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September 28, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852.

Re: ***Use of Materials Derived from Cattle in Human Food and Cosmetics -- Docket No. 2004N-0081.***

To Whom It May Concern:

The National Renderers Association (NRA) and the Animal Protein Producers Industry (APPI) submit the following comments on FDA's Interim Final Rule, *Use of Materials Derived from Cattle in Human Food and Cosmetics* (Docket No. 2004N-0081).

NRA is the international trade association for the industry that safely and efficiently recycles animal agriculture by-products into valuable ingredients for the livestock, pet food, chemical and consumer product industries. NRA represents its members' interests to Congress, regulatory and other government agencies, promotes greater use of rendered products, and fosters the opening and expansion of trade between North American exporters and foreign buyers.

The APPI association was established by the rendering industry in 1980 to address biosecurity issues. APPI also developed a voluntary Salmonella education and monitoring program. In 2001, APPI created an industry-wide third party certification program to specifically address compliance with the FDA restricted use protein feed rule (21 CFR 589.2000).

NRA and APPI continue to support scientifically based regulations to restrict the use of certain animal products derived from cattle tissues when risks to human health exist. We

agree that regulations need to be reviewed from time-to-time if new risks are identified or new, relevant science is brought to light.

Required Testing Methods

Tallow with impurities of less than 0.15% insoluble impurities do not pose any risk of Bovine Spongiform Encephalopathy (BSE) transmission, regardless of the source of the raw material. The International Office of Epizootics (OIE) categorizes tallow with insoluble impurities of no more than 0.15% to be protein-free tallow and indicates tallow meeting this standard can be safely used, regardless of the source raw materials.

Insoluble impurities are defined as the small amount of sediment of nonglyceride content in all fats and oils, including tallow. The moisture, impurities, and unsaponifiables (MIU) are commercial trading specifications established for these impurities in fats and oils. The impurities consist principally of free fatty acids and sterol glucoides, which are colorless and heat stable but for all practical purposes inert. Phosphatides, mucilaginous material, precipitates from processing and transport equipment and fragments of the refining and bleaching processes are all inconsequential components of the impurities. Protein is a miniscule component of the impurity faction.

The rendering industry has a problem with the method for measuring the "hexane-insoluble matter" as stipulated in the IFR. The method cited from "Food Chemicals Codes," 5th Edition (2004) is not the method used by the laboratories that service the animal production, rendering, feed production, or oleochemical industries in the U.S. The laboratories used by industry are not equipped to perform the hexane-insoluble matter assay, because these labs commonly use the American Oil Chemist Society (AOCS) method Ca 3a-46.

The differences between the two methods are substantial. Costs for the hexane-insoluble matter assay range from $150 to $275, compared to $8-$10 for the AOCS procedure. In addition, the method stipulated by the FDA would be burdensome to perform. The FDA-stipulated method uses a sample size of 100gm, 1500ml of hexane per sample, and a fritted porcelain filter funnel. The AOCS method requires 2 grams of sample, 100ml of kerosene and a small amount of pet ether, and uses glass-fiber filter paper. Keeping the pores in the porcelain filter funnels from plugging and changing the filtering dynamics from sample to sample is troublesome. Commercial labs would be reluctant to use these filters as they would either have to discard and replace them at $118 each, or invest the labor to clean and verify their efficiency from sample to sample. In addition, the volume of hexane required per sample is also economically and environmentally unsound compared with the volume of solvents required by AOCS method. The solvent-related costs of the FDA stipulated method are approximately 30-times greater, considering the cost of the solvents and the cost of properly disposing of the solvent wastes.

We strongly recommend FDA approve the AOCS method for measuring insoluble impurities.

Clarification on Requirements for Tallow Derivatives

NRA and APPI also request the agency to clarify whether or not tallow derivatives must be derived from tallow that is free of SRM or from tallow containing not more than 0.15% impurities. Tallow derivatives are defined as "...any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow" while tallow is defined 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 tissues." The definition section for tallow goes on to say that "Tallow must be free of prohibited cattle risk material or must contain not more than 0.15 percent hexane-insoluble impurities ..."

In the preamble (Section M. Tallow and Tallow Derivatives), the agency states: "The TSEAC considered tallow derivatives in 1998 [Ref. 50] and determined that the rigorous conditions of manufacture are sufficient to further reduce the BSE risk in tallow derivatives. In addition, the OIE also recommends that derivatives of protein-free tallow be freely traded among countries because they pose insignificant BSE risk to animals [Ref. 48]. Because we believe tallow has negligible risk of transmitting BSE, and tallow derivatives undergo additional processing, we do not believe tallow derivatives pose a risk of transmitting the agent that causes BSE to humans." Thus, we urge FDA to clearly state in the IFR that tallow derivatives are not required to be manufactured from SRM-free or from "protein-free" tallow.

Summary

Renderers pledge to do their part in mitigating risk to humans from BSE in cattle even without any indigenous BSE cases in the U.S. We strongly recommend FDA reconsider the method approved for measuring insoluble impurities. In addition, we urge FDA to clearly state in the IFR that tallow derivatives are not required to be manufactured from SRM-free or from "protein-free" tallow.

Thank you for consideration of our views.

Sincerely,

Doug Anderson
Chairman
National Renderers Association

Max Schaefer
Chairman
Animal Protein Producers Industry