Environmental Assessment for the IFR on Use of Materials Derived from Cattle in Human Food and Cosmetics.

July 9, 2004

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I. Description of the Selected Action.

The Food and Drug Administration is issuing an interim final rule to prohibit the use of certain cattle material (referred to as prohibited cattle materials), because of the risk of bovine spongiform encephalopathy (BSE), in human food, including dietary supplements, and cosmetics. Prohibited cattle materials include specified risk materials, the small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) (Beef). Specified risk materials (SRMs) are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow with 0.15% or less insoluble impurities or tallow derivatives. The United States Department of Agriculture (USDA) issued an IFR on January 12, 2004, declaring SRMs and the carcasses and parts of nonambulatory disabled cattle to be inedible, unfit for human food, and prohibiting their use in human food. The agency is issuing this IFR, consistent with USDA's IFR, to minimize human exposure to the materials that scientific studies have demonstrated to contain the BSE agent in cattle infected with BSE.

II. Need for Action.

Based on the information presented in the preamble to the rule and consistent with USDA's regulation issued in an IFR on January 12, 2004, (69 FR 1862), FDA has determined that the tissues of highest risk of harboring BSE infectivity (the SRMs) are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of animals 30 months and older and tonsil and distal ileum of cattle of all ages. Though the skull and the vertebral column have not been shown to harbor BSE infectivity, they contain tissues that have been shown to be infectious; therefore, the agency is including the skull and the vertebral column in the list of SRMs. The agency is not including the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum as SRMs with the rest of the vertebral column, because they do not contain spinal cord or dorsal root ganglia. The preamble to the IFR also discusses in detail the basis for tissue selection and for animal age selection as well as the source of the prohibited cattle materials.

The prohibition would cover the same materials prohibited by USDA' IFR and also materials from cattle that are not inspected and passed for human consumption. Because SRMs, the small intestine, non-ambulatory disabled cattle, and MS (beef) are subject to USDA's disposition requirements (e.g., destruction or use in inedible rendering), we assume that generally these materials are not likely to be widely available for use in the manufacture of FDA-regulated human food and cosmetics. The manufacturers and processors of products currently using materials that are considered SRMs (e.g., the brain, skull, and spinal cord) would presumably be able to continue to use these ingredients, but exclusively from cattle younger than 30 months of age. The manufacturers of FDA-regulated food products that use rendered material would continue to use rendered material that is the product of edible rendering (e.g., edible tallow). The manufacturers of products using the tonsils and small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) (Beef) would need to find substitutes for these ingredients. We assume that the recent USDA rulemaking has already led many of these manufacturers to search for alternative ingredients.

FDA believes that there is a need for the IFR to reduce risk to human health from uses of prohibited cattle materials in domestic and imported human food and cosmetics.

III. How the Selected Action Addresses the Need for Action

The Harvard-Tuskegee risk assessment (referred to below as the Harvard-Tuskegee study) was published in November 2001, and determined that the U.S. was highly resistant to any proliferation of BSE or a similar disease. The Harvard-Tuskegee study determined that the greatest sources of infectivity are direct consumption of cattle brain and spinal cord and also meat from advanced meat recovery (AMR) systems that contains central nervous system tissue. The Harvard-Tuskegee study did not address potential human exposure to the BSE agent through products containing ingredients of bovine origin, such as gelatin, beef stocks, extracts, and flavorings, and did not address potential exposure from cosmetics. The Harvard-Tuskegee study identified three pathways by which BSE could be spread or human exposure to it could be increased; these are:

(1) Non-compliance with FDA's ruminant feed regulation prohibiting the use of certain proteins in feed for cattle and other ruminants;
(2) Rendering of animals that die on the farm and use (through illegal diversion or cross-contamination) of the rendered product in ruminant feed; and
(3) The inclusion of high-risk tissues from cattle, such as brain and spinal cord, in products for human oral consumption.

Evaluation of potential risk mitigation measures in the study found that a prohibition against rendering of animals that die on the farm would reduce the

potential cases of BSE following hypothetical exposure by 82 percent. In addition, a ban on specified risk materials (SRMs) including brains, spinal cord and vertebral column from inclusion in human and animal food would reduce potential BSE cases in cattle by 88 percent and potential human exposure to BSE by 95 percent. Consideration of FDA-regulated products was not included in the Harvard-Tuskegee study. Hence, the selected action would meet the need for the action; specifically, it will provide an increased level of protection for human health by ensuring that prohibited cattle materials are not used in FDA-regulated human food and cosmetics.

In this interim final rule, FDA is extending similar protections to FDA-regulated human food and cosmetics. USDA's IFR will reduce but will not, by itself, eliminate the availability and use of prohibited cattle materials in domestic and imported FDA-regulated human food and cosmetics. Domestically, generally food that contains meat only in a relatively small proportion or that historically has not been considered by consumers to be products of the meat food industry (e.g., soup stock, beef flavors and extracts, gelatin), is not produced under USDA inspection (see definition of "meat food product" in 21 USC 601(j)) and may be physically available for use in FDA-regulated human food and cosmetics. Further, even when excluded from food produced in USDA-inspected establishments, prohibited cattle materials may leave the establishments for inedible rendering or destruction. These materials, which previously have not been explicitly prohibited in human food and cosmetics by FDA, might then be used in FDA-regulated human food or cosmetics. For example, prohibited cattle materials leaving a USDA-inspected facility might not be denatured sufficiently to preclude their use in FDA-regulated human food and cosmetics.

Under FSIS' rule, SRMs, small intestine from all cattle, and material from non-ambulatory disabled cattle must be designated as inedible. However, certain products, such as gelatin and collagen used in FDA-regulated human food and cosmetics, have traditionally been produced from cattle material deemed inedible by USDA. Therefore, such a designation by USDA may not be enough to preclude use of prohibited cattle materials in FDA-regulated human food and cosmetics without additional regulation by FDA. Further, some cattle are not slaughtered under continuous USDA inspection (e.g., some are sent directly to rendering). Cattle material from these animals, such as brains or bones which include SRMs, could end up as starting material for human food, such as meat extracts or gelatin, respectively. Furthermore, if prohibited cattle materials were used in FDA-regulated human food or cosmetics, the rule would facilitate FDA's ability to use the enforcement mechanisms of the Act that apply to adulterated products (e.g., seizure) to prevent human exposure to prohibited cattle materials.

Imported products also may contain the types of materials prohibited by USDA, but which would not fall within the scope of USDA's import regulations either because of the nature of the products or their country of origin. Specifically, although both FSIS and APHIS impose BSE-related prohibitions, these

prohibitions collectively do not cover all FDA-regulated human food and cosmetics. FSIS' restrictions, contained in its IFR described earlier in this document, do not apply to importation of dietary supplements, cosmetics, and FDA-regulated human food not considered to be "meat food products" under the Federal Meat Inspection Act (21 USC 601(j)). APHIS' BSE-related restrictions on imports do not cover gelatin for human use (beyond requiring a permit) or cosmetics, and apply only to a limited number of countries (9 CFR 94.18).

In conclusion, the agency believes that the selected action would satisfy the need for the action, specifically, protection of public health, by 1) making it clear that prohibited cattle materials cannot be used in FDA- regulated human food and cosmetics; 2) creating an additional regulatory barrier, beyond existing USDA and FDA regulations, between consumers and human food and cosmetics potentially contaminated with BSE; and 3) clarifying FDA's ability to prohibit importation of products, such as gelatin, beef extracts, and dietary supplements, that may contain the types of materials prohibited by USDA, but may not fall under the scope of USDA's import restrictions.

IV. Regulatory Authority.

A. FDCA.

FDA is issuing these regulations under the adulteration provisions in sections 402(a)(2)(C), 402(a)(3), 402(a)(4), 402(a)(5), 601(c), and under section 701(a) of the act (21 U.S.C. 342 (a)(2)(C), (a)(3), (a)(4), (a)(5), 361(c), and 371(a)). The preamble to the IFR discusses also in detail the legal authority regarding prior sanctions, GRAS, color additives, dietary supplements, and cosmetics. The IFR discusses enforcement.

B. NEPA.

Sec. 101 [42 USC § 4331] of Title I of the National Environmental Policy Act (NEPA) declares that it is the continuing policy of the Federal government, in cooperation with State and local governments, and other concerned public and private organizations, to use all practicable means and measures to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations of Americans.

According to Sec. 102 [42 USC § 4332] of Title I of the Act, all agencies of the Federal Government shall include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on:

1. The need for action,
2. The environmental impact of the selected action,

3. Any adverse environmental effects which cannot be avoided should the proposal be implemented,
4. Alternatives to the selected action,
5. Mitigation measures if the action may result in significant environmental impacts

The policies and goals set forth in NEPA provide Federal agencies with authority supplemental to those set forth in existing authorizations of Federal agencies (Sec. 105 of Title I of NEPA).

V. Background of Current U.S. Regulations.

In an effort to minimize human exposure to materials that contain the BSE agent in cattle infected with the disease, following identification of a BSE-positive cow in the U.S., USDA published on January 12, 2004, an interim final rule banning the use of SRMs from animals 30 months and older and tonsils and small intestine from all animals, materials from non-ambulatory disabled animals, and MS (beef) from human food. From the early 1990s, FDA has published guidance and regulations and issued letters to the industry on the sourcing of bovine materials from BSE countries and other BSE-related measures. A detailed discussion of CVM/FDA BSE regulations and guidance are available at CVM's web site at http://www.fda.gov/cvm. For CFSAN/FDA's current BSE regulations and guidelines, see the preamble to the IFR, and for USDA's current BSE regulations see 69 FR 1862, January 12, 2004.

VI. Uses of Cattle Products in Human Food and Cosmetics.

When cattle are slaughtered, abdominal fat is pooled with fat trimmings from primary cuts of meat. This edible fat is processed to produce edible tallow and tallow derivatives for use in human food applications such as frying, pizza, soups, frozen dinners, and other food products. Organs and tissues not commonly considered meat, henceforth referred to as by-products, are harvested during slaughter. These by-products are separated into edible (e.g., liver, heart, kidneys, spleen, thymus, testicles, and pancreas) and inedible (e.g., lungs and condemned parts) by-products. The former can be used in FDA-regulated bovine-origin food (e.g., stocks, flavoring, and dietary supplements) and cosmetic products; the latter are, in general, not used in human food or cosmetic products. While cattle hides are not treated as edible tissues in slaughter plants, some parts of hides are transformed into hide gelatin, which can be used in food products. As for diseased, dead, dying, and disabled cattle, and cattle not inspected and passed for human consumption, they are otherwise considered in-edible by USDA and are not permitted for use in human food. This material is either disposed of or is sent to inedible rendering where they are cooked down to produce (1) meat and bone meal (MBM), which is not used in FDA-regulated human food and cosmetics, and (2) inedible tallow and tallow derivatives that have many uses. Before December 2003, surveillance had not indicated that there was BSE in the U.S., so tissues

now considered prohibited cattle materials were allowed in human food by both USDA and FDA. However, USDA published its interim final rule in January 12, 2004, to label these materials as inedible and prohibit their use in human food.

As we discussed in the last paragraph of Section III of this EA, FDA's IFR will make it clear that prohibited cattle materials cannot be used in FDA- regulated human food and cosmetics, will create an additional regulatory barrier, beyond existing USDA and FDA regulations, between consumers and food and cosmetics potentially contaminated with BSE, and will clarify FDA's ability to prohibit importation of human food and cosmetics, such as gelatin, beef extracts, and dietary supplements, that may contain the types of materials prohibited by USDA, but may not fall under the scope of USDA's import restrictions.

?? Edible fat gets rendered into edible tallow for use in human food, mainly for baking and frying. Soaps and many cosmetics also use a tremendous amount of tallow derivatives, which may come from edible or inedible tallow. Tallow derivatives are exempt from the regulation in the IFR.

?? Edible by-products that may become part of FDA-regulated human food or cosmetics include the brain, spinal cord, and eyes of cattle under 30 months of age, and the liver, heart, kidneys, spleen, thymus, testicles, pancreas, esophagus, bile, mesentery, stomachs, and probably a few other body parts from cattle of all ages. These may be used in dietary supplements and other human food including soups, stocks, flavorings, extracts, collagen, and amino acids.

VII. Alternatives to the Selected Action.

Consistent with NEPA, with CEQ's regulations, and with FDA's regulations in 21 *CFR* 25.40, this EA provides a brief discussion of the alternatives to the selected action. In making the decision on the preferable alternative, FDA evaluated the impact of the action and its alternative in the context of the larger effort to minimize and manage the potential risks posed by BSE to the populations of the U.S. In making its decision of what alternatives it could consider, the agency weighed the environmental cost of more prohibitive actions that may be more protective of human health and the environmental benefit of the less prohibitive action that is less protective of human health; specifically, no action.

The agency believes that the selected action is the one that provides the most reasonable protection of human health and the least environmental impacts. The only alternative with no impact, No Action, is not responsive to the problem. The alternatives discussed are:

A. **Alternative 1:** No Action;
B. **Alternative 2:** Ban use of prohibited cattle materials in human food and cosmetics, the selected action;

C. **Alternative 3:** Ban Use of all Non-Meat Material from Cattle in Human Food and Cosmetics.

D. **Alternative 4:** Ban Use of Prohibited Cattle Material from Cattle over 12 Months in human food and cosmetics.

A. Alternative 1: No action.

As long as the country was free of BSE, the responsible Federal agencies relied on a firewall that consisted of import restrictions, surveillance of the U.S. cattle population, and FDA's animal feed ban to prevent the introduction of BSE and to detect it if it were introduced in the U.S. Shortly after BSE was diagnosed in one cow in the State of Washington, the USDA published its IFR to strengthen the firewall and minimize the risk to humans from BSE. FDA, consistent with USDA, and to provide greater protection for public health, decided to act by publishing the current IFR.

The first alternative the agency considered was "no action." Under this option, FDA would not publish any rules but would continue monitoring the disease. This option would not be the best option to protect human health after the discovery of a BSE positive animal in the U.S. The "No Action Alternative" would have the least environmental consequences because the status quo practices of the cattle and rendering industries would continue with no additional material destined for disposal. However, this is not the best alternative for protecting public health, which is the main responsibility of the FDA. Domestically, generally food that contains meat only in a relatively small proportion or that historically has not been considered by consumers to be products of the meat food industry (e.g., soup stock, beef flavors and extracts, gelatin), is not produced under USDA inspection (see definition of "meat food product" in 21 USC 601(j)) and may be physically available for use in FDA-regulated human food and cosmetics. Further, even when excluded from for food produced in USDA-inspected establishments, prohibited cattle materials may leave the establishments for inedible rendering or destruction. These materials, which previously have not been explicitly prohibited in human food and cosmetics by FDA, might then be used in FDA-regulated human food or cosmetics. As a result, by not acting, the agency would not be explicitly prohibiting use of material considered by USDA to be inedible and unfit for food because of the possible presence of the BSE infectious agent.

B. **Alternative 2:** Ban use of prohibited cattle materials in human food and cosmetics, the selected action

The USDA rule prohibits the use of SRMs, small intestine of all cattle, material from non-ambulatory disabled cattle, and MS (Beef) in human food. FDA's IFR bans the use of prohibited cattle materials in human food, including dietary supplements, and cosmetics.

To have a better understanding of how much material is produced by the slaughtering and rendering industries, we are providing relevant information about these industries in Appendix A. It is imperative to keep in mind that USDA's prohibitions on cattle material theoretically should prevent most animals that were not inspected and animals that were condemned by USDA from being used in FDA-regulated human food and cosmetics.

1. Food ingredients affected.

Prohibited cattle materials include specified risk materials (SRMs), small intestine from all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS)(Beef). SRMs are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older; and the tonsils and distal ileum of the small intestine of cattle of all ages. Tallow may be used if it contains no prohibited cattle materials or if it contains 0.15% or less hexane-insoluble impurities. Tallow derivatives are exempt from the rule.

This alternative would only prohibit the use of ingredients produced by the processing of by-products that contain, in whole or in part, prohibited cattle materials from cattle and that are intended for use in human food, including dietary supplements, and cosmetics (See Figure 1, below). Most of the rendered materials used in FDA-regulated human food and cosmetics are tallow and tallow derivatives. Because the proposed BSE agent is a protein and has not been detected in fat (MAFF, 1993), FDA would not prohibit the use of tallow and tallow derivatives from this source as long as they comply with the specifications set forth in the interim final rule.

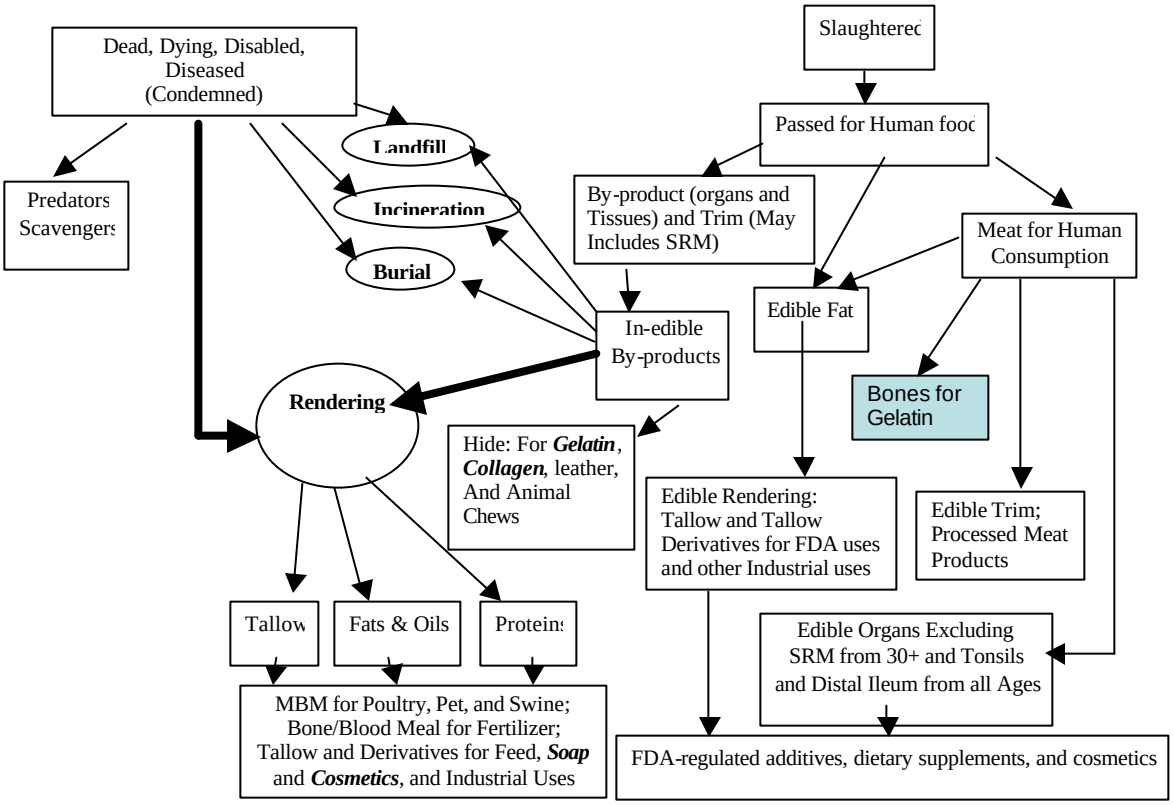

Figure1: A Flow Diagram of Material Fate from Slaughter to Final Product

2. Environmental Consequences of the Selected Action.

Under USDA's IFR, slaughterers separate SRMs and arrange for their disposal. Slaughterers will modify their animal killing operations to arrange for the separation of SRMs, and delivery of the materials to a disposal or disposal/rendering operation.

USDA has banned the use of SRMs from food for human consumption. Until now, SRMs have generally gone to rendering where they contribute to the production of meat and bone meal (MBM) and tallow. For the purpose of this analysis, we are assuming that SRMs will be rendered and the tallow will be recovered; the tallow will be purified to meet the specifications set forth in the IFR if it is to be used in human food or cosmetics. The rendered MBM from SRMs then will be used as discussed below.

This analysis is based on the SRM definition used by USDA and FDA in their interim final rules. SRMs are defined as:

(1) 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.
(2) The tonsils of all cattle;
(3) The distal ileum of all cattle.

Because of USDA's IFR, we are assuming that slaughterers are already not including deads and downers in their slaughtering operations; thus, we are not including the SRMs produced from dead and downers (692,150,000 pounds) in our analysis. Only SRMs produced from healthy slaughtered cattle (1,423,044,000 pounds) is included in this analysis. We are also presuming that meat processors are not expected to handle SRMs and are excluded from this analysis.

As indicated in the shaded part of Figure 1, almost all of the cattle products currently used as human food or in human food come from cattle parts considered edible by USDA. As a result of USDA's IFR, SRMs from slaughtered cattle have to be segregated early in the process to avoid contamination of the materials considered edible and destined for human food. Consequently, FDA's action is not the primary reason why these materials must be segregated from edible material in cattle slaughtering facilities and are made unavailable for uses in human food and cosmetics.

The environmental impact of most consequence as a result of the IFR would be the disposal of SRMs that will be clearly prohibited from use in FDA-regulated human food and cosmetics (FDA's IFR).

a. Protein Use: In Appendix A, we estimated that 355,761,000 pounds of protein result from material considered SRMs collected by renderers from slaughtering facilities. We expect most of this protein to be used in poultry feed (36%), pet food (36%), swine food (15%), and other uses. We have no evidence to believe that the category "other uses" include uses in human food, such as food additives and dietary supplements or in cosmetics; however, if we assume that all this material (13% of total protein produced) is currently being used in the subject FDA-regulated human food or cosmetics, then renderers have to dispose of only 46,248,930 pounds (355,761,000 * 13%). This material is a very small fraction of the total material that cattle farmers and renderers have to dispose off. Specifically this material constitutes only 1% of the materials of dead and downers that slaughterers have to dispose of (4,621,250,000 pounds-Appendix A). In addition, this material could be diverted for use in animal feed which is the main market for use of this protein. Therefore, we do not expect this IFR to lead to a significant environmental impact as a result of disposal of proteins not used in the regulated products mentioned in the rule.

b. Tallow Use: The interim final rule allows the use of tallow that contains no more than 0.15 percent hexane-insoluble impurities as outlined in the rule. Consequently, we expect renderers to purify the rendered tallow to meet the

required specifications and do not expect FDA's IFR to result in additional waste. In addition, tallow derivatives are exempt from the rule.

C. Alternative 3: Ban Use of all Non-Meat Material from Cattle in Human Food and Cosmetics.

The action, prohibition of use of SRMs, reduces the risk posed to humans from BSE but does not eliminate it. The removal of SRMs removes over 95% of the infectivity in an animal infected with BSE (FSA-http://www.foodlaw.rdg.ac.uk/news/uk-03028.htm). One alternative to reduce further the potential for exposure to infectious material would be to ban not just SRMs but all cattle by-products. Specifically, all organs and tissues not commonly considered meat that are harvested during slaughter in a sanitary manner could be banned. This alternative would result in the need to find alternative methods of disposal of almost 50 percent of the live weight of cattle because less than 50 percent of a cow ends up as prime cut for human consumption. This alternative would result in huge amounts of waste needing disposal. The costs associated with this alternative would be high, while providing only minimal additional protection to humans.

D. Alternative 4: Ban Use of Prohibited Cattle Material from Cattle over 12 Months in human food and cosmetics.

This option is the ban of prohibited cattle materials from animals over 12 months of age. The European Union requires removal of SRMs from animals over 12 months of age. The EU set their age limit at the level they deemed appropriate for countries that experienced widespread BSE among cattle. USDA and FDA believe an SRM ban in animals over 30 months of age is protective of human health based on research described in the preamble of the IFR.
This alternative would increase the amount of waste for disposal. The costs associated with this alternative would be higher, while providing additional protection to humans only from the relatively small number of cattle between the ages of 12 and 30 months that would be expected to be infectious for BSE.

VIII. Mitigation Measures.

The agency has concluded that no significant environmental impacts are expected as a result of the action; therefore, there is no need to discuss mitigation measures.

IX. Preparer.

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?? Dave Harlan (2004): By-products Marketing Manager for Cargill Taylor Beef Business Unit.

Appendix A: Cattle Industry and Slaughtering By-products

In the United States, there are about 900 slaughtering facilities that are inspected by USDA. These account for at least 95% of the total animals slaughtered for meat. The rest of the animals are slaughtered in non-Federal inspected facilities, which are inspected by individual States.

Under USDA's IFR, slaughterers will be asked to separate SRMs and arrange for their disposal. Slaughterers are expected to modify their animal killing operations to arrange for the separation of SRMs and delivery of the materials to a disposal or disposal/rendering operation. USDA has banned the use of SRMs in food for human consumption. Until now, SRMs have generally gone to rendering where they contribute to the production of meat and bone meal (MBM) and tallow.

This analysis is based on the SRM definition used by USDA and FDA in their interim final rules. SRMs are defined as:

1. 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.
2. The tonsils of all cattle; and
3. The distal ileum of all cattle.

Under this definition, older cows generate considerably more SRM per head than younger animals. To quantify the SRM generation, the agency used estimates provided by Dave Harlan, Byproducts Marketing Manager for Cargill Taylor Beef Business Unit (Harlan, 2004). In the estimates presented in Table 1 below, slaughterers are forecast to extract on average 28.3 lbs of SRM from cattle under 30 months of age and 88.5 lbs from cattle over 30 months of age. The average total cattle weight at slaughter was calculated in 2003 at approximately 1,250 lbs, of which hides and skin represent approximately 5 percent and for which cattle offal represents 34.1 percent (Sparks International, Inc, 2001). This translates to approximately 425 lbs of offal per animal before SRM are removed. Based on these calculations, SRM will represent 6.7 or 20.8 percent of offal of the animal. [Other sources provide slightly different estimates of the weight of SRM per cow. ERG used the Harlan estimates based on the judgment that they were reasonably consistent with other estimates and were combined in his analysis with other useful data for this analysis. Some of the other estimates of SRM weights are somewhat higher, such as sources estimating 100 lbs for SRM in older cattle. Weight estimates for specific SRM components are also variable, depending partly on the interpretation of the definition of each SRM component.]

Table 1. Estimated Volumes and Value of Specified Risk Material, per Ambulatory Cow Slaughtered

Cattle part	Pounds SRM/Head
Brain	0.936
Spinal cord	0.374
Eyes	0.220
Dorsal root ganglia	NA
Tonsils	0.300
Skull (including trigeminal ganglia)	15.200
Vertebral column	36.500
Small intestine (incl. distal ileum) - < 30 months (a)	28.000
Small intestine (incl. distal ileum) - > 30 months (a)	35.000
Total - for cattle not over 30 months (Includes only tonsils and small intestine) (lbs)	28.3
Total - for cattle over 30 months old (lbs)	88.5

NA=Not applicable or not available

(a) The source estimates different values for cattle below or over 30 months of age

Source: Harlan, 2004a. Other sources provide different average weights for various cow parts, with some estimates as high as 100 lbs of material for older cattle.

Table 2 below (Harlan, 2004) includes estimates of total quantities of SRMs produced per year from slaughtered animals and from dead and downers. We have no information to support that material from dead and downers is used in human food or in the manufacture of FDA-regulated human food or cosmetics that are the subject of this rule. Therefore, the weight of SRMs produced from dead and downers will not be included in the assessment. The SRM calculations were based on the 2003 annual cattle slaughter of approximately 35.3 million animals (USDA, 2004).

Table 2. SRMs Quantities from Dead, Downer and Antemortem Condemned Cattle

	Number of Head (000)(a)	Percent Rendered(b)	Number Rendered (000)	Avg. SRMs Wt. Per Head (lbs) (c)	Total SRMs Wt. (000 lbs)
Slaughtered					
For cattle over 30 months of age	7,054	100%	7,054	88.5	624,508
For cattle under 30 months of age	28,217	100%	28,217	28.3	798,535
SRM totals	35,271		35,271		**1,423,044**
Dead and Downers					
All deads under 500 lbs	2,365	5%	118	200.0	23,650
Feedlot deads	300	90%	270	750.0	202,500
Beef cow deads & downers	1,400	10%	140	1,100.0	154,000

Dairy cow deads & downers	400	60%	240	1,300.0	312,000
Deads and downer totals	4,465	17%	768		**692,150**
Total - All SRM and dead and downer animals					**2,115,194**

(a) FDA assumed that 20 percent of cattle slaughtered are over 30 months of age. This estimate is within the range defined by various industry and literature estimates. The total slaughter figure for cattle is based on 2003 slaughter (USDA, 2004). Dead and downer estimates were derived from Harlan, 2004a.
(b) Estimated by Harlan, 2004a.
(c) See calculations in Table 1.
Source: Information provided by Harlan, 2004, except where otherwise specified.

The total number of dead and downers is 4,465,000 giving a total weight of 5,581,250,000 pounds (heads*1250 pounds/head). As shown in the above table, only 768,000 heads of deads and downers are collected by renderers leaving 3,697,000 heads, or 4,621,250,000 pounds (3,697,000 heads * 1,250 pounds/head) to be disposed off by farmers. We found no specific information on how much of the material not collected by renderers is disposed of. We expect that cattle producers dispose of deads and downers that are not picked up by renderers using any of the following legal methods:1) land burial, 2) incineration, 3) composting, and 4) landfills.

The total amount of SRM that will be totally prohibited from use in FDA's human food and cosmetics is 1,423,044,000 pounds. We are not including the amount of SRMs obtained by renderers from deads and downers since these are prohibited from use in human food and cosmetics. According to EPA report, about 50% of this material is moister and 25 % is fat and 25% is protein. Therefore, rendering of this material produces 355,761,000 pounds each of fats and proteins. These numbers will be used in the discussion of the impact of the IFR on the environment under Section B.2 of the EA.