circumstances warranting an out-of-cycle review, within 30 days of that determination USTR will announce a schedule for the review in the **Federal Register**. The schedule will include the deadline and guidelines for any party to submit written comments supporting, opposing or otherwise commenting on any proposed action.

(3) For any out-of-cycle review initiated under this paragraph (c), the AGOA Implementation Subcommittee will consider public input received by the applicable deadline and any other relevant information and report to the TPSC. The TPSC will conduct further review as necessary and prepare recommendations for the U.S. Trade Representative. The U.S. Trade Representative may convene the TPRG or the TPC for further review of recommendations and other decisions. The U.S. Trade Representative will make recommendations to the President, which may include a recommendation that no action be taken.

§ 2017.3 Publication regarding petitions.

USTR will publish in the **Federal Register**:

(a) A list of actions taken in response to a petition, such as the publication of a Presidential proclamation modifying the designation of a country or the application of duty-free treatment with respect to articles from a country pursuant to the AGOA; and

(b) A list of petitions upon which no decision was made, and thus which are pending further review.

§ 2017.4 Public inspection.

USTR will make publicly available at *www.regulations.gov:*

(a) Any written request, brief or similar submission of information made pursuant to this part; and

(b) Any stenographic record of any public hearing that may be held pursuant to this part.

(c)(1) USTR will grant business confidential status and withhold from public disclosure the information submitted if the petitioner certifies that the information customarily would not be released to the public and clearly designates the information as confidential business information.

(2) To request business confidential status the petitioner must mark the submission ''BUSINESS CONFIDENTIAL'' at the top and bottom of the cover page and on each succeeding page, and the submission should indicate, via brackets, the specific information that is confidential.

(3) If the submission contains business confidential information, the petitioner also must submit a non-confidential version or summary, indicating where confidential information has been redacted, and a written explanation of why the material should be protected.

(4) The non-confidential version or summary will be made publicly available at *www.regulations.gov.*

(5) A request for exemption of any particular information may be denied if it is determined that such information is not entitled to exemption under law. In the event of such a denial, the information will be returned to the person who submitted it, with a statement of the reasons for the denial.

§ 2017.5 Expiration.

The Trade Preferences Extension Act of 2015 extended the AGOA until September 30, 2025 (Pub. L. 114–27, sec. 103, 129 Stat. 364). Accordingly, this Part will expire on that date unless extended by statute.

Florizelle Liser,

Assistant U.S. Trade Representative for African Affairs.

[FR Doc. 2016–06127 Filed 3–17–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 189 and 700

[Docket No. FDA–2004–N–0188; (Formerly 2004N–0081)]

RIN 0910–AF47

Use of Materials Derived From Cattle in Human Food and Cosmetics

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; adoption of interim final rule as final with amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule prohibiting the use of certain cattle material to address the potential risk of bovine spongiform encephalopathy (BSE) in human food, including dietary supplements, and cosmetics. We have designated the following items as prohibited cattle materials: Specified risk materials (SRMs), the small intestine from all cattle (unless the distal ileum has been removed), material from nonambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated (MS) (Beef). We are taking this action to minimize human exposure to certain cattle material that could potentially contain the BSE agent.

DATES: This final rule is effective on April 18, 2016.

FOR FURTHER INFORMATION CONTACT: Johnny Braddy, Center for Food Safety and Applied Nutrition (HFS–315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1709.

SUPPLEMENTARY INFORMATION:

Executive Summary

A. Purpose of the Rule

BSE is a fatal neurological disorder of cattle that has a long incubation period (2 to 8 years). It is transmitted when cattle ingest protein meal containing the BSE infectious agent. Cattle affected by BSE are usually apart from the herd and will show progressively deteriorating behavioral and neurological signs. Cattle will react excessively to noise or touch and will eventually stumble, fall, and experience seizures, coma, and death. Studies have linked variant Creutzfeldt-Jakob disease (vCJD) in humans to exposure to the BSE agent, most likely through human consumption of beef products contaminated with the BSE agent. There is no known treatment of vCJD, and it is invariably fatal.

The final rule completes a rulemaking process that began with an interim final rule (IFR) in 2004 and was followed by IFRs in 2005 and 2008. The final rule establishes measures to prohibit the use of certain cattle material in FDA-regulated human food and cosmetics to address the potential risk of BSE. Because the United States has had measures in place to prevent the introduction and spread of BSE, including those affirmed in this rule, the risk of human exposure to the BSE agent from FDA-regulated human food and cosmetics is negligible.

B. Legal Authority

We are issuing these regulations under the adulteration provisions in sections 402, 409, 601, and under section 701 (21 U.S.C. 342, 348, 361, and 371) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

C. Summary of the Major Provisions of the Rule

The final rule provides definitions for prohibited cattle materials and prohibits their use in human food, dietary supplements, and cosmetics, to address the potential risk of BSE. We designate the following items as prohibited cattle materials: SRMs, the small intestine from all cattle unless the distal ileum has been properly removed, material from nonambulatory disabled cattle,

material from cattle not inspected and passed, or MS (Beef). We also confirm that milk and milk products, hides and hide-derived products, tallow that contains no more than 0.15 percent insoluble impurities, and tallow derivatives are not prohibited cattle materials. Further, we are amending the final rule to provide a definition of gelatin and to clarify that gelatin is not considered a prohibited cattle material under 21 CFR 189.5(a)(1) and 700.27(a)(1) as long as it is manufactured using the customary industry processes specified. Finally, we are finalizing the process for designating a country as not subject to BSE-related restrictions applicable to FDA regulated human food and cosmetics. Specific requirements regarding record maintenance, retention, and accessibility, for manufacturers and processors of a human food or cosmetic product made with material from cattle were previously finalized (see 71 FR 59653).

D. Costs and Benefits

This final rule reaffirms the provisions in the 2004 IFR, as well as the 2005 and 2008 amendments, to address the potential risk of BSE in human food including dietary supplements, and in cosmetics. As the final rule's coverage does not differ from the 2004 IFR and the 2005 and 2008 amendments, no additional costs or benefits will accrue from this rulemaking.

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I. Introduction—what is BSE?

BSE is a progressive and fatal neurological disorder of cattle caused by an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). In the late stages of disease, all TSEs affect the central nervous system of infected animals. However, the distribution of infectivity in the body of the animal and mode of transmission differ according to the species and TSE agent. Other types of TSEs include scrapie in sheep and goats, chronic wasting disease in deer and elk, and Creutzfeldt-Jakob disease (CJD) in humans.

BSE has a long incubation period (2 to 8 years), and is most likely transmitted when tissues from infected cattle are rendered and processed into protein meal, which is then used as an additive in livestock feed (Refs. 1 and 2). The clinical signs of BSE include behavioral, gait, and postural abnormalities. Cattle with the disease often present with increased apprehension, increased reaction to sound and touch, and a swaying gait. These signs may be accompanied by subtle changes in the normal behavior of the cow, such as separation from the herd while at pasture, disorientation, staring, and excessive licking of the nose or flanks. The disease progresses to stumbling and falling, and ends with seizures, coma, and death (Ref. 3).

Scientific and epidemiological studies have linked vCJD in humans to exposure to the BSE agent, most likely through human consumption of beef products contaminated with the agent. In several cases that occurred in the United Kingdom (UK), it is believed that the persons became infected through transfusion of blood from an asymptomatic infected donor. There is no known treatment of vCJD, and it is invariably fatal (Ref. 4).

As of June 2, 2014, vCJD has been identified in 229 patients from 12 countries. One hundred seventy-seven probable and confirmed cases of vCJD have been reported in the UK, 27 in France, 5 in Spain, 4 in Ireland, 4 in the United States, 3 in the Netherlands, 2 in Portugal, 2 in Italy, 2 in Canada, and one each from Japan, Saudi Arabia, and Taiwan (Ref. 5). In two of the four U.S. cases, exposure to the BSE agent is believed to have occurred while the individuals were residing in the UK. A third case was likely exposed while residing in Saudi Arabia. An investigation of the fourth case found that the patient's exposure to the BSE agent likely occurred before the patient moved to the United States (Ref. 5). In the United States, where measures to prevent the introduction and spread of BSE have been in place for some time, the risk of human exposure to the BSE agent is extremely low. Indeed, in May 2013, the World Organization for Animal Health (OIE) recognized the effectiveness of these mitigation measures and categorized the United States as negligible BSE risk, in accordance with Chapter 11.4 of the OIE Terrestrial Animal Health Code (Refs. 6 and 7).

II. Background—what is the history for this rulemaking?

In the **Federal Register** of July 14, 2004 (69 FR 42256), we issued an IFR entitled ''Use of Materials Derived From Cattle in Human Food and Cosmetics'' (also referred to as ''the 2004 IFR'') to prohibit the use of certain cattle material, to address the potential risk of BSE in human food, including dietary supplements, and cosmetics. The 2004 IFR designated the following items as prohibited cattle materials: SRMs, the small intestine from all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed 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 (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine from all cattle. These restrictions were codified at § 189.5, ''Prohibited cattle materials,'' and § 700.27, ''Use of prohibited cattle materials in cosmetic products.'' The requirements in §§ 189.5 and 700.27 are almost identical, except that the latter pertains only to cosmetic products.

Previously, the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) published an IFR in the **Federal Register** on January 12, 2004 (69 FR 1862) (FSIS IFR). The FSIS IFR prohibited certain cattle material from use in meat and meat products. The FSIS IFR designated the same items as SRMs as specified in FDA's 2004 IFR. In the **Federal Register** of July 13, 2007, FSIS affirmed the FSIS IFR with amendments (72 FR 38700) (''2007 FSIS affirmation''). In the **Federal Register** of September 7, 2005 (70 FR 53063), we amended our regulations to permit the use of the small intestine of cattle in human food and cosmetics provided the distal ileum portion has been removed properly (also referred to as the ''2005 amendment''). The 2005 amendment also clarified that milk and milk products, hides and hide-derived products, and tallow derivatives are not prohibited cattle materials, and we provided for a different method for

determining impurities in tallow. FSIS also amended its regulations on September 7, 2005, to permit the use of the small intestine of cattle in human food provided the distal ileum is removed properly (70 FR 53043).

In the **Federal Register** of April 17, 2008 (73 FR 20785), we amended our regulations again to provide a process for designating certain countries as not subject to certain BSE-related restrictions (also referred to as the ''2008 amendment''). FSIS provided a similar country-specific exception from certain BSE restrictions covered in its regulations.

We also published a notice in the **Federal Register** on March 4, 2013 (78 FR 14012) (also referred to as the 2013 notice), reopening the comment period for the interim final rule. We invited comment on our assessment of recently published peer-reviewed scientific studies in which trace amounts of BSE infectivity were found in parts of the small intestines other than the distal ileum of cattle with both experimental and natural occurring BSE.

In this rule, we are finalizing, with changes related to gelatin, the 2004 IFR, as amended in 2005 and 2008, to restrict certain cattle materials used in human foods and cosmetics that carry a risk of transmitting BSE. The final rule complements similar restrictions that apply to meat and meat products regulated by USDA.

III. What is the legal authority for this rulemaking?

We are issuing these regulations under the adulteration provisions in sections 402, 409, 601, and under section 701 of the FD&C Act.

Under section 402(a)(3) of the FD&C Act, a food is deemed adulterated ''if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.'' The term ''otherwise unfit for food'' in section 402(a)(3) of the FD&C Act does not require that a food be filthy, putrid, or decomposed for it to be ''otherwise unfit for food.'' A food can be ''otherwise unfit for food'' based on health risks. Further, the possibility of disease transmission to humans from exposure to prohibited cattle material, SRM, MS Beef, material from nonambulatory disabled cattle, and material from cattle not inspected and passed) may present a risk to human health. Under section 402(a)(3) of the FD&C Act, these materials are unfit for food. Under section 402(a)(4) of the FD&C Act, a food is adulterated ''if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.'' The failure to ensure that food is prepared, packed, or held under conditions in which prohibited cattle materials do not contaminate the food constitutes an insanitary condition whereby it may have been rendered injurious to health and thus renders the food adulterated under section 402(a)(4) of the FD&C Act. Under section 402(a)(5) of the FD&C Act, food is deemed adulterated if it is, in whole or in part, the product of an animal which has died otherwise than by slaughter. Some cattle are not inspected and passed because they have died before slaughter. Material from cattle that die otherwise than by slaughter is adulterated under section 402(a)(5) of the FD&C Act. As further explained in the 2004 IFR, prohibited cattle materials for use in human food are food additives subject to section 409 of the FD&C Act, except when used as dietary ingredients in dietary supplements. The use or intended use of any prohibited cattle material in human food, except for dietary ingredients in dietary supplements, causes the material and the food to be adulterated under section 402(a)(2)(C) of the FD&C Act.

Under section 601(c) of the FD&C Act, a cosmetic is adulterated ''if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.'' The failure to ensure that a cosmetic is prepared, packed, or held under conditions in which prohibited cattle materials do not contaminate the cosmetic constitutes an insanitary condition whereby it may have been rendered injurious to health and, thus, renders the cosmetic adulterated under section 601(c) of the FD&C Act.

Under section 701(a) of the FD&C Act, we may issue regulations for the efficient enforcement of the FD&C Act. A regulation that requires measures to prevent human food from being unfit for food, from being or bearing an unsafe food additive, from being the product of an animal that died otherwise than by slaughter, and to prevent human food and cosmetics from being held under insanitary conditions, allows for efficient enforcement of the FD&C Act.

IV. What comments did we receive? What are our responses?

We received approximately 1,464 comments, each containing one or more issues, to the 2004 IFR, and approximately 20 comments, each containing one or more issues, to the 2005 and 2008 amendments, and 31 comments to the 2013 notice. Animal welfare advocacy organizations, private consultants, consumer groups, foreign governments, Members of Congress, industry, and consumers submitted comments. Comments previously addressed in the 2005 and 2008 amendments, and comments addressing issues outside the scope of this rulemaking (*e.g.,* those addressing potential concerns regarding diseases other than BSE; those addressing animal welfare concerns, which are covered in the Humane Methods of Slaughter Act of 1978 (7 U.S.C. 1901 *et seq.*) and administered by USDA); the prohibition of the use of materials from nonambulatory animals other than cattle (*i.e.,* deer, elk, and sheep); and those responding to rules issued by other federal agencies will not be addressed in this document.

To make it easier to identify the comments and FDA's responses, the word ''Comment,'' in parentheses, appears before the comment's description and the word ''Response,'' in parentheses, appears before FDA's response. Each comment is numbered to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance.

A. Definitions (§§ 189.5(a) and 700.27(a))

Sections 189.5(a) and 700.27(a) state that the definitions and interpretations of terms in section 201 of the FD&C Act apply (21 U.S.C. 321) and also define the following terms: ''prohibited cattle materials,'' ''inspected and passed,'' ''mechanically separated,'' ''nonambulatory disabled cattle,'' ''specified risk material,'' ''tallow,'' ''tallow derivative,'' and ''gelatin.'' Several comments pertained to our regulatory definitions, and we discuss those comments here.

1. ''Prohibited Cattle Materials'' (§§ 189.5(a)(1) and 700.27(a)(1))

The 2004 interim final rule defined ''prohibited cattle materials'' as specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or MS (Beef). The 2004 IFR also defined ''prohibited cattle material'' as not to include tallow that contains ''no more than 0.15 percent hexane-insoluble impurities and tallow derivatives.'' The 2005 amendment made an exception in the case of the small intestine such that the small intestine would not be considered prohibited cattle material if the distal ileum is removed by a

procedure that removes at least 80 inches of the uncoiled and trimmed small intestine in a manner specified in § 189.5(b)(2) (or, in the case of § 700.27, § 700.27(b)(2)) and also changed ''hexane-insoluble'' to ''insoluble'' in the definition of ''tallow.'' The 2005 amendment also excluded hides and hide-derived products, and milk and milk products from the definition of ''prohibited cattle materials.'' The 2008 amendment provided that FDA may designate a country as not subject to certain BSE-related restrictions applicable to FDA regulated human food and cosmetics.

We did not receive comments specific to the definition of ''prohibited cattle materials at §§ 189.5(a)(1) and 700.27(a)(1), and we have finalized that portion of the definition without change.

a. Tallow, Tallow Derivatives, Gelatin, Hides and Hide-Derived Products, and Milk and Milk Products (§§ 189.5(a)(1)(i) and 700.27(a)(1)(i))

(Comment 1) One comment supported the exclusion of hides and hide-derived products from the definition of prohibited cattle materials but said that we need to address the possible cross-contamination of hides and other non-prohibited cattle materials with prohibited cattle materials during slaughter and processing.

(Response 1) As noted in the 2005 amendment, manufacturers and processors must take precautions to avoid cross contamination of hides and other non-prohibited cattle material with prohibited cattle material during slaughter and processing (70 FR 53063 at 53066). Further, food establishments are subject to the current good manufacturing practice requirements (CGMPs) at 21 CFR part 110, and the failure to take adequate measures to prevent cross-contamination could result in insanitary conditions whereby the food may be rendered injurious to health and, therefore, adulterated under section 402(a)(4) of the FD&C Act.

(Comment 2) While most comments found the clarification as to the allowable composition of tallow source material used in tallow derivatives in the preamble to the 2005 amendment helpful, one comment suggested that we revise the definition of ''prohibited cattle materials'' to state that: ''Prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives (regardless of the source of tallow), hides and hide-derived products, and milk and milk products.''

(Response 2) We understand that the intent of the parenthetical ''regardless of the source of the tallow'' is to make clear that the chemical processes (hydrolysis, transesterification, and saponification) involving high temperature and pressure are sufficiently rigorous even if the starting tallow is, for example, inedible tallow or tallow containing greater than 0.15 percent insoluble impurities. We agree that the processes to produce tallow derivatives are sufficiently rigorous, but believe that by excluding tallow derivatives, without the parenthetical, from the definition of prohibited cattle material, it is clear that we are excluding all tallow derivatives. Prohibited cattle material does not include tallow derivatives. We do not believe the parenthetical ''regardless of the source of tallow'' is needed.

(Comment 3) One comment would revise the definition of prohibited cattle materials to emphasize the rigorousness of the processing involved in the production of tallow derivatives (*i.e.,* transesterification or saponification) to minimize the risk of transmitting TSE agents. The comment was concerned that the ''lack of alignment'' between U.S. and non-U.S. requirements and guidance with respect to tallow derivatives will continue to affect the acceptance of U.S.-origin materials in non-U.S. markets.

(Response 3) We decline to revise the definition as suggested by the comment. Our objective in developing our BSE regulations for human food and cosmetics, including these involving tallow derivatives, is to apply appropriate measures to safeguard life and health and be no more trade restrictive than necessary to achieve the food and cosmetic safety objective. As to the degree of processing involved in producing tallow derivatives, we addressed this subject in the preamble to the 2004 IFR (69 FR 42256 at 42261) and discussed how tallow derivatives are produced by subjecting tallow to chemical processes (hydrolysis, transesterification, and saponification) that involve high temperature and pressure. We further noted in the 2004 IFR that FDA's Transmissible Spongiform Encephalopathy Advisory Committee (TSEAC) considered the safety of tallow and tallow derivatives in 1998 and ''determined that the rigorous conditions of manufacture are sufficient to further reduce the BSE risk in tallow derivatives'' (69 FR 42256 at 42261).

We have revised the list of materials not considered prohibited cattle materials at §§ 189.5(a)(1)(i) and 700.27(a)(1)(i) to include gelatin. To ensure that only gelatin derived from customary industry processes qualifies for this exclusion, §§ 189.5(a)(8) and 700.27(a)(8) of the final rule provide that ''Gelatin means a product that has been obtained by the partial hydrolysis of collagen derived from hides, connective tissue, and/or bone bones of cattle and swine. Gelatin may be either Type A (derived from an acid-treated precursor) or Type B (derived from an alkali-treated precursor) that has gone through processing steps that include filtration and sterilization or an equivalent process in terms of infectivity reduction.''

There has been increasing recognition based on scientific evidence as to the safety of gelatin for human use irrespective of the source materials from which it is made. For example, laboratory studies have indicated that gelatin manufacturing processes are capable of reducing inoculated BSE prion titers by at least six to eight orders of magnitude (Ref. 8). The OIE Code does not recommend any restrictions, regardless of the BSE status of a country, in trade of gelatin prepared from bones and intended for food, cosmetics, pharmaceuticals including biologicals, or medical devices, among other items (Ref. 9). A 2006 scientific panel of the European Food Safety Authority (EFSA)—reviewing a 2003 EFSA Scientific Steering Committee opinion—concluded that there was no support for prohibition of or restrictions on the use of skull and vertebrae of cattle that had passed ante mortem and post mortem inspections in the production of gelatin (Ref. 10). Based on this evidence, we conclude that gelatin manufactured from bovine raw materials using customary industry processes presents a negligible risk of transmitting the agent that causes BSE.

(b) Cattle Materials Inspected and Passed From Designated Countries (§§ 189.5(a)(1)(ii) and 700.27(a)(1)(ii))

(Comment 4) One comment supporting a mechanism to designate countries as not subject to certain BSE-related restrictions (provided under § 189.5(a)(1)(ii)) expressed concerns that interested countries would need to go through separate application and evaluation processes at USDA and FDA for a country to receive a USDA and FDA-granted designation. The comment requested that the application and evaluation procedures used by the different U.S. regulating agencies be streamlined to reduce the potential duplication of time and effort by the applying country.

(Response 4) We understand the concern expressed by the comment.

However, as we explained in the 2008 amendment, FDA and USDA have different regulatory responsibilities with respect to preventing BSE and ensuring food safety (73 FR 20785 at 20788). While we have our own evaluation process, we will consult with USDA as part of this process (73 FR 20785 at 20788). Further, we will take into consideration available risk assessments of other competent authorities in conducting our evaluations (73 FR 20785 at 20788.). Although not required, a previous BSE evaluation performed by USDA's FSIS or Animal and Plant Health Inspection Service (APHIS), or by OIE, or by another country or competent authority, could be used by FDA as part of our review (73 FR 20785 at 20788).

(Comment 5) Several comments from the gelatin industry requested that gelatin be excluded from consideration as a prohibited cattle material. The comments noted that standard industry practice is to produce gelatin using raw materials from animals inspected and passed for human consumption, that SRMs and materials from nonambulatory disabled cattle are excluded, that the safety of gelatin is based on adherence to industry practices, as well as our CGMPs and USDA regulations, and that gelatin made from bovine raw materials undergoes manufacturing processes that inactivate possible BSE infectivity, citing studies by the European Commission (EC) and the Gelatine Manufacturers of Europe. Several comments noted that TSEAC reviewed these studies and concluded on July 17, 2003, that these studies ''demonstrate a reduction in infectivity that is sufficient to protect human health.''

(Response 5) We agree with the comments and have revised §§ 189.5(a)(1)(i) and 700.27(a)(1)(i) to include gelatin in the list of materials not considered ''prohibited cattle materials.'' We are making this change because gelatin manufactured according to customary industry processes present a negligible risk of transmitting the BSE agent and should not be considered ''prohibited cattle materials.''

(Comment 6) Several comments took issue with an FDA statement appearing in the background section to the 2004 IFR that provided certain products, such as gelatin and collagen, ''have traditionally been produced from cattle material deemed inedible by the USDA'' (69 FR 42256 at 42261). The comments pointed out that U.S. raw materials used to produce gelatin come from cattle that have been inspected and passed by USDA for human consumption and are produced in accordance with FDA and USDA regulations, and in accordance with applicable FDA human food CGMPs. These comments further noted that only safe raw materials are used to produce gelatin and that SRMs and materials from nonambulatory disabled cattle are excluded. One comment specifically requested that we publish a correction in the **Federal Register** clarifying that gelatin is not produced from inedible material.

(Response 6) The quoted statement was included in a broader discussion explaining in part why we were extending similar protections to FDA-regulated human foods and cosmetics as USDA had already imposed in USDA-inspected facilities. We agree that gelatin is manufactured from raw materials that have been inspected and passed for human consumption.

(Comment 7) Several comments requested that we clarify whether our gelatin guidance document published in 1997 (Ref. 11) will be revoked or revised in light of this regulation. The comments expressed concern that gelatin manufacturers would face an unnecessary regulatory burden depending on whether the product the gelatin is used in is a food product or dietary supplement, or a pharmaceutical product, or for other FDA-regulated uses. The comments also requested that we explicitly state that our gelatin guidance document is no longer applicable for products intended for oral consumption or cosmetic use by humans.

(Response 7) This final rule supersedes the 1997 guidance with respect to human food and cosmetics. We intend to review the 1997 guidance and will consider withdrawing or revising the guidance, as appropriate, consistent with this final rule.

2. ''Inspected and Passed'' (§§ 189.5(a)(2) and 700.27(a)(2))

The regulations define ''inspected and passed'' as meaning that the product has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time it was inspected and passed, it was found to be not adulterated. We did not receive comments specific to our definition of ''inspected and passed,'' and we have finalized the definition without change.

3. ''Mechanically Separated (MS) (Beef)'' (§§ 189.5(a)(3) and 700.27(a)(3))

The regulations define ''mechanically separated (MS) (beef)'' as a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most bone from the attached skeletal muscle of cattle carcasses or parts of carcasses that meet certain USDA specifications. We did not receive comments specific to our definition of ''(MS) (Beef).''

On our own initiative, we have revised the definition of ''mechanically separated (MS) (Beef)'' to clarify that 9 CFR 319.5, which we cite in §§ 189.5(a)(3) and 700.27(a)(3), refers to a USDA regulation. Thus, the final rule adds ''U.S. Department of Agriculture'' before ''regulation.''

4. ''Nonambulatory Disabled Cattle'' (§§ 189.5(a)(4) and 700.27(a)(4))

The regulations define ''nonambulatory disabled cattle'' as cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, cattle with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(Comment 8) One comment suggested that downer animals should be tested first for BSE and held pending the outcome of the testing before deciding to prohibit the use of material from nonambulatory disabled cattle in human food and cosmetics. If the test results are negative, then the carcass could be used for human food and cosmetics.

(Response 8) This option is not feasible due to the limitations of currently available tests. No validated ante mortem test for BSE currently exists. Available post mortem tests, although useful for disease surveillance purposes in terms of determining the rate of disease in the population of cattle, are not appropriate as a safety indicator for human food or cosmetics because there is a potentially long period in the life of an infected animal where tests using the current methodology would not detect the disease (Refs. 12 through 14). This is due, in part, to limitations on existing testing methods, which rely on the use of post mortem brain tissue. Experimental evidence demonstrates that for cattle infected orally, certain potentially infective tissues (such as the distal ileum and tonsils) are the first tissues to accumulate infectivity in the incubation period and this infectivity occurs prior to any demonstrated infectivity in brain tissue (Refs. 12 through 14). Therefore, tests conducted on brain tissue may not accurately reflect the potential infectivity in other tissues that develop infectivity earlier, such as the distal ileum.

As a result, we have finalized the definition of ''nonambulatory disabled cattle'' without change.

(Comment 9) One comment stated that our restrictions relating to materials

from nonambulatory disabled cattle should not apply to custom slaughtered animals.

(Response 9) This final rule does not apply to custom slaughtered cattle because such cattle are for the owner's exclusive use and not for use in FDA regulated human food and cosmetics. FDA notes that, in our 2007 affirmation of our interim final rule with amendments, FSIS determined that it cannot permit the custom slaughter or preparation of products of nonambulatory disabled cattle for human food even if it is for the owner's exclusive use because FSIS considers the carcasses of these animals to be adulterated (72 FR 38700 at 38703 to 38704).

5. ''Specified Risk Material'' (§§ 189.5(a)(5) and 700.27(a)(5))

The regulations define ''specified risk material'' as meaning 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. The definition also includes tonsils and distal ileum of the small intestine of all cattle as ''specified risk material.''

In the **Federal Register** of March 4, 2013 (78 FR 14012), we reopened the comment period for the IFR due to new studies showing infectivity in parts of the small intestine other than the distal ileum. We noted that there were studies showing the presence of some infectivity in the proximal ileum, jejunum, ileocecal junction, and colon of cattle with BSE. We also noted that the infectivity levels reported in the studies were lower than the infectivity levels previously demonstrated for the distal ileum (78 FR 14012 at 14013). We put the studies into the administrative record and invited comment on them, and also said that we had tentatively concluded that the effect of these traces of infectivity on the risk of human or ruminant exposure to BSE in the United States is negligible (78 FR 14012). We tentatively concluded that ''requiring the removal of additional parts of the small intestine would not provide a measurable risk reduction compared to that already being achieved by removal of the distal ileum in all cattle and that it would be appropriate to finalize our interim final rule without changing any provisions related to the small intestine'' (78 FR 14012).

(Comment 10) One comment asked whether the pituitary gland of cattle is considered an SRM and would have to be removed from the carcass when the brain is removed if the cattle is 30 months of age or older.

(Response 10) The pituitary gland or hypophysis lies at the base of the brain, contacting the hypothalamus. Anatomically, it is considered part of the brain. Thus, the pituitary gland or hypophysis is considered an SRM in cattle 30 months or age or older and must be removed from the carcass when the brain is removed.

(Comment 11) One comment requested that the vertebral column not be considered an SRM because the attached DRG as well as the loosely attached spinal cord, which are sources of BSE infectivity, can be safely separated and removed from the vertebral column. (In general terms, DRG are nerves attached to the spinal cord.) The comment did not submit any data in support of its position nor did it explain the method or methods for safely separating and removing the DRG from the vertebral column.

(Response 11) We decline to revise the rule as suggested by the comment. While the vertebral column has not been shown to harbor BSE infectivity, it does contain tissues (*i.e.,* DRG, spinal cord) that have been shown to be infectious. Technologies are not currently available to safely remove the DRG without removing part of the vertebral column (see 2007 FSIS affirmation, 72 FR 38700 at 38710). The 2007 FSIS affirmation also noted that while the DRG is located within the vertebral bones, it could potentially become dislodged during consumption of bone-in-beef products. Therefore, the vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older is included in the list of SRMs. We will reconsider this issue if technology becomes available to safely remove the DRG from the vertebral column, but we have finalized the definition of ''specified risk material'' without change.

(Comment 12) One comment requested that we revise the definition of SRMs to include meat obtained from vertebral columns processed with Advanced Meat Recovery (AMR) systems because of the instances of DRG and spinal cord being detected in AMR products.

(Response 12) We decline to revise the rule as suggested by the comment. USDA regulations, at 9 CFR 318.24, provide that vertebral columns of cattle 30 months of age and older (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) are SRMs and therefore cannot be used as source materials for AMR systems.

(Comment 13) One comment stated that, although we noted that the OIE has not designated any intestinal sections other than the distal ileum as SRM, the OIE did not conduct a risk assessment to support that statement.

(Response 13) We did not intend to imply that the OIE had conducted a risk assessment or studied the new research findings and published its conclusions about the significance to human health. We meant that the OIE had not added parts of the small intestine other than the distal ileum to its recommendations on commodities that should not be traded (Ref. 15).

(Comment 14) Some comments recommended that the 30-month age cutoff, which provides a basis for designating certain cattle materials as SRMs, should be changed to a 12-month cutoff because of scientific uncertainty about how BSE spreads in cattle, and because the true prevalence of the disease in the United States is not fully known.

(Response 14) We disagree with these comments. Experimental and epidemiological evidence have clearly linked transmission of BSE to using protein derived from BSE infected cattle as an additive in cattle feed. FDA's 1997 and 2008 BSE feed regulations prohibit this practice. Further, ongoing BSE surveillance conducted by USDA APHIS, which tests approximately 40,000 animals from the highest risk cattle population per year, shows that the prevalence in the United States is less than one case per million adult cattle in the United States (Ref. 16). We therefore believe that the 30-month cutoff is appropriate for the BSE risk status in the United States, as we first discussed in our 2004 IFR (69 FR 42256 at 42259–60).

(Comment 15) One comment recommended that a 12-month cutoff for purposes of designating certain cattle materials as SRMs would be more prudent given the scientific uncertainty in fully understanding the possible ways that the BSE agent might infect humans.

(Response 15) We disagree that an additional margin of safety in the age cutoff is needed because of scientific uncertainty about how humans are exposed to the BSE agent. The 30-month cutoff is internationally recognized and well supported by pathogenesis studies that were designed to determine the tissue distribution of the BSE agent as the disease progresses in BSE-infected cattle.

(Comment 16) Several comments recommended that materials currently

designated as SRMs if they are from cattle 30 months of age and older should be considered SRMs regardless of the animal's age and should be prohibited from entering the food supply. According to the comment, a broad prohibition on the use of SRMs regardless of the animal's age would significantly reduce the need of determining the age of each animal, and thereby improve enforcement. Some comments pointed out that, in the absence of a national animal identification system, any determination of an animal's age is based typically on a physical assessment, and such an assessment can be subjective.

(Response 16) We disagree that the full list of SRMs should be removed from all cattle to eliminate the need for aging the animals. Methods of aging allowed under FSIS regulations, such as documentation and dentition, are reliable for identifying cattle over 30 months of age.

(Comment 17) One comment recommended that vertebral columns of cattle of all ages should be considered SRMs, not just vertebral columns of cattle 30 months of age and older, but the comment did not provide evidence or data to support the change.

(Response 17) We disagree with this recommendation. As previously stated in Comment and Response 14, pathogenesis studies support a 30-month cutoff in low BSE prevalence countries like the United States.

(Comment 18) Several comments noted that available post mortem tests are capable of identifying the presence of the BSE agent only near the end of the animal's incubation period; therefore cattle younger than 30 months of age in the early stages of BSE that do not test positive for the disease may be harboring the BSE agent. The comments suggested that the definition of SRM not exclude certain materials from cattle younger than 30 months.

(Response 18) We agree about the limitation of BSE test methods, but disagree that the limitations should influence the SRM definition. The 30-month cutoff is based on pathogenesis studies, not on diagnostic capabilities.

(Comment 19) One comment supported a 12-month cutoff for classifying animal age-related SRMs due to uncertainty surrounding a published study that suggested that there may be another form of TSE in cattle, referred to as bovine amyloidotic spongiform encephalopathy (BASE).

(Response 19) We do not agree that the 12-month cutoff is necessary for the BASE strain of BSE, also known as L-type BSE. FSIS pointed out in the 2007 FSIS affirmation that the available data on the BASE strain do not indicate that cattle with this form of BSE are more likely to contain higher levels of the infective agent early in the incubation period than cattle with the ''typical'' BSE strain (72 FR 38700 at 38707). As FSIS concluded, additional study on the BASE form of BSE will be needed to determine its significance.

(Comment 20) One comment recommended expanding the SRM definition to include the entire head of cattle 30 months of age and older. The comment also stated that cheek and head meat of cattle 12 months of age and older should be removed before the skull is fragmented or split, based on concerns that the head or cheek meat may contain central nervous system materials if the meat is not removed before the skull is fragmented or split. To support its arguments, the comment referred to a 2002 USDA FSIS paper that discussed the prohibition of cheek meat from cattle aged 24 months and older for human food if the meat is not removed before the skull is fragmented or split.

(Response 20) We disagree that the entire head of cattle 30 months of age and older should be condemned because of concerns that head meat and cheek meat could be contaminated with central nervous system tissue. FSIS regulations (9 CFR 310.22(e)) require that establishment procedures for removal of SRMS at slaughter must address potential contamination of edible materials with specified risk materials. Such procedures would include taking steps to ensure that cheek meat, for example, is not cross-contaminated with brain matter or central nervous system matter.

(Comment 21) One comment recommended using a 12-month cutoff for purposes of designating certain cattle materials as SRMs so that it would be consistent with the European Union (EU) standard 12-month cutoff period.

(Response 21) We decline to revise the rule as suggested by the comment. The EU established its BSE requirements because of a small number of BSE cases detected in young animals. These cases are now believed to be the result of cattle being exposed to large exposure doses of the BSE agent at the height of their BSE outbreak, before appropriate mitigations were put in place to reduce high levels of BSE infectivity circulating in their cattle population. In contrast, early control measures were put in place in the United States to protect against the establishment and amplification of BSE in the U.S. cattle population.

Further, the EC has published a roadmap for relaxing its BSE mitigations, including age cutoffs, because of the downward trend in BSE cases across the EU (Ref. 17).

(Comment 22) Several comments supported using a 12-month cutoff for purposes of designating certain cattle materials as SRMs because cattle as young as 21 months have tested positive for BSE in the UK and Japan.

(Response 22) We disagree with these comments. As discussed in the 2004 IFR (69 FR 42256 at 42259), we are aware of documented cases of BSE in the UK in animals younger than 30 months of age. As noted in the 2004 IFR (69 FR 42256 at 42259), at the height of the epidemic in the UK when thousands of animals were being diagnosed with BSE each year, fewer than 20 animals younger than 30 months were confirmed with the disease (Ref. 18). The youngest animal with a confirmed case of BSE was 20 months old (Ref. 19). The occurrence of BSE in young animals in the UK was most likely the result of exposure to a high infective dose of the BSE agent at a young age.

We also noted in the 2004 IFR the two reported cases of BSE in 21-month and 23-month-old animals in Japan discovered during the testing of animals presented for slaughter (69 FR 42256 at 42259). FSIS addressed a similar comment in the 2007 FSIS affirmation (72 FR 38700 at 38721) and concluded that the available evidence surrounding the two very young cases reported in Japan is insufficient to support any changes in FSIS's existing measures to prevent human exposure to the BSE agent. FSIS referred to a report by EFSA's Scientific Panel on Biological Hazards, which stated that ''it is unclear whether the very young cases [reported in Japan] were adequately identified and formally confirmed'' (Ref. 20). This same EFSA report concluded that these cases ''seem to be epidemiologically peculiar as their cohort would have been expected to yield further cases.''

(Comment 23) One comment said a 12-month age cutoff would be consistent with the International Review Team (IRT) recommendation that the brain, skull, spinal cord, and vertebral column of cattle over 12 months of age be excluded from both human food and animal food chains unless aggressive surveillance shows that the BSE risk in the United States is minimal (Ref. 21).

(Response 23) We decline to revise the rule in response to the comment. The IRT was convened at the request of the U.S. Secretary of Agriculture on December 30, 2003, to review the actions taken by the United States in response to the confirmation of BSE in an imported dairy cow in Washington State on December 23, 2003. The IRT recommended that, among other things,

the brain, skull, spinal cord, and vertebral column of cattle over 12 months be excluded from both the human food and animal food chains unless aggressive surveillance proves the BSE risk in the United States to be minimal (Ref. 22). As a follow up to the IRT report, USDA's APHIS conducted the aggressive surveillance and found the BSE prevalence in the United States to be minimal. Therefore, a 30-month cutoff is consistent with the recommendations of the IRT.

(Comment 24) One comment noted that many countries have imported vast amounts of meat-and-bone meal from countries with BSE-infected cattle, some of which do not have adequate surveillance and other mitigations in place to prevent contamination of the animal feed and human food chains. The comment further noted that these countries may still serve as a source of disease, and if the entire intestine is not designated as SRM, BSE-infected bovine products could be imported and enter the U.S. food or feed supply.

(Response 24) We disagree that the scenario described provides sufficient justification for designating the entire intestine as SRM. Our trading partners in cattle and cattle derived products are countries that have performed a BSE risk assessment, conducted the required level of BSE surveillance, and have the necessary BSE mitigations in place to meet OIE requirements for negligible or controlled risk status.

(Comment 25) One comment stated that we should err on the side of caution when it comes to protecting public health and designate the entire length of the intestines as SRM. The comment noted that scientific research demonstrates that immunostaining was observed in the myenteric plexus of the distal ileum in both naturally infected and experimentally challenged cattle with BSE, so one cannot eliminate the possibility of infectivity in other sections because the myenteric plexus exists throughout the entire intestine. Another comment stated that even a trace of BSE infectivity is concern enough to prohibit the use of the jejunum, proximal ileum, ileocecal junction, and colon of cattle.

(Response 25) We agree that it is reasonable to assume that increasingly sensitive detection methods could demonstrate that BSE infectivity is present anywhere along the intestinal tract, associated either with the enteric nervous system or lymphoreticular tissue. However, all available evidence to date shows that levels outside the distal ileum are much lower than levels in the distal ileum. As we explained in the 2013 notice, our tentative conclusion took into consideration not just the lower levels, but also the other safeguards in place in the United States, the sharp decline in the worldwide incidence of BSE, and the extremely low prevalence of BSE in the U.S. cattle population as indicated by USDA's BSE surveillance program (78 FR 14012). This conclusion is consistent with the recommendation in the 2009 EFSA Scientific Opinion that future consideration of risk associated with infectivity in the intestine take into account the BSE prevalence in cattle at that time (Ref. 18).

(Comment 26) Comments from the Biological Hazards Unit of EFSA in response to FDA's 2013 notice reopening the comment period clarified EFSA's current thinking on BSE infectivity in bovine intestines. EFSA stated that it had concluded that BSE infectivity in the bovine ileum is found mainly in association with the lymphoid follicles, the ileal Peyer's patches (Refs. 23 through 25). The ileal Peyer's patches are aggregated into a long continuous structure called the ileocecal plate. The ileocecal plate extends the full length of the ileum, and may extend proximally into the jejunum. EFSA concluded that, when assessing the BSE infectious load potentially present in the intestines of BSE-infected cattle, the ileocecal plate should be considered as the main contributor to BSE infectivity in the intestine.

(Response 26) Since submitting comments to the 2013 notice, the EFSA Panel on Biological Hazards (BIOHAZ) published on May 13, 2014, a Scientific Opinion on BSE risk in bovine intestines and mesentery (Ref. 25). This scientific opinion provides additional information about the distribution of intestinal lymphoid tissue with which BSE infectivity is associated in the early stages of disease. EFSA concluded that the BSE infectious load in the intestines is primarily associated with the lymphoid tissue making up the ileocecal plate. According to anatomical data presented in the report, the length of the ileocecal plate could reach four meters (157 inches), with considerable animal-to-animal variation, in cattle younger than 18 month of age, before the ileocecal plate starts to diminish in length as the animal ages. So, while studies to date show that infectivity levels outside the distal ileum are much lower than in the distal ileum, the anatomical data in the report show that in young cattle lymphoid tissue could extend two meters outside (proximal to) the distal ileum. This anatomical data does not alter our decision to leave the SRM definition unchanged. We believe that given the United States and worldwide BSE prevalence data, removal of prohibited cattle materials as required by this rule, together with the other effective BSE mitigations implemented by the U.S. government, provides the appropriate level of protection against human exposure to the BSE agent.

6. ''Tallow'' (§§ 189.5(a)(6) and 700.27(a)(6))

The regulations define ''tallow'' as the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissue. The definition also states that tallow must be produced from tissues that are not prohibited cattle materials and must not contain more than 0.15 insoluble impurities as determined by the method entitled ''Insoluble Impurities'' (AOCS Official Method Ca 3a–46, American Oil Chemists' Society (AOCS), 5th Edition, 1997, or another equivalent method.

(Comment 27) One comment questioned the basis (*i.e.,* underlying data) for selecting the 0.15 percent level as the allowable cutoff for insoluble impurities in tallow, but did not provide evidence or data to support changing the allowable level.

(Response 27) We discussed the underlying research that provided the basis for permitting tallow to be used in human food and cosmetics if it contains no more than 0.15 percent insoluble impurities in the 2004 IFR (69 FR 42256 at 42260 through 42261). In addition, the 0.15 percent cutoff is consistent with the level used by the Office International des Epizooties (OIE) in the BSE chapter of the OIE Terrestrial Animal Health Code (Ref. 7). Therefore, we are not making any further changes with respect to using the 0.15 percent level as the allowable cutoff of insoluble impurities.

7. ''Tallow Derivatives'' (§§ 189.5(a)(7) and 700.27(a)(7))

The regulations define ''tallow derivative'' as any chemical obtained through initial hydrolysis, saponification, or transesterification of tallow. The definition also states that chemical conversion of material obtained by hydrolysis, saponification, or transesterification may be applied to obtain the desired product.

We did not receive comments specific to our definition of ''tallow derivative,'' and we have finalized the definition without change.

8. ''Gelatin'' (§§ 189.5(a)(8) and 700.27(a)(8))

Our regulations at §§ 189.5 and 700.27 mention, but do not define, ''gelatin.'' Thus, on our own initiative, we have decided to define gelatin as a product that has been obtained by the partial hydrolysis of collagen derived from hides, connective tissue, and/or bones of cattle and swine. Gelatin may be either Type A (derived from an acid-treated precursor) or Type B (derived from an alkali-treated precursor) that has gone through processing steps that include filtration and sterilization or an equivalent process in terms of infectivity reduction (Ref. 26).

B. Requirements (§§ 189.5(b) and 700.27(b))

The regulations at §§ 189.5(b)(1) and 700.27(b)(1) provide that no human food or cosmetic shall be manufactured from, processed with, or otherwise contain, prohibited cattle materials. We further clarify in §§ 189.5(b)(2) and 700.27(b)(2) that the small intestine is not considered prohibited cattle material as long as the distal ileum is removed by a procedure that removes at least 80 inches of the small intestine or by another procedure that the establishment can show is equally effective at ensuring the distal ileum is completely removed.

(Comment 28) One comment objected to the use of cattle materials in any products and believed that our ''published policy'' is much too lenient, but did not provide evidence or data to support this assertion.

(Response 28) We disagree with the comment's broad generalization. In the absence of data or other information, we do not have a basis on which to evaluate the comment's assertion that our published policy is too lenient.

(Comment 29) One comment questioned the validity of relying on the Harvard-Tuskegee study to support the restrictions being applied by this regulation to externally applied cosmetics. The comment also questioned whether the restrictions that cover materials derived from cattle not inspected and passed are predicated on unfounded assumptions with respect to potential infectivity.

(Response 29) The Harvard-Tuskegee study does not specifically address potential human exposure to the BSE agent from cosmetics (69 FR 42256 at 42258), so it was not relied on to support the restrictions applied by the 2004 IFR to externally applied cosmetics. However, we are concerned that cosmetics, because of the ways they are used, could serve as another potential route for BSE infectivity to enter the human system. We therefore conclude that the wide range of cattle-derived ingredients used in cosmetics should not contain prohibited cattle materials (Ref. 27).

(Comment 30) One comment said that the United States should test every cow for TSEs, extend and enhance the feed ban, enhance surveillance and testing programs to test all cattle destined for human and animal consumption, ban all animal tissue in vaccines and nutritional supplements, and stop feeding ruminant and non-ruminant protein to all species.

(Response 30) We disagree with the recommendation to change current U.S. BSE control measures. The mitigations currently in place in the U.S. adequately protect human and animal health from BSE. Testing cattle and enhancing surveillance and testing programs fall under the purview of USDA. USDA's surveillance strategy is to target testing on those animals in the cattle population where the disease is most likely to be found if it is present. USDA has concluded that this is the most effective way to meet OIE and domestic surveillance standards. USDA determined that a level of 40,000 samples per year from these targeted, high-risk cattle far exceeds the standards recommended by the OIE (Ref. 16). With respect to animal feed restrictions, FDA's 1997 feed ban prohibited the use of ruminant protein in cattle feed, while the 2008 enhanced feed ban prohibits the use of the highest risk cattle tissues in all animal feed. Lastly, we are not aware of scientific justification for banning all animal tissue in vaccines and nutritional supplements.

(Comment 31) While many comments supported the use of material from nonambulatory disabled cattle, a few comments requested that these materials be prohibited regardless of the reason for the animal's condition (*e.g.,* obesity, fatigue, stress, nerve paralysis, or physical injury such as a fractured appendage, severed tendon or ligament, or dislocated joint). Other comments were concerned that visual examination was not sufficient for determining whether an animal is safe to be slaughtered. Other comments thought the current prohibition involving nonambulatory disabled cattle is too broad in its application, particularly when applied to animals that are nonambulatory due to clear physical injuries, such as a broken limb.

(Response 31) We decline to make changes to the rule regarding the prohibition on the use of cattle materials from nonambulatory disabled cattle in human food and cosmetics. As discussed in the 2007 FSIS affirmation, surveillance data from the EU indicate that cattle that cannot rise from a recumbent position are among the cattle that have a greater prevalence of BSE than healthy slaughter cattle, and the typical clinical signs of BSE may not always be observed when cattle are nonambulatory (72 FR 38700 at 38701 to 38706).

(Comment 32) Several comments requested that SRMs be kept out of all cosmetics over which FDA has jurisdiction.

(Response 32) Under § 700.27, no cosmetic shall be manufactured from, processed with, or otherwise contain, prohibited cattle materials. This includes SRMs.

(Comment 33) One comment stated that human consumption of any trace of BSE can be fatal, and that the use of materials derived from cattle should not be allowed in human food and cosmetics.

(Response 33) We strongly disagree that cattle derived products should not be used in human food and cosmetics. The sharp decline in vCJD cases worldwide demonstrates that internationally recognized BSE mitigations that remove only specified risk materials are highly effective in protecting humans against BSE. (Refs. 4, 22, 28, and 29). We note that the World Health Organization (WHO), in the 2010 update to the WHO Tables on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies (Ref. 30), stated that the amount of pathological prion or infectious agent detected by exquisitely sensitive assays may well fall below the threshold of transmissibility for humans, and that consideration also has to be given to the level of infectivity in tissue, the amount of tissue to which a person is exposed, and that oral exposure is a comparatively inefficient route of transmission.

(Comment 34) One comment stated that one of the most important and still unanswered questions is the significance of atypical BSE with respect to human and animal health. The comment said that if the U.S. government considers atypical BSE to be a sporadic disease, at present there is no means to eliminate cases from the national herd, and thus the food supply. The comment noted that in atypical BSE the extent of infectivity in bovine tissue is unknown, and hence, it would be important to at least remove the tissues having infectivity in classical BSE cases.

(Response 34) We agree with the comment's assertion that there are still unanswered questions about the

significance of atypical BSE with respect to human and animal health. We also agree that if atypical cases are sporadic, their occurrence will continue to be an ongoing rare event in our cattle population. However, based on the available science, we believe that the mitigations currently in place in the United States to protect against classical BSE are adequate to protect against atypical BSE. We note that this was also the conclusion of the OIE Scientific Commission for Animal Diseases. The February 2013 meeting report concluded that ''the ruminant-to-ruminant feed ban which mitigates the risk of classical BSE concurrently reduces the recycling of atypical BSE in the cattle populations of the controlled and negligible BSE risk countries within which it is applied.'' (Ref. 31).

C. Records (§§ 189.5(c) and 700.27(c))

In the 2004 IFR, FDA required that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, cattle material must make existing records relevant to compliance available to FDA for inspection and copying. In a companion rulemaking at the same time, FDA proposed a rule entitled ''Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material from Cattle'' (69 FR 42275). The rule proposed to require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle establish and maintain records sufficient to demonstrate the food or cosmetic is not manufactured from, processed, with, or does not otherwise contain, prohibited cattle materials. The records requirements were finalized in 2006 and incorporated the requirement from the 2004 IFR that existing records relevant to compliance be made available to FDA (71 FR 59653).

D. Adulteration (§§ 189.5(d) and 700.27(d))

Under § 189.5(d)(1), failure of a manufacturer or processor to operate in compliance with the requirements or records provisions renders human food adulterated under section 402(a)(4) of the FD&C Act. Under § 700.27(d), failure of a manufacturer or processor to operate in compliance with the requirements or records provisions renders a cosmetic adulterated under section 601(c) of the FD&C Act. Further, under § 189.5(d)(2), human food manufactured from, processed with, or otherwise containing, prohibited cattle materials is unfit for human food and deemed adulterated under section 402(a)(3) of the FD&C Act. Under § 189.5(d)(3), the use or intended use of any prohibited cattle material in human food causes the material and the food to be adulterated under section 402(a)(2)(C) of the FD&C Act if the prohibited cattle material is a food additive, unless it is the subject of a food additive regulation or of an investigational exemption for a food additive under § 170.17.

We did not receive comments specific to the adulteration provisions, and we have finalized them without change.

E. Process for Designating Countries (§§ 189.5(e) and 700.27(e))

Sections 189.5(e) and 700.27(e) establish a process for designating a country as not subject to certain 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.

We did not receive comments specific to the process for designating countries, and we have finalized those aspects of the rule without change.

F. Other Comments

Several comments addressed matters that were not specific to a particular provision in the IFRs. We address those comments here.

(Comment 35) Several comments said that prohibiting the use of cattle materials from nonambulatory disabled cattle in human food and cosmetics also should apply to the use of such materials in animal food or feed.

(Response 35) This final rule applies to the use of cattle materials in human food and cosmetics regulated by FDA. Our regulations in effect at the time of the 2004 IFR prohibited the use of certain protein from mammalian tissues in ruminant feed and have since been revised to prohibit the use of certain cattle-derived risk materials (*e.g.,* the brains and spinal cords from cattle 30 months of age and older, as well as the entire carcass of cattle not inspected and passed for human consumption) in all animal feeds. In a feed rule published in the **Federal Register** on April 25, 2008 (73 FR 22720), FDA's Center for Veterinary Medicine (CVM) explained that, because of the low prevalence of BSE in the United States, it is not necessary to prohibit all ruminant material from animal feed, nor is it necessary to prohibit all animal or all mammalian products in cattle feed. (See 73 FR 22720 at 22724, as well as similar discussion provided in the preamble to the earlier CVM proposal published in the **Federal Register** on October 6, 2005 (70 FR 58570 at 58578).)

(Comment 36) One comment stated that we do not truly know or understand the real risk to the public in regards to vCJD as caused by classical BSE. The comment said that based on results of an appendix tissue survey in the UK, the dose to infect humans may be much smaller than previously considered, and even small amounts of the BSE agent could infect humans resulting in a subclinical disease that may pose a risk to other people via blood transfusions, etc. According to the comment, this is justification for prohibiting the use of the entire intestine for human consumption or cosmetics.

(Response 36) We are aware of the results of the appendix survey published October 15, 2013, in the British Medical Journal (Ref. 32). We agree that the survey results underscore the need for better understanding of BSE and vCJD. In the appendix survey, 32,441 archived appendix samples collected during surgical operations performed in the UK between 2000 and 2012 were analyzed for the presence of abnormal prion protein. Sixteen samples were positive for abnormal prions. We did not conclude from these findings that they provide the scientific justification to modify our SRM definition to include the entire intestine of cattle. As the article points out, the samples were collected after the large BSE epizootic in the United Kingdom that resulted in a substantial amount of BSE infectivity entering the human food supply. We continue to believe that the SRM definition we are finalizing is appropriate for managing the BSE situation risk in the United States.

(Comment 37) One comment stated that FDA does not require reporting on CJD, so the United States is unable to track the incidence rate of the disease.

(Response 37) Tracking the incidence of CJD and vCJD is the responsibility of the Center for Disease Control and Prevention (CDC). The CDC collaborates with the American Association of Neuropathologists, the National Prion Disease Pathology Surveillance Center, and State health departments to monitor the prevalence of human prion diseases in the United States (Ref. 33).

(Comment 38) Several comments were from individuals who had suffered the loss of a loved one from sporadic CJD (sCJD) and were concerned about sCJD risks as well as vCJD risks. Many

comments said that, because the etiology of sCJD is unknown, FDA should take every precaution possible to eliminate human exposure to what could potentially be a causative agent of sCJD.

(Response 38) Although sCJD and vCJD are both prion diseases of humans and are similar in many respects, the available scientific evidence does not support a conclusion that the BSE agent causes sCJD. Therefore, we believe that requiring removal of parts of the small intestines other than the distal ileum would not provide any additional protection against sCJD.

(Comment 39) A comment inquired as to the impact of sequestration and budget cuts upon the availability of FDA inspectors in slaughter facilities to insure the proper removal of the distal ileum and keep the public safe.

(Response 39) FDA does not inspect cattle slaughter facilities. They are inspected by USDA under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601).

(Comment 40) One comment requested that bovine blood-derived products, such as beef blood plasma and fibrinogen, be prohibited until it is more certain that such blood-derived products do not have the potential for transmitting TSEs to humans. While noting the current thinking that the lymphatic system is the primary route of infectivity for TSEs, the comment suggested that TSEs may be transmitted via the blood through cut or abraded skin and damaged oral mucosal tissue.

(Response 40) We recognize that there are a number of animal species in which blood from TSE-infected animals have been shown to be capable of transmitting the TSE agent, and that there have been several cases in the UK of people acquiring vCJD after receiving transfusions of blood from donors who later were found to have vCJD. However, there is no evidence that blood from infected cattle can transmit the BSE agent to humans when the blood is incorporated into human food or cosmetics. Therefore, the final rule does not prohibit use of cattle blood or impose any special requirements on cattle blood materials that might be used in human food, including dietary supplements, and in cosmetics.

(Comment 41) One comment said that the U.S. government issued an official communication that it has a longstanding system of interlocking safeguards against BSE that protects public and animal health in the United States and that the most important safeguard is the removal of SRM or the parts of an animal that would contain BSE should an animal have the disease from all animals presented for slaughter in the United States. The comment stated that this could lead the public to believe any tissue that may contain BSE infectivity is removed at slaughter and concluded that this is definitely not the case with certain parts of the intestine and potentially other tissue such as peripheral nerves.

(Response 41) We understand the concern about how the message on the removal of SRM could be interpreted. We intend for the term SRM to mean the list of tissues identified in our final rule that must be removed from beef products for human consumption. We believe the official communication was correct that the United States has interlocking safeguards in place in addition to removal of specified risk material. These interlocking safeguards include a strong ruminant-to-ruminant feed ban, an ongoing BSE surveillance program capable of detecting the disease at very low levels in the U.S. cattle population, and strict controls on imports of animals and animal products from countries at risk for BSE.

(Comment 42) One comment expressed concern about the possibility of SRMs getting into the food supply through rendering.

(Response 42) In edible rendering (applying the rendering process to edible tissues for use as human food) only materials from cattle sources that have been inspected and passed for human consumption and do not contain SRMs or other materials considered to be prohibited cattle materials may be rendered for use in human food and cosmetics. It is the responsibility of manufacturers and processors, including renderers, to take precautions to avoid cross contamination of non-prohibited cattle material with prohibited cattle material during slaughter and processing. In this regard, manufacturers and processors of human food and cosmetics manufactured from, processed with, or that otherwise contain, material from cattle must maintain records sufficient to demonstrate that the human food and cosmetics are not manufactured from, processed with, or otherwise contain, prohibited cattle materials under §§ 189.5(c)(1) and 700.27(c)(1). Further, food establishments are subject to the CGMP requirements in part 110, and failure to take adequate measures to prevent cross-contamination could result in insanitary conditions whereby the food may be rendered injurious to health and, therefore, adulterated under section 402(a)(4) of the FD&C Act.

V. Regulatory Impact Analysis

A. Overview

Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us 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). We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule finalizes an existing IFR with no substantive changes, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any 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 $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

This final rule reaffirms the provisions in the 2004 IFR, as well as the 2005 and 2008 amendments, to address the potential risk of BSE in human food including dietary supplements, and in cosmetics. As the final rule's coverage and requirements do not differ from the 2004 IFR and the 2005 and 2008 amendments, no additional costs or benefits will accrue from this rulemaking.

The summary analysis of benefits and costs included in this document is drawn from the detailed IFR RIA (69 FR 42255 at 42265–42271).

B. Comments on the IFR RIA

We received two comments on our interim final regulatory impact analysis

and are declining to make changes to the RIA in the final rule.

(Comment 43) One comment stated that our economic analysis appears to consider only the industries that are end users of cattle materials and to overlook industries that produce intermediate products. As a result, there is no mention of the rule's impact on manufacturers of collagen casings, gelatin, and other intermediate products.

(Response 43) We disagree. We did estimate the impact of the 2004 IFR (and amendments) to both producers of intermediate cattle-derived products and producers of cattle-derived end products (69 FR 42256 at 42266). In the case of gelatin, depending on the product, we had information on cattle-derived materials manufactured by intermediate producers (*i.e.,* input suppliers to cosmetics manufacturers) or information on end products that contained cattle-derived materials (*i.e.* foods). Whether our information was on intermediate manufacturers or end products, we estimated the impact of the 2004 IFR on both the upstream and downstream facilities.

The final rule clarifies that gelatin was never considered a prohibited cattle material. This final rule defines ''gelatin'' to clarify that gelatin is not considered to be a prohibited cattle material as long as it is manufactured using the customary industry processes specified in the Gelatin Manufacturers Institute of America's (GMIA) Gelatin Manual.

In the 2005 amendment to the 2004 IFR, we revised the definition of ''prohibited cattle materials'' that appears at §§ 189.5(a)(1) and 700.27(a)(1) to clarify that ''hides and hide-derived products'' are not to be considered prohibited cattle materials (70 FR 53063 at 53066). Thus, collagen casings made from hides are not banned by this final rule, since the cattle hides from which they are made are not prohibited cattle materials.

(Comment 44) One comment stated that the 2004 IFR does not consider the cost to gelatin producers of tracing cattle to their origin, nor does it consider that other cattle-derived ingredients from inedible rendering (*i.e.,* tallow-derived products) are commonly used in cosmetics.

(Response 44) The final rule does not require users of cattle material to certify from which animal a specific material was derived. Users of cattle-derived material must only maintain records sufficient to demonstrate that cattle derived material is not made from, processed with, or does not otherwise contain prohibited cattle materials. We included the costs of generating and keeping records on cattle-derived material in the BSE recordkeeping rule (71 FR 59653 at 59661).

Our 2004 IFR analysis (69 FR 42256 at 42267) took into consideration the potential costs to cosmetic manufacturers to switch from inedible rendering to using edible tallow (and derivatives) in cosmetic products. We estimated in the 2004 IFR analysis that the cost of this change would range from $0 to $18 million.

C. Final Regulatory Impact Analysis

1. Need for Regulation

This final rule reaffirms the provisions in the 2004 IFR, as well as the 2005 and 2008 amendments, to address the potential risk of BSE in human food including dietary supplements, and in cosmetics. As the final rule's coverage does not differ from the 2004 IFR and the 2005 and 2008 amendments, no additional costs or benefits will accrue from this rulemaking.

2. Final Rule Coverage

We have 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. We have designated the following items as prohibited cattle 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), and mechanically separated 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 DRG of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine from all cattle. These restrictions appear in §§ 189.5 and 700.27 (21 CFR 189.5 and 21 CFR 700.27). Milk and milk products, cattle hides and hide-derived products, tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives (regardless of the tallow source), and gelatin are not prohibited cattle materials. In addition, we may designate a country as not subject to certain BSE-related restrictions following an evaluation of the country's BSE situation.

3. Costs of the Final Rule

Because of the 2004 IFR and 2005 and 2008 amendments already in effect, manufacturers and processors of food and cosmetic products using bovine materials such as the brain, skull, and spinal cord are obtaining these ingredients exclusively from cattle younger than 30 months of age. The manufacturers and processors of products that use the tonsils or the distal ileum of small intestine of cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, or MS (Beef) have found substitutes for those ingredients. To the extent that the 2004 IFR and 2005 and 2008 amendments led to increased use of alternative ingredients or ingredients from cattle under the age of 30 months, exposure to potentially BSE-infected cattle materials was reduced.

This final rule also clarifies that gelatin made from cattle-derived material is not, and never was, considered a prohibited cattle material so long as it is manufactured using customary industry processes. If there remained in the marketplace any confusion as to the status of gelatin derived from cattle materials, the new definition provided by this final rule should remove that confusion.

4. Countries Requesting Designation

To date, New Zealand and Australia have requested and received designation as not subject to certain FDA restrictions on cattle-derived materials. No other countries have applied to the FDA for designation. In the 2008 amendment, we estimated that it would cost a country about $9,000 to assemble a petition package for us to consider, and it would cost us $3,700 to review each package (73 FR 20785 at 20790). We did not receive any comments on these costs.

5. Benefits of the Final Rule

The benefits of this final rule are the value of the public health benefits. The public health benefit is the reduction in the risk of the human illness associated with consumption of the agent that causes BSE. In the 2004 IFR and 2005 and 2008 amendments, we were unable to quantify the benefits of these rule-makings, but provided estimates of the illness burden that could be avoided if we reduced the potential exposure to BSE agents.

In the 2004 IFR we estimated the benefits as the value of preventing a case of vCJD, the human illness that results from being infected from eating contaminated cattle-derived materials. (69 FR 42256 at 42267) The cost of a case of vCJD is the value of a statistical life (VSL) plus the value of preventing a year-long or longer illness that precedes certain death for victims of

vCJD. In 2004 we estimated this value to be in the range of $5.7 to $7.1 million. Updating using a central estimate of $369,000 for the value of a statistical life year (VSLY) and a central estimate of $8.3 million for VSL,[3] results in a single case of vCJD being valued at about $10 million in 2013 dollars. This estimate included direct medical costs, reduced ability of the ill person to function at home and at work, and the cost of premature death.

As we stated in the 2004 IFR, we do not know the baseline expected annual number of cases, but based on the epidemiology of vCJD in the UK, we anticipated much less than one case of vCJD per year in the United States. Because the IFR and amendments were expected to reduce, rather than eliminate, the risk of exposure to BSE infectious materials, the reduction in the number of cases was estimated to be an unknown fraction of the less than one case annually. We stated in the 2004 IFR RIA that the IFR, in conjunction with USDA's requirements on cattle-derived materials, would help reduce a potential human exposure in the United States that was previously estimated at less than 1 percent (69 FR 1862 at 1867).

The benefits of this final rule have already been realized as the IFR has been in place since 2004. We do not estimate any additional benefits as a result of this finalizing this IFR.

VI. Environmental Impact, No Significant Impact

We have determined under 21 CFR 25.32(m) 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.

VII. Paperwork Reduction Act of 1995

The collection of information provisions of this final rule are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 189.5(e) and 700.27(e), added by the 2008 amendment, have been previously approved under OMB control number 0910–0623. This final rule does not revise the information collection requirements of §§ 189.5(e) and 700.27(e). Therefore we are not submitting this final rule to OMB as a revision of the information collection approved under OMB control number 0910–0623.

VIII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the 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 have concluded that the 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 are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

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List of Subjects

21 CFR Part 189

Food additives, Food packaging.

21 CFR Part 700

Cosmetics, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the interim final rule amending 21 CFR parts 189 and 700, which was published on July 13, 2004, at 69 FR 42255, and amended on September 7, 2005, at 70 FR 53063, and amended on April 17, 2008, at 73 FR 20785, is adopted as a final rule with the following changes:

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

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

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

■ 2. Section 189.5 is amended by revising paragraph (a) to read as follows:

§ 189.5 Prohibited cattle materials.

(a) *Definitions.* The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) apply to such terms when used in this part. The following definitions also apply:

(1) *Prohibited cattle materials* mean 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, gelatin, 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.

(2) *Inspected and passed* means that the product has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time it was inspected and passed, it was found to be not adulterated.

(3) *Mechanically separated (MS) (Beef)* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses that meets the specifications contained in 9 CFR 319.5, the U.S. Department of Agriculture regulation that prescribes the standard of identity for MS (Species).

(4) *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(5) *Specified risk material* means 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.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be produced from tissues that are not prohibited cattle materials or must contain no more than 0.15 percent insoluble impurities as determined by the method entitled ''Insoluble Impurities'' (AOCS Official Method Ca 3a-46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a–46. You may obtain copies of the method from AOCS (*http://www.aocs.org*) 2211 W. Bradley Ave. Champaign, IL 61821. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

(8) *Gelatin* means a product that has been obtained by the partial hydrolysis of collagen derived from hides, connective tissue, and/or bone bones of cattle and swine. Gelatin may be either Type A (derived from an acid-treated precursor) or Type B (derived from an

alkali-treated precursor) that has gone through processing steps that include filtration and sterilization or an equivalent process in terms of infectivity reduction.

* * * * *

PART 700—GENERAL

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

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

■ 4. Section 700.27 by is amended by revising paragraph (a) to read as follows:

§ 700.27 Use of prohibited cattle materials in cosmetic products.

(a) *Definitions.* The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) apply to such terms when used in this part. The following definitions also apply:

(1) *Prohibited cattle materials* mean 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, gelatin, 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.

(2) *Inspected and passed* means that the product has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time it was inspected and passed, it was found to be not adulterated.

(3) *Mechanically separated (MS) (Beef)* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses that meets the specifications contained in 9 CFR 319.5, the U.S. Department of Agriculture regulation that prescribes the standard of identity for MS (Species).

(4) *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(5) *Specified risk material* means 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.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be produced from tissues that are not prohibited cattle materials or must contain no more than 0.15 percent insoluble impurities as determined by the method entitled ''Insoluble Impurities'' (AOCS Official Method Ca 3a–46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a–46. You may obtain copies of the method from AOCS (*http://www.aocs.org*) 2211 W. Bradley Ave. Champaign, IL 61821. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

(8) *Gelatin* means a product that has been obtained by the partial hydrolysis of collagen derived from hides, connective tissue, and/or bone bones of cattle and swine. Gelatin may be either Type A (derived from an acid-treated precursor) or Type B (derived from an alkali-treated precursor) that has gone through processing steps that include filtration and sterilization or an equivalent process in terms of infectivity reduction.

* * * * *

Dated: March 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–06123 Filed 3–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0093]

Drawbridge Operation Regulation; Sacramento River, Sacramento, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Tower Drawbridge across the Sacramento River, mile 59.0, at Sacramento, CA. The deviation is necessary to allow the community to participate in the Peace Love run. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period.

DATES: This deviation is effective from 8:30 a.m. to 10:30 a.m. on March 26, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0093] is available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, email *David.H.Sulouff@uscg.mil.*

SUPPLEMENTARY INFORMATION: California Department of Transportation has requested a temporary change to the operation of the Tower Drawbridge, mile 59.0, over Sacramento River, at Sacramento, CA. The vertical lift bridge navigation span provides a vertical clearance of 30 feet above Mean High Water in the closed-to-navigation position. The draw operates as required by 33 CFR 117.189(a). Navigation on the waterway is commercial and recreational.

The drawspan will be secured in the closed-to-navigation position from 8:30 a.m. to 10:30 a.m. on March 26, 2016, to allow the community to participate in the Peace Love run. This temporary deviation has been coordinated with the waterway users. No objections to the proposed temporary deviation were raised.

Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our