cosmetics. In these regulations, FDA has designated certain materials from cattle as ``prohibited cattle materials'' and has banned the use of such materials in human food, including dietary supplements, and in cosmetics. Prohibited cattle materials include specified risk materials (SRMs), the small intestine of all cattle unless the distal ileum is removed, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, or mechanically separated (MS) (Beef). Specified risk materials include 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 of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle. FDA is amending its regulations so that FDA may designate a country as not subject to certain bovine spongiform encephalopathy (BSE)-related restrictions applicable to FDA regulated human food and cosmetics. A country seeking to be so designated must send a written request to the Director of FDA's Center for Food Safety and Applied Nutrition, including information about the country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other relevant information.

DATES: This interim final rule is effective July 16, 2008. Submit written or electronic comments on this interim final rule by July 16, 2008. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by May 19, 2008 (see the ``Paperwork

Reduction Act of 1995'' section of this document).

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ADDRESSES: You may submit comments, identified by Docket No. 2004N-0081 and RIN 0910-AF47, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

FAX: 301-827-6870.

Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously in the ADDRESSES portion of this document under Electronic Submissions.

Instructions: All submissions received must include the agency name and Docket No. and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see section IV of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the ``Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rebecca Buckner, Center for Food Safety and Applied Nutrition (HFS-316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1486.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 14, 2004 (69 FR 42256), FDA issued an interim final rule entitled ``Use of Materials Derived From Cattle in Human Food and Cosmetics'' (``the 2004 IFR'') to address the potential risk of BSE in human food and cosmetics. In the 2004 IFR, FDA designated certain materials from cattle as ``prohibited cattle materials'' and banned the use of such materials in human food, including dietary supplements, and in cosmetics. These restrictions appear in Sec. Sec. 189.5 and 700.27 (21 CFR 189.5 and 21 CFR 700.27) of FDA's regulations.

The 2004 IFR designated the following as prohibited cattle materials: SRMs, the small intestine from all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and

passed for human consumption, or MS (Beef). SRMs include 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 of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine from all cattle. The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) designated the same list of materials as SRMs in its interim final rule entitled ``Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle'' (69 FR 1862, January 12, 2004).

In the Federal Register of September 7, 2005 (70 FR 53063), FDA amended the 2004 IFR to permit the use of the small intestine in human food and cosmetics provided the distal ileum portion of the small intestine has been removed. FDA also clarified that milk and milk products, hide and hide-derived products, and tallow derivatives are not prohibited cattle materials, and cited a different method for determining impurities in tallow. Also in the Federal Register of September 7, 2005 (70 FR 53043), FSIS published a similar amendment to its interim final rule, permitting the use of the small intestine in human food provided the distal ileum is removed.

II. Amendments to the Interim Final Rule's Provisions on Prohibited Cattle Materials

In the 2004 IFR, FDA requested comment on whether materials from countries believed to be free of BSE should be exempt from the ``prohibited cattle materials'' requirements. FDA further solicited comment on what standards it should apply in determining whether to exempt a country and how it should determine whether a country meets such standards (69 FR 42256 at 42263). FSIS requested similar comment on the issue of equivalence in applying its BSE requirements in an advance notice of proposed rulemaking (ANPR) entitled ``Federal Measures to Mitigate BSE Risks: Considerations for Further Actions,'' jointly published by USDA's Animal and Plant Health Inspection Service (APHIS) and FSIS, and FDA on July 14, 2004 (69 FR 42299-42300).

A. Comments Received

In response to FDA's solicitation on this issue, FDA received comments from representatives of several foreign countries that export cattle materials or products derived from such materials into the United States and from several trade associations. The comments take issue with the uniform application of FDA's BSE-related measures to all human food and cosmetics imported into the United States, without regard to the BSE risk status of the originating country. Several comments state that their countries have a comprehensive range of control measures in place to prevent the entry and/or amplification of the BSE agent. These comments maintain that countries classified as BSE-free do not present a BSE risk and therefore should not be expected to comply with FDA's BSE-related restrictions. These comments further maintain that U.S. requirements are forcing establishments and firms in countries considered to be free of BSE to carry out costly and

unnecessary measures that are not scientifically justified so that they can export cattle materials to the United States.

These comments also state that providing an exemption from BSE-related restrictions for countries classified as free of BSE would be consistent with guidelines established by the World Organization for Animal Health (referred to as ``OIE,'' based on its previous name, Office International des Epizooties), an international standard-setting body with 169 member countries, that publishes health standards for international trade in animal products. These comments state that the OIE recommends that countries restrict the importation of cattle material of potential concern on the basis of the BSE risk classification of the country or zone of origin. (See Terrestrial Animal Health Code, Ref. 1). These comments also point out that OIE recommends the removal of SRMs for imports from countries classified as minimal, moderate, and high risk for BSE but not for imports from countries with BSE-free status.\1\ Further, these comments

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point out that the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) requires member countries to recognize regionalization of diseases and not put in place measures that are more trade restrictive than necessary to achieve public health goals.

\1\ At the time the comments were submitted, OIE classified countries for purposes of BSE into one of five categories: ``free,'' ``provisionally free,'' ``minimal,'' ``moderate,'' and ``high risk.'' OIE subsequently revised its categories and now uses only three categories: ``negligible,'' ``controlled,'' and ``undetermined'' risk. Countries previously categorized as ``BSE-free'' or ``provisionally free'' are now categorized as having ``negligible'' BSE risk.

Several of the comments also note that Canada and the European Union (EU) do not apply all of their BSE-related restrictions to countries recognized as BSE-free. For example, EU food and cosmetic regulations exclude countries that fall within the EU's lowest risk range of BSE risk categories from restrictions on the use of SRMs. Canada provides a similar exemption from its BSE-related restrictions for countries it considers to be free from BSE.\2\

\2\ Since these comments were submitted, Canada has adopted the OIE BSE risk categorization system of negligible, controlled, and undetermined risk. The EU is in the process of transitioning from its geographical BSE risk (GBR) system, which includes four levels of risk, to the OIE 3-tiered risk categorization system.

One comment suggests that in considering the BSE risk status of another country, FDA should refer to available country assessments

already completed by USDA's APHIS in carrying out its BSE-related restrictions on imports of meat and edible products from ruminants (codified at 9 CFR 94.18), or otherwise rely on criteria provided by OIE for determining BSE-free countries. One comment recommends that if the assessment is conducted by U.S. authorities, it should be conducted by a single U.S. agency, preferably APHIS, given its prior experience in conducting this type of assessment.

B. USDA Amendment

USDA's FSIS received similar comments in response to its interim final rule published on January 12, 2004, and the ANPR published July 14, 2004, regarding the application of its BSE-related restrictions for imported products without taking into account a country's BSE risk status. Based in part on these comments, FSIS, in its affirmation of interim final rules with amendments published on July 13, 2007 (72 FR 38699), amended its regulations to exclude from its definition of SRMs those materials from cattle that come from foreign countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from exposure to the BSE agent as does prohibiting the use of SRMs in the United States.

C. Response to Comments

FDA agrees with the views expressed by the comments and has determined that it is not necessary for all BSE-related restrictions to apply to human food and cosmetics regardless of a country's BSE status. FDA's BSE-related restrictions for human food and cosmetics are intended to address the potential presence of BSE in a country's cattle population. SRMs are prohibited because they are the tissues most likely to harbor infectivity in cattle with BSE. The small intestine is prohibited unless the distal ileum portion of the small intestine, which is considered an SRM, is effectively removed. Material from nonambulatory disabled cattle are prohibited because evidence has indicated that this segment of the cattle population is more likely to have BSE than healthy-appearing cattle and the typical clinical signs of BSE having to do with gait and movement cannot be observed in nonambulatory cattle. MS (Beef) is included in the definition because it may contain concentrated amounts of the following SRMs: spinal cord, dorsal root ganglia, and vertebral column. Material from cattle not inspected and passed is prohibited because they are at higher risk of harboring undetected BSE.

As described in the 2004 IFR, epidemiological evidence indicates that the BSE epidemic in the United Kingdom (U.K.) was a result of consumption of animal feed contaminated by the BSE agent. The spread of BSE outside the U.K. has been attributed to the export of BSE-contaminated feed from the U.K. to other countries prior to the realization of the role of feed in transmitting the disease and the implementation of restrictions on such trade. However, a country may not have engaged in trade in animal feed with the U.K. or other affected countries, and it may have had preventive measures in place for a length of time adequate to make the chance remote that BSE currently is present in its national herds.

Such a country may be able to demonstrate to FDA that its BSE case history, risk factors, and measures to prevent the introduction and transmission of BSE make certain BSE-related restrictions unnecessary. Not restricting cattle materials inspected and passed for human consumption from such a country to be used in human food and cosmetics is consistent with all applicable statutory standards. Further, this approach is consistent with OIE's recommendation that cattle materials from negligible risk countries not be restricted.

Material from cattle not inspected and passed for human consumption will continue to be prohibited, regardless of the country of origin. We are retaining this provision as a universal requirement because the exception for designated countries in this amendment is predicated on application of a country's food safety controls, including inspection of source animals, to human food or cosmetics made with cattle materials and imported into the United States. It is critical to ensuring safety that, regardless of the country of origin, source cattle have been evaluated and determined appropriate for human consumption. In addition, applying this requirement universally is consistent with OIE recommendations, which recognize the importance that cattle pass antemortem and post-mortem inspections even in ``negligible risk'' countries.

Therefore, FDA is amending its regulations in Sec. Sec. 189.5 and 700.27 to provide that FDA may designate a country as not subject to the restrictions applicable to human food and cosmetics manufactured from, processed with, or that otherwise contain SRMs, the small intestine of cattle, material from nonambulatory disabled cattle, or MS (Beef). Cattle materials inspected and passed from a designated country will not be considered prohibited cattle materials and their use will not render a human food or cosmetic adulterated. The amendment further provides that a country seeking to be so designated must send a written request to the Director of FDA's Center for Food Safety and Applied Nutrition, including information about a country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and other information relevant to determining whether SRMs, the small intestine of cattle (unless the distal ileum has been removed), material from nonambulatory disabled cattle, or MS (Beef) should be considered prohibited cattle materials.

In its application, the requesting country will be expected to provide information to FDA on its BSE case history, including whether cattle in that country have tested positive for BSE, and if so, the circumstances and the country's response. In addition, FDA will review information that addresses the extent to which the requesting country has identified and taken into account relevant risk factors such as the following:

Possible presence of BSE in indigenous and/or imported cattle;

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Geographic origin of imported cattle;

Materials used in the production of ruminant feed and feed ingredients; and

Importation of ruminant feed and feed ingredients.

FDA will consider information relating to the possible presence of BSE in indigenous and imported cattle in the requesting country as well as the requesting country's production and importation of ruminant feed and feed ingredients. With respect to imported cattle, relevant information includes the identification of any countries where imported cattle were born or raised and the dates any cattle were imported. With regard to ruminant feed, FDA will consider, among other things, how ruminant feed was produced in the requesting country, including what animal origin materials were allowed to be included. FDA will also consider whether ruminant feed and feed ingredients were imported, and if so, the source countries and dates of import.

In addition to reviewing risk factors such as those identified previously, FDA will assess how the requesting country has addressed and managed any identified BSE risks through the implementation of appropriate measures to prevent the introduction and transmission of BSE. FDA will consider how long such preventive measures have been in place and whether they have been effectively carried out. Examples of preventive measures include the following:

A prohibition on the use of ruminant feed that might carry a risk of transmitting the BSE agent;

A prohibition on the importation of cattle and cattle-derived products that might carry a risk of transmitting the BSE agent;

Surveillance systems for BSE in cattle populations with appropriate examination of brain or other tissues collected for surveillance in approved laboratories;

Mandatory notification and examination of all cattle showing signs consistent with BSE; and

Protocols or other written procedures for investigating potential cases of BSE, including ability to trace former herdmates of BSE-positive animals.

As part of its evaluation of feed restrictions, FDA will consider factors including whether appropriate feed restrictions are in place and the adequacy of enforcement of those restrictions (e.g., the frequency of facility inspections and level of compliance). FDA also will consider a requesting country's import controls for cattle material. Such consideration will include whether the country effectively monitors and controls potential pathways of SRMs and other potentially infective materials into its country from other countries for whom such controls are necessary.

In addition, FDA will consider the requesting country's surveillance and monitoring efforts with respect to BSE. For example, FDA will evaluate the level at which the country performs surveillance and monitoring, whether tissue samples are collected and examined at approved laboratories, and whether recognized diagnostic procedures and methods are used, such as those procedures and methods provided in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Ref. 2).

FDA also will consider whether the country has an ongoing program for notification and investigation of all cattle showing signs consistent with BSE. In evaluating such a program, FDA will consider, among other factors, whether notification and investigation are mandated, whether veterinarians, producers, and others involved in cattle production have been provided sufficient information about BSE,

such as through an awareness program, and whether there are additional measures in place to stimulate reporting of suspect cattle, such as compensation or penalties.

FDA also will consider a country's written procedures for investigating potential cases of BSE. Such a consideration will include whether the country has written procedures for the investigation of suspect animals and whether the country has the investigative capability to followup positive findings by tracing former herdmates of animals determined to be BSE positive. Finally, FDA also will consider any other information relevant to determining whether the country should be designated under Sec. Sec. 189.5(e) and 700.27(e).

FDA and the USDA agencies, APHIS and FSIS, have different regulatory responsibilities with respect to preventing BSE and ensuring food safety. Further, it is not necessary or practical for one of the three agencies to conduct every evaluation of a country's BSE status, regardless of the purpose of the evaluation. FDA will, however, consult with APHIS and FSIS as part of its evaluation process. Further, FDA will take into consideration available risk assessments of other competent authorities in conducting its evaluation. Though it is not required, a previous BSE evaluation by USDA, OIE, or by another country or another competent authority, will be helpful to FDA in its review and may decrease the time needed for FDA to make a determination.

Upon completion of its review, FDA will provide written notification of its decision to the applicant country, including the basis for the decision. FDA may impose conditions in granting a request for designation. Further, any designation granted under Sec. 189.5 or Sec. 700.27 will be subject to future review by FDA to ensure that the designation remains appropriate. As part of this process, FDA may ask designated countries to confirm that their BSE situation and the information submitted by them in support of their original application remain unchanged. Further, FDA may revoke a country's designation if FDA determines that it is no longer appropriate.

FDA will provide further information on its evaluation process, the scope of the review, and the types of supporting information that it would find helpful in reviewing a country's submission at the time of the request.

III. Summary of Amendments to the Interim Final Rule

FDA is amending its regulations in Sec. Sec. 189.5(a) and 700.27(a) by revising the definition of ``prohibited cattle materials'' to exclude cattle materials inspected and passed for human consumption from a country designated by FDA under Sec. 189.5(e) or Sec. 700.27(e). New Sec. Sec. 189.5(e) and 700.27(e) provide that a country seeking such a designation must send a written request to the Director, Office of the Center Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835. Further, the request shall include information about a country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and other information relevant to determining whether SRMs, the small intestine of cattle (unless the distal ileum has been removed), material from nonambulatory disabled cattle, or MS (Beef) should be considered

prohibited cattle materials. The new sections further provide that FDA shall respond in writing to any such request and that FDA may revoke a country's designation if FDA determines that it is no longer appropriate.

IV. Effective Date and Opportunity for Public Comment

In the 2004 IFR, FDA solicited comment on whether materials from countries believed to be free from BSE should be exempt from the ``prohibited cattle materials'' requirements. FDA

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addresses the comments it received in this document. This amendment is effective on July 16, 2008. FDA invites public comment on the current amendment to the interim final rule; submit written or electronic comments on the interim final rule by July 16, 2008. The agency will consider modifications to the current amendment to the interim final rule based on comments made during the comment period. Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

FDA will address other comments received in response to the 2004 IFR and comments received in response to this document in further rulemaking.

V. Executive Order 12866 and Regulatory Flexibility Act

A. Interim Final Regulatory Impact Analysis

FDA has examined the economic impacts of the interim final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this interim final rule is not a significant regulatory action as defined by Executive Order 12866.

1. Need for Regulation

FDA agrees with FSIS and the international community that cattle materials imported from countries that can demonstrate that their BSE case history and their having in place effective measures to prevent the introduction and transmission of BSE may be such that they should not be subject to the same BSE-related restrictions applied to cattle materials imported into the United States from other countries. Restricting the importation of potentially infective materials on the basis of the BSE risk of the region of origin is more efficient than an approach that does not consider a country's circumstances regarding BSE.

As comments on the 2004 IFR have noted, the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) requires member countries to recognize regionalization of diseases and not put in place measures that are more trade restrictive than necessary to achieve public health goals. Thus, the uniform application by FDA of BSE-related restrictions to all imports of food and cosmetic products into the United States without taking into account a country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and other relevant information means that other countries must implement costly and unnecessary measures that may not be scientifically justified. Providing this exception from certain requirements relating to human food and cosmetics for designated countries is more efficient in the sense that it achieves essentially the same protection of public health with fewer restrictions on the market for cattle-derived materials.

2. Interim Final Rule Coverage

Foreign countries need to make formal application to FDA in order to be considered for this exception from the provision on prohibited cattle materials in Sec. Sec. 189.5 and 700.27. FDA will make a determination as to a country's request based on an evaluation that is carried out in consultation with the USDA's APHIS and FSIS. FDA will take into consideration relevant technical information provided by the requesting country with respect to its BSE case history, including whether cattle in that country have tested positive for BSE, and if so, the circumstance and the country's response. In addition, FDA will review information that addresses the extent to which the requesting country has identified and taken into account relevant risk factors such as the following:

- The possible presence of BSE in indigenous and/or imported cattle;
- Geographic origin of imported cattle;
- Materials used in the production of ruminant feed and feed ingredients; and
- Importation of ruminant feed and feed ingredients.

FDA will also assess how the requesting country has addressed and managed any identified BSE risks through the implementation of appropriate measures to prevent the introduction and transmission of BSE, such as the following:

- A prohibition on the use of ruminant feed that might carry a risk of transmitting the BSE agent;
- A prohibition on the importation of cattle and cattle-derived products that might carry a risk of transmitting the BSE agent;
- Surveillance systems for BSE in cattle populations with

appropriate examination of brain or other tissues collected for surveillance in approved laboratories;

Mandatory notification and examination of all cattle showing signs consistent with BSE; and

Protocol or other written procedures for investigating potential cases of BSE, including ability to trace former herdmates of BSE-positive animals.

Number of Countries Affected

We do not know how many countries will take advantage of the option to petition FDA for a designation under Sec. Sec. 189.5(e) and 700.27(e). According to information from the OIE, countries that are officially recognized as having a ``negligible BSE risk'' in accordance with the requirements of the OIE Terrestrial Animal Health Code (16th edition 2007) include the following: Australia, Argentina, New Zealand, Singapore, and Uruguay. Two countries, Iceland and Paraguay, are recognized as ``provisionally free''\3\ from BSE. For these two categories of countries, OIE does not recommend the removal of SRMs (Ref. 4).

\3\ The OIE ``provisionally free'' designation is in accordance with the 2004 edition (13th edition) of the Terrestrial Animal Health Code, and remains in effect for Iceland and Paraguay until May 2008. See Ref. 3.

Table 1 presents data from the U.S. International Trade Commission (Ref. 5) showing for 2006 the top 10 exporters of meat products\4\ and animal fats, oils, and by-products to the United States.

\4\ The data sorted by NAICS code does not allow for the separation of beef products that are imported from other imported meat products such as pork.

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Table 1.--Top 10 Countries Exporting Specified North American Industry Classification System (NAICS) Code Products to United States for 2006

NAICS 311611\1\--Meat Products (Excluding Poultry)	Quantity (thousands of kilograms)\2\
Canada	681,899
Australia	376,585
New Zealand	211,873
Uruguay	103,305
Brazil	83,897

Denmark	46,652
Mexico	35,553
China	28,530
Argentina	22,353
Nicaragua	21,303

NAIC 311613--Animal Fats, Oils, & By-Products	(thousands of kilograms)\3\
Canada	94,306
New Zealand	32,550
China	7,809
Australia	6,807
Brazil	6,589
Mexico	2,130
Colombia	1,826
Germany	1,642
Ecuador	1,149
Japan	1,138

\1\ The NAIC code 31161 covers the animal slaughtering and processing industry. The industry is composed of establishments that are primarily engaged in one or more of the following: (1) Slaughtering animals, (2) preparing processed meats and meat by-products, and (3) rendering and refining animal fat, bones, and meat scraps. The subcategory 311611 comprises those establishments primarily engaged in slaughtering animals (except poultry and small game). Establishments that slaughter and prepare meats are included in this classification. (Ref. 5) We use this data as an indicator of the countries that are most likely to petition FDA regarding their BSE status.

\2\ These figures do not include exports measured in ``clean yield kilograms'' and ``pieces.''

\3\ These figures do not include exports measured in ``grams,'' ``liters,'' ``metric tons,'' and ``pieces.''

We do not know how many countries might petition the FDA. However, taking into consideration the previous information on countries officially recognized as having a negligible BSE risk or being provisionally free of BSE under OIE, as well as the information in table 1 on countries that export large amounts of meat products and

animal fats, oils, and byproducts to the United States, we are estimating for this analysis that 10 countries may be interested in petitioning FDA to be excepted from certain BSE-related restrictions applicable to human food and cosmetics. Our estimate is not intended to suggest that all of these countries would be able to qualify for a designation under Sec. Sec. 189.5(e) and 700.27(e).

3. Costs and Benefits of Exemption Provision

Countries that petition the FDA to be designated as excepted from certain BSE-related restrictions applicable to human food and cosmetics may also petition USDA for exclusion from USDA's BSE-related requirements. Some of the costs to countries to petition FDA may be shared with costs to petition USDA because of similarities regarding how countries' products can qualify for the exceptions. Even so, we will outline here a potential scenario for calculating the costs of petitioning FDA for an exception from certain provisions of the agency's BSE regulations.

a. Assumptions and costs associated with this interim final rule. We would expect countries that wish to petition FDA to be excepted from certain BSE-related restrictions applicable to human food and cosmetics to have already completed a risk assessment and put risk management strategies into place.\5\ Whether these risk assessment and mitigation strategies are sufficient for a country to be so designated by FDA will be determined on a case-by-case basis.

\5\ We assume such measures were necessary to continue marketing cattle products following the surge of BSE cases in the U.K. and the rulemakings that followed.

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b. Petition process. We assume petitions to FDA for this designation would include an already developed risk assessment or other technical information on the country's BSE situation, a detailed outline of risk mitigation strategies, and information on the country's cattle-derived products that are exported to the United States. The petition is assumed to take 80 hours per country for assembly of the information and the wage for a government employee earning a GS-14 step 1 (Ref. 6) is used to estimate the costs. The cost of assembling a single petition is estimated to be about $5,400 (80 hours x $67.44 per hour including overhead). The petition will also be reviewed by higher level government managers before being sent to the FDA. We assume the wage for a high level government executive is a GS-15 step 3 (Ref. 6) and that they will spend 40 hours reviewing the petition. The cost of review by a government manager is estimated to be about $3,400 (40 hours x $84.62 per hour including overhead). Thus, the total cost to each country to prepare and submit a petition to FDA to be considered for this designation would be about $9,000.

c. Petition review by FDA. It will take FDA approximately 80 hours to review a petition. The cost of each petition review would be about $3,700 (80 hours x $45.65 per hour).\6\

\6\ Pay for an employee earning a GS-13 step 7 adjusted to

include locality pay for Washington D.C. and surrounding area (Ref. 6).

Table 2.--Total Cost of Initial Petition Application and Review

Petition Assembly and Review per Country	$9,000
FDA Review per Petition	$3,700
Total Cost per Country	$12,700
Cost for 10 Countries	$127,000

d. Petition success uncertainty. It is possible that some countries that petition the FDA to be designated as excepted from certain BSE-related restrictions applicable to human food and cosmetics will not be successful. We do not know how likely it will be that countries with insufficient BSE risk assessment and mitigation strategies will petition the FDA.

e. Future petitions to FDA. It is likely that those countries that currently sell a significant amount of cattle-derived material will be most interested in seeking possible relief under this change to FDA's prohibited cattle materials requirements. It is possible in the future, if new markets for cattle derived products develop, that other countries may want to petition FDA to be designated as not subject to certain BSE-related restrictions applicable to human food and cosmetics. We do not attempt to forecast new markets for cattle derived products here. We also do not attempt to forecast the frequency of, or estimate the costs associated with, FDA review in the future of successful petitions.

f. Future review of successful petitions by FDA. Countries that successfully

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petition the FDA to be designated as excepted from certain BSE-related restrictions applicable to human food and cosmetics will be subject to future review by FDA to ensure that their designation remains appropriate. As part of this process, FDA may ask designated countries to confirm that their BSE situation and the information submitted by them in support of their original application remain unchanged. FDA may revoke a country's designation if FDA determines that it is no longer appropriate.

FDA has not yet determined the method by which the agency will conduct these future reviews. One possible method would be for FDA to send a letter to designated countries asking whether there has been a change in their status or circumstances relative to their BSE history, surveillance, import activities, or other relevant criteria and then compare any changed information with the information that was originally submitted. The OIE requires that countries it has recognized in regard to their BSE status ``should annually confirm during the month of November whether their status and the criteria by which their status was recognized have remained unchanged.'' In some cases, the FDA

reviewer might rely on this information, if available, in conducting a future review of the country's designation.

We assume it will take FDA and the designated country undergoing a review in the future about one third the time and effort it did when the original information was submitted. Thus, if the total cost to initially submit a petition and have it reviewed by FDA was $12,700, then a future review of the petition by FDA and the submitting country will cost about $4,200 (see Table 3).

Table 3.--Cost of Future Review of Successful Petitions

Submission of Additional Information and Response by Country	$3,000
FDA Review per Country	$1,200
Total Cost per Country	$4,200
Cost for 10 Countries	$42,000

4. Other Options Considered

FDA considered the following options when examining the costs and benefits of this IFR.

Option 1--Do nothing.

This option is the baseline for which the costs and benefits of other options are compared. The costs and benefits of this option have already been realized. Firms buying and selling cattle-derived materials in the United States and other countries have found alternatives to using products covered by the definition of prohibited cattle materials in the manufacture of their products.

Option 2--Amend definition of prohibited cattle materials (the chosen option).

The costs and benefits of this option are outlined previously. The main benefit of this option is that it is more efficient than the current regulation because it achieves essentially the same protection of public health with fewer restrictions on the market for cattle-derived materials. With this interim final rule, FDA can continue to prevent the potential introduction and transmission of BSE from cattle materials from non-designated countries, while at the same time reducing the restrictions on the market for cattle-derived materials from designated countries.

Option 3--Amend the definition of prohibited cattle materials to allow material from cattle not inspected and passed for human consumption for use in human food and cosmetics.

This option is less stringent than option 2, which would reduce the costs of cattle-derived materials used in the manufacture of human food and cosmetics, but it would not provide the same public health benefits as options 1 and 2. Material from cattle not inspected and passed for human consumption has not been approved by a regulatory authority (USDA or other) and thus we cannot make the determination that, among other things, the cattle material is from an animal that was evaluated for a neurological disorder such as BSE. In requiring that material from cattle for use in FDA-regulated human food and cosmetics be inspected

and passed for human consumption, we are minimizing the risk of exposure to the agent that causes BSE, and therefore maximizing the protection of public health from variant Creutzfeldt-Jakob disease, the human disease linked to consumption of BSE-infected cattle material.

5. Benefits

Under this interim final rule, foreign countries would have the option of demonstrating (through information submitted to FDA) that their BSE case history, their identifying and taking into account relevant risk factors, their implementing appropriate measures to prevent the introduction and transmission of BSE, and any other relevant information shows that certain BSE-related restrictions, in their case, are unnecessary. Countries that successfully petition FDA would be able to again export human food and cosmetics to the United States without the removal of the following items:

- SRMs
- Small intestine (including the distal ileum)
- Material from nonambulatory disabled cattle
- MS (Beef)

6. Effect on Food Supply in the United States

We expect this interim final rule amendment will increase the availability of certain cattle materials (and products containing those materials) for sale in the United States. The most significant gain in supply will probably occur from the increased availability of FDA-regulated products that contain MS (Beef) and material from nonambulatory disabled cattle for use in human food regulated by FDA. Few, if any, human food or cosmetic products use SRMs as an ingredient, but to the extent that these materials are needed, they will again be available in the United States.

B. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 et seq.) and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a proposed rule will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires that the agency present an initial regulatory flexibility analysis at the time of the publication of the notice of proposed rulemaking describing the impact of the rule on small entities and seeking public comment on such impact. Because this rule is being issued as an interim final rule, the RFA does not apply and FDA is not required to either certify that the rule will not have a significant impact on a substantial number of small businesses or conduct an initial regulatory flexibility analysis. Also, FDA does not have information on how many small firms in foreign countries designated by the agency may benefit from this rule. Examining the effect this interim final rule has on small foreign firms is outside the scope of the RFA requirements.

The extent to which small firms within the United States are affected by this rule is unknown. FDA

acknowledges that small U.S. businesses that use imported cattle materials in manufacture or for sale as final products will likely benefit from this rulemaking as costs of these inputs are expected to decrease as supply increases. Small U.S. firms that compete with foreign firms in order to supply cattle-derived inputs and products to U.S. business and markets may be adversely affected if foreign firms can more cheaply supply these materials and products. FDA seeks public comment on the question of whether such small U.S. businesses will be adversely impacted by this rule.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires cost-benefit and other analyses before any rule making if the rule would include a ``Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA has determined that this interim final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VI. Paperwork Reduction Act of 1995

This interim final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of these provisions are shown in the following paragraphs with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Petition To Be Designated as Not Subject to Certain BSE-Related Restrictions Applicable to FDA Regulated Human Food and Cosmetics

Description: FDA is amending the interim final rule on use of materials derived from cattle in human food and cosmetics published in the Federal Register of July 14, 2004, and then amended on September 7, 2005. In the 2004 interim final rule and its amendments, FDA designated certain materials from cattle as ``prohibited cattle materials'' and

banned the use of such materials in human food, including dietary supplements, and in cosmetics. Prohibited cattle materials include SRMs, the small intestine of all cattle unless the distal portion of the ileum is removed, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and MS (Beef). SRMs include 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 of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Therefore, FDA is amending its regulations at Sec. Sec. 189.5 and 700.27 to provide that FDA may designate a country as not subject to the restrictions applicable to human food and cosmetics manufactured from, processed with, or that otherwise contain SRMs, the small intestine of cattle, material from nonambulatory disabled cattle, or MS (Beef). The interim final rule, as amended, provides that these materials, when from cattle from a designated country, are not considered prohibited cattle materials, and their use does not render a human food or cosmetic adulterated. The amendment further provides that a country seeking to be so designated must send a written request to the Director of FDA's Center for Food Safety and Applied Nutrition, including information about a country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and other information relevant to determining whether SRMs, the small intestine of cattle (unless the distal ileum has been removed), material from nonambulatory disabled cattle, or MS (Beef) should be considered prohibited cattle materials.

Description of Respondents: Countries with firms that would like to use SRMs, the small intestine of cattle, material from nonambulatory disabled cattle, or MS (Beef) in products exported to the United States.

Information Collection Burden Estimate

FDA estimates the burden for this information collection as follows:

Table 4.--Estimated One-Time and Recurring Reporting Burden\1\

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
189.5 and 700.27\2\	10	1	10	80	800
189.5(e) and 700.27(e)	10	1	10	26.4	264

Total one time burden	800
Total recurring burden	264

\1\ There are no capital costs or operating and maintenance costs associated with the collection of information under this interim final rule.
\2\ One-time burden.

One Time Reporting Burden

There will be a one time burden to countries that apply to FDA seeking to be designated as not subject to restrictions applicable to SRMs, the small intestine of cattle, nonambulatory disabled cattle, or MS (Beef). We estimate that each country that applies for an exclusion will spend 80 hours putting information together to submit to FDA. Table 4 row 3 of this document presents the one-time burden expected for countries who apply for the exclusion.

Recurring Burden

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Countries that successfully petition the FDA to be designated as excepted from certain BSE-related restrictions applicable to human food and cosmetics will be subject to future review by FDA to ensure that their designation remains appropriate. As part of this process, FDA may ask designated countries from time to time to confirm that their BSE situation and the information submitted by them in support of their original application remain unchanged. We assume it will take FDA and the designated country undergoing a review in the future about one third the time and effort it did when the information was submitted. Table 4 row 4 of this document presents the expected recurring burden.

The information collection provisions of this interim final rule have been submitted to OMB for review. Interested persons are requested to fax comments regarding information collection by (see DATES), to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

Prior to the effective date of this interim final rule, FDA will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this interim final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VII. Environmental Impact Analysis

The agency has determined under 21 CFR 25.30(h) that this action is

of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

FDA has analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires agencies to ``construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' FDA has determined that the interim final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the interim final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

1. World Organization for Animal Health, Terrestrial Animal Health Code (2007), Chapter 2.3.13, Bovine Spongiform Encephalopathy. See also Appendix 3.8.4 (Surveillance for Bovine Spongiform Encephalopathy) and Appendix 3.8.5 (Factors to Consider in Conducting the Bovine Spongiform Encephalopathy Risk Assessment Recommended in Chapter 2.3.13). Accessed online at http://www.oie.int/eng/normes/mcode/en_sommaire.htm.

2. World Organization for Animal Health, Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2004 (updated 2006). Accessed online at http://www.oie.int/eng/normes/mmanual/A_summry.htm.

3. World Organization for Animal Health (OIE), Recognition of the Bovine Spongiform Encephalopathy Status of Member Countries, OIE Resolution No. XXIV, adopted by the International Committee of the OIE on May 22, 2007. See http://www.oie.int/eng/info/en_statesb.htm?eld6, accessed August 30, 2007.

4. United States International Trade Commission, Interactive Tariff and Trade Dataweb, http://dataweb.usitc.gov/, accessed April 6, 2007.

5. NAICS Association, http://www.naics.com/censusfiles/NDEF311.HTM, accessed August 27, 2007.

6. U.S Office of Personnel Management Salaries and Wages 2007

General Schedule, http://www.opm.gov/oca/07tables/indexGS.asp, accessed on April 11, 2007.

List of Subjects

21 CFR Part 189

Food additives, Food packaging.

21 CFR Part 700

Cosmetics, Packaging and containers.

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Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 189 and 700 are amended as follows:

PART 189--SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

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1. The authority citation for 21 CFR part 189 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371, 381.

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2. Section 189.5 is amended by revising paragraph (a)(1) and by adding paragraph (e) to read as follows:

Sec. 189.5 Prohibited cattle materials.

(a) * * *
(1) Prohibited cattle materials means specified risk materials, small intestine of all cattle except as provided in paragraph (b)(2) of this section, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated (MS) (Beef). Prohibited cattle materials do not include the following:
(i) Tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products, and
(ii) Cattle materials inspected and passed from a country designated under paragraph (e) of this section.
* * * * *
(e) Process for designating countries. A country seeking designation must send a written request to the Director, Office of the Center Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, at the address designated in 21 CFR 5.1100. The request shall include information about a country's bovine spongiform encephalopathy (BSE) case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether specified risk materials, the small intestine of cattle except as provided in paragraph (b)(2) of this section, material from nonambulatory disabled cattle, or MS (Beef) from

cattle from the country should be considered prohibited cattle materials. FDA shall respond in writing to any such request and may impose conditions in granting any such request. A country designation granted by FDA under this paragraph will be subject to future review by FDA, and may be revoked if FDA determines that it is no longer appropriate.

PART 700--GENERAL

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3. The authority citation for 21 CFR part 700 continues to read as follows:

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Authority: 21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374.

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4. Section 700.27 is amended by revising paragraph (a)(1) and by adding paragraph (e) to read as follows:

Sec. 700.27 Use of prohibited cattle materials in cosmetic products.

(a) * * *

(1) Prohibited cattle materials means specified risk materials, small intestine of all cattle except as provided in paragraph (b)(2) of this section, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated (MS) (Beef). Prohibited cattle materials do not include the following:

(i) Tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products, and

(ii) Cattle materials inspected and passed from a country designated under paragraph (e) of this section.

* * * * *

(e) Process for designating countries. A country seeking designation must send a written request to the Director, Office of the Center Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, at the address designated in 21 CFR 5.1100. The request shall include information about a country's bovine spongiform encephalopathy (BSE) case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether specified risk materials, the small intestine of cattle except as provided in paragraph (b)(2) of this section, material from nonambulatory disabled cattle, or MS (Beef) from cattle from the country should be considered prohibited cattle materials. FDA shall respond in writing to any such request and may impose conditions in granting any such request. A country designation granted by FDA under this paragraph will be subject to future review by FDA, and may be revoked if FDA determines that it is no longer appropriate.

Dated: April 11, 2008.
Jeffrey Shuren,
Associate Commissioner for Policy and Planning.
[FR Doc. 08-1142 Filed 4-15-08; 8:45 am]

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