C T F A

February 3, 2004

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

Linda Katz, M.D.
Director, Office of Cosmetics and Colors HFS-100
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

E. EDWARD KAVANAUGH
PRESIDENT

RE: January 26, 2004 Department of Health and Human Services press release "Expanded Mad Cow' Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission"

Dear Dr. Katz:

The Cosmetic, Toiletry, and Fragrance Association, CTFA[1], is pleased to provide the following comments regarding the above referenced press release, and the anticipated interim final rule to be published affecting the formulation of cosmetics and the use of bovine derived cosmetic ingredients. Such ingredients may include those that are directly identified as having a bovine source, such as Tallow, and those whose source is not directly specified, which might come from either animal (bovine or other) or vegetable sources, such as Magnesium Stearate.

The news release states that one interim final rule will ban the following material from cosmetics:

- Any material from "downer" cattle. ("Downer" cattle are animals that cannot walk.)
- Any material from "dead" cattle. ("Dead" cattle are cattle that die on the farm (i.e. before reaching the slaughter plant);
- Specified Risk Materials (SRMs) that are known to harbor the highest concentrations of the infectious agent for BSE, such as the brain, skull, eyes, and spinal cord of cattle 30 months or older, and a portion of the small intestine and tonsils from all cattle, regardless of their age or health; and

[1] CTFA is the national trade association representing the personal care products industry. Founded over 100 years ago in 1894, CTFA has an active membership of approximately 300 companies that manufacture or distribute the vast majority of the finished personal care products marketed in the United States. These products include over-the-counter drugs such as anti-dandruff shampoos, antiperspirants, astringents, sunscreens, antimicrobial soaps, anti-caries toothpastes and oral care products that may be subject to the compendial requirements of this chapter. CTFA's membership also includes over 277 associate member companies that supply materials and services to manufacturers and distributors. These include companies that provide raw ingredients, as well as suppliers of materials used in the packaging and delivery of personal care products to consumers. These proposed requirements are of vital importance to our industry because they have an impact on the formulation and testing of personal care products that are also OTC drugs.

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- The product known as mechanically separated beef, a product which may contain SRMs. Meat obtained by Advanced Meat Recovery (an automated system for cutting meat from bones), may be used since USDA regulations do not allow the presence of SRMs in this product.

The news release also states that the interim final rule will take effect immediately upon publication. It is not possible to identify all of the ingredients potentially affected by the anticipated interim final rule, but it is expected to be a significant number of the most commonly used ingredients, particularly those of fatty acid, fatty alcohol, and fatty ester complexes, as well as Tallow itself.

Our members, both those producing and marketing cosmetic finished products and those providing ingredients that are produced from bovine source material, are dependent on the beef industry for source material, which is a byproduct of that industry. Hence, CTFA believes it is important for FDA to consider the availability of that source material when developing the interim final rule.

Tallow is a byproduct of the meat industry, dependent primarily in the U.S. on the demand for beef (for both internal consumption and export). About 70% of the source material for tallow in the U.S. comes from 4-5 large meat-packing companies.

An individual cow will produce about 80-85 lbs of edible/technical tallow (without fallen stock or SRMs), and 90-100 lbs of inedible tallow. As the cow is slaughtered, the fat and other material that will be used to produce inedible Tallow and other byproducts are removed from the carcass first. This material now includes the specific risk materials. The carcass is then butchered for human food, and the meat fat is removed to make edible Tallow.

In general terms, the slaughter of cows for human food resulted in about 1.6 billion pounds of edible tallow last year, and about 2 billion pounds of inedible, "bleachable fancy tallow" from the meat packing companies. Other renderers, who acquire source material from many sources (including material from the meat packing companies not used to make edible or bleachable fancy tallow) produced about 4.5 billion pounds of inedible tallow, mainly classified as "choice white grease (2.5 billion pounds)," or "yellow grease (2 billion pounds)." A general breakdown of the market use for Tallow includes:

- Edible/Technical Tallow
  - 30% baking/frying (food use)
  - 30% export
  - 15% pet food
  - 10% fatty acids/chemical derivatives
  - 5% soap
  - 10% other

- Inedible Tallow (BPT, CWG, YG grades)
  - 30-45% animal feed

- 13% pet food
- 15-30% export
- 17% fatty acids/chemical derivatives
- 10% soap

Although these values are not exact, they can be used in a general way to test certain assumptions. For example, is there enough Tallow available to provide cosmetic ingredients that would comply with the anticipated interim final rule? Only the edible Tallow would meet the limitations set out in the news release.

Taking only soap as an example, last year there was about 80 million pounds of Tallow used in soap that would meet the requirements set out in the news release (edible Tallow). At the same time, there was about 650 million pounds of Tallow used to make soap that would not meet those requirements (produced from inedible Tallow). In order to meet this increased demand for raw material, about 43% of the edible Tallow being used for other purposes would have to have been diverted to soap production.

Looking at the second major use of Tallow for our industry, the fatty acid and chemical derivative manufacture, we see a similar situation. Only 160 million pounds of edible Tallow went into the production of fatty acids and chemical derivatives last year, while 1.1 billion pounds of inedible Tallow was used for the same purpose. CTFA has contacted some of the major suppliers of these types of products for our industry, and has found that they were not using edible Tallow as a starting material. Hence, we can assume that a significant portion of the current edible Tallow would also have to be diverted to that purpose if we are to maintain the current production of cosmetic products in the U.S

And, to make matters worse, the meat packing industry is expecting a 5% decrease in beef demand this year, and that decrease could be even larger if the export concerns are not settled very soon. This will result in a concomitant decrease in the material available to make Tallow and Tallow derivatives.

CTFA understands the Food and Drug Administration's desire to have consistent regulations on the BSE topic, particularly to ensure consistency with the safeguards of the food supply of the U.S. Department of Agriculture. CTFA also commends the FDA for acknowledging the current safety of cosmetics, and for assuring the public that there is no concern for a BSE risk from these products (quoting from the New York Times, January 29, 2004, "Dr. Murray M. Lumpkin, the F.D.A.'s principal associate commissioner, said most additives in everyday products carried little risk. 'You don't want to give people an idea that cosmetics are something you have to worry about,' Dr. Lumpkin said. 'They're not.'"). However, we are concerned that the anticipated interim final rule may not have considered the realities of supply for the cosmetic ingredients.

In order to comply with the expected interim final rule, there will have to be major changes in the slaughtering and rendering industry. The primary change will have to be in the handling of SRMs at the slaughter house, and the segregation and disposal of these materials in a manner that ensures they cannot enter the Tallow stream used to make cosmetics and cosmetic products.

This will require changes in procedures and practices, materials handling and distribution of raw materials that are not currently in place. When similar changes were made in the industry in Europe, the transition took three years.

In order to ensure that there will not be unreasonable dislocation in the marketplace, CTFA requests that the FDA consider a transition period for implementation of the interim final rule that will allow sufficient time for changes in the slaughtering and SRM disposal processes, and time for the required material to fill the channels of distribution for the production of the fatty acid and Tallow derivatives market. Such a transition should be developed after consultation with the Tallow producers, derivative manufacturers, and cosmetic industry. CTFA is ready to assist in this effort to ensure that the application of the final rule can be affected in the shortest possible time.

Please call me if you have any questions.

Best regards,

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