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Committee on Sanitary and Phytosanitary Measures

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EC DIRECTIVE ON THE MARKETING OF COSMETIC PRODUCTS

Submission by the United States for the Meeting of 1-2 July 1997

Introduction

1. In January 1997, the European Community published Commission Directive 97/1/EC, which prohibits the marketing of cosmetic products containing bovine, ovine, and caprine tissues and fluids from the brain, spinal cord, eyes, or ingredients derived therefrom. This Directive goes into effect on 1 July 1997.

2. The basis given for this Directive is to ensure the health and safety of consumers against the possible risk of bovine spongiform encephalopathy (BSE) or variant Creutzfeldt-Jakob Disease (CJD). As of 18 June 1997, the EC Directorate General XXIV (Consumer Affairs and Relations) has informed us that this directive applies to tallow and its derivatives, many of which are exported from the United States to the Community for manufacturers of soap and other cosmetics.

3. This legislation would essentially stop all US exports of tallow and tallow derivatives because the risk materials referenced in the directive - brain, spinal cord, and eyes - are not excluded from the raw materials from which tallow is made. It would also impact US exports of finished cosmetics and soaps made from US tallow, and could also impact trade to third countries which import tallow for manufacture of cosmetics intended for final export to the European Community.

4. BSE is not known to occur in the United States. The United States has had and continues to maintain an aggressive and active surveillance programme for BSE. The United States raised its concerns about the EC Directive in a meeting with the European Community in Brussels in February 1997. This meeting was also attended by representatives from Canada, Australia, and New Zealand, who had similar concerns.

5. The European Community notified this Directive to the WTO in March. The United States submitted comments through normal procedures. The Commission has received comments on this issue from the United States, Australia, New Zealand, and its own cosmetic and rendering industries.

6. The European Community itself is reviewing whether to exempt tallow from the Directive. We understand that the EC scientific Committee on Cosmetics will meet on 24 and 25 June to examine whether tallow could be considered safe under certain rendering processes. If the Scientific Committee recommends exempting tallow from the Directive, there will not be sufficient time for the European Community to amend the Directive prior to the 1 July implementation date. In anticipation of this outcome, it is understood that the European Community may be developing strategies to expedite the amendment of the Directive. To prevent unnecessary disruptions in trade in tallow products, the United States encourages temporary flexibility in the implementation of this Directive and, in the long term, a permanent exemption for these products.

Available Scientific Evidence / Relevant International Standards

7. The United States questions the scientific basis of this Directive. Studies performed on BSE have shown that tallow does not contain any detectable level of infectivity (refer to Veterinary Record 137:605; 1995; Taylor, Woodgate, and Atkinson).

8. The Office international des épizooties (OIE) Zoosanitary Code Chapter on BSE recognizes the fact that tallow does not present a risk of transmission. Specifically, Chapter 3.2.13, Article 3.2.13.2 states the following: "Veterinary Administrations can authorize without restriction the import or transit through their territory, directly or indirectly, of milk, milk products, tallow, hides and skins originating from healthy animals from countries where BSE has been reported". By the inclusion of tallow in this statement, the OIE recognizes that there is no evidence that tallow presents a risk of transmission of BSE. In addition to the relevant OIE guidelines, the World Health Organization has also concluded that tallow is safe.

9. Another important factor to consider is the manufacturing process to which this tallow is subjected. The cosmetics and soap industries use processing procedures and temperatures which are generally far above all known transmissible spongiform encephalopathy (TSE) inactivation requirements. For example, the first step in the production process of fatty acids is the hydrolysis of tallow to produce a crude fatty acid and dilute crude glycerine. The hydrolysis requires temperatures of about 250ºC, with 40 bars of pressure for over 2 hours. This step alone is well above any published parameters for TSE inactivation, and these compounds may then be subjected to further treatment in the manufacturing process. Products which have gone through these rigorous procedures may generally be assumed to be safe in reference to TSE transmission, especially if one assumes that tallow is safe even before the manufacturing process begins.

10. The EC Directive also appears to be inconsistent with other Community legislation. Specifically, it seems to conflict with Commission Decision 94/382/EEC and the subsequent Commission Decision 96/449/EEC. These decisions laid down the requirements for processing animal waste with a view to the inactivation of spongiform encephalopathy agents. Decision 96/449/EEC requires that mammalian waste be treated within specific parameters, but it exempts certain products which supposedly do not present a risk of TSE transmission from these requirements--these products had also been exempt from Decision 94/382/EEC. Rendered fats are one such product which have been exempt. This legislation, which is based on the assumption that rendered fats do not present a risk of BSE transmission, appears to be contradictory to Directive 97/1/EC, which assumes that rendered fats do present a risk.

11. The EC Directive also is inconsistent with other EC legislation which allows the import of lard and rendered fats, such as tallow, for human consumption. Currently, there are no restrictions related to BSE on such products imported into the Community. However, Directive 97/1/EC proposes to limit these products for use in cosmetics, whose use would provide indirect exposure, if any, to such agents.

12. Directive 97/1/EC also does not allow for recognition of differences in animal disease status. These differences are the first step in assessing the risk of transmission of such agents. If the risk agent, such as BSE, is not present in the country of origin of the product, (i.e., the United States) then the product can be assumed to be safe.

13. BSE is not known to occur in the United States. The United States has had and continues to maintain an aggressive and active surveillance programme for BSE. There are more than 250 federal and state regulatory veterinarians specially trained to diagnose foreign animal diseases, including BSE. There are several agencies involved in the surveillance programme, including the Food Safety and Inspection Service (FSIS) and the Centers for Disease Control (CDC), and the Animal and Plant Health

Inspection Service (APHIS), which leads this interagency effort. The surveillance samples include field cases of cattle exhibiting signs of neurological disease, cattle condemned at slaughter for neurological reasons, rabies-negative cattle submitted to public health laboratories, neurological cases submitted to veterinary diagnostic laboratories and teaching hospitals, and random sampling of cattle which are non-ambulatory at slaughter. As of March 1997, a total of at least 5,544 brains had been examined for BSE or another form of a transmissible spongiform encephalopathy in cattle. No evidence of either condition has been found. This surveillance programme meets and exceeds the standards recently adopted by the OIE (Chapter 3.2.1.3.1). With the possible exception of the United Kingdom, we believe that most EC member States do not have active surveillance programmes which meet OIE standards.

Conclusion

14. The EC Cosmetics Directive fails to account for scientific evidence regarding animal disease status in the United States and the risk of BSE transmission in tallow. Furthermore, the measure is not based on relevant OIE standards, particularly OIE guidelines related to BSE. In the absence of using a relevant OIE standard, the European Community has not provided the scientific risk assessment which would support this difference.

15. As a result, the Cosmetics Directive, in its current form, raises a number of concerns with respect to WTO requirements, including those set out in the SPS Agreement. Anticipating that the EC Scientific Committee on Cosmetology will take into account the available scientific evidence and make appropriate recommendations for revising the Directive to allow for trade in tallow and tallow products, we encourage the Commission to ensure that its implementation of the Directive does not unnecessarily disrupt trade in these products.