WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures

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NEW EUROPEAN UNION RULES ON "SPECIFIED RISK MATERIALS" IN PRODUCTS OF ANIMAL ORIGIN

Submission by the United States at the Meeting of 15-16 October 1997

Introduction

1. On 30 July 1997, the European Commission adopted Commission Decision 97/534/EC, governing the "Prohibition of the Use of Material Presenting Risks as Regards Transmissible Spongiform Encephalopathies (TSEs)." This measure was notified on 19 September 1997, more than six weeks after its adoption (G/SPS/N/EEC/49). The deadline for comments on this notification is 2 November 1997. The Decision is scheduled to be implemented on 1 January 1998.

2. The Decision does not take into account the disease status of different regions. It requires the removal of "specified risk materials" from materials derived from all bovine, ovine, and caprine animal populations, even those in which TSEs have not been identified following rigorous testing and surveillance procedures recommended by the Office international des épizooties (OIE).

3. As a result, regardless of the safety of the source material, the Decision appears to require the removal from the market of all existing supplies, from all sources, of a very broad range of products, including cosmetics, food, feed, and medical (pharmaceutical, biological, and device) products. In adopting this measure, the Commission disregarded the advice of its Scientific Committee on Cosmetology and apparently failed to obtain the advice of its Pharmaceutical Committee.

4. US public health agencies are concerned that the measure would, either directly or indirectly, cause international shortages of needed medical products, which could adversely impact the health of consumers. In addition, implementation of this Decision would have a major restrictive impact on WTO members' trade, including US exports of tallow, tallow derivatives, gelatin, pharmaceuticals and many food products.

Scientific and Procedural Considerations

5. The United States shares the European Communities' desire to control Bovine Spongiform Encephalopathy (BSE) and supports efforts to develop appropriate science-based measures to protect the public against the associated risks. In order to avoid unnecessary adverse effects on public health and trade, however, those measures must be carefully designed to address the sources of risk, while not disrupting the availability of safe products. This Decision does not meet those criteria.

6. The United States agrees with the EC Pharmaceutical Committee's 17 September 1997 recommendation that the Decision not be implemented "in such a way that it raises equal or larger

public health concerns in the short or medium term such as would be caused by failures of supply or confidence in pharmaceuticals". Unfortunately, although the Decision affects a wide range of pharmaceutical and medical products, it appears that this Committee was not consulted prior to the adoption of this measure.

7. One of the first steps in efficiently addressing a risk is to identify its source. If BSE is not present in the animal populations from which the source materials of consumable products are derived, then those products can be considered to be safe.

8. Since 1990, the United States has maintained an aggressive surveillance program for BSE. As of 30 June 1997, more than 6,000 brains had been examined for BSE and any other form of a transmissible spongiform encephalopathy in cattle. The surveillance samples focused on 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. No evidence of BSE has been found in these samplings from the highest risk populations, either through histological examination or immunohistochemistry.

9. Taking into consideration the size of the herd, the US surveillance program far exceeds the guidelines recently adopted by the OIE (Chapter 3.2.13.1). The United States, therefore, meets the OIE recommendation for determining a region to be free of BSE. Where such programs are not in place, the United States agrees that the removal of "specified risk materials" is appropriate. This is particularly the case when, unlike in the United States, relatively limited sampling and testing procedures have revealed positive cases of BSE.

10. Despite these differences in disease status, Decision 97/534/EC imposes identical restrictions on products sourced from the United States, where BSE has not been identified, and those sourced from regions in which BSE is present. As a result, the measure is unnecessarily restrictive, with potentially serious adverse consequences for public health and international trade.

11. Other aspects of the decision appear to lack a sound scientific basis. On 24 June 1997, the European Commission's Scientific Committee on Cosmetology advised the Commission that tallow derivatives obtained from specified processes are safe for use in cosmetics. This finding was consistent with independent scientific studies performed on BSE, which have suggested that tallow does not contain detectable levels of infectivity.[1] On 8 September 1997, the European Commission's Scientific Steering Committee adopted an opinion which appears to confirm the Committee on Cosmetology's findings with respect to tallow derivatives.

12. These conclusions are also reflected in decisions taken by the Office international des épizooties (OIE) in May 1997, which state that: "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". If these products are safe when sourced from regions in which BSE has been reported, they will certainly be safe when sourced from regions where BSE is not known to occur.

13. The Decision appears to be inconsistent with other Community legislation. Specifically, it seems to conflict with Commission Decision 94/382/EC and the subsequent Commission Decision 96/449/EC. These decisions laid down the requirements for processing animal waste with a view to the inactivation of spongiform encephalopathy agents. Decision 96/449/EC requires that mammalian

[1]See, for example, Veterinary Record 137:605; 1995; Taylor, Woodgate and Atkinson.

waste be treated within specific parameters, but it exempts certain products (such as tallow) which supposedly do not present a risk of TSE transmission from these requirements; these products had also been exempt from Decision 94/382/EC. The new EU Decision 97/534 contradicts these previous Decisions (96/449 and 94/382), which are based on the assumption that tallow does not present a risk of BSE transmission.

14. Noting that Decision 97/534/EC fails to take any of the above scientific evidence into account, the Commission's Pharmaceutical Committee has stated:

> "The Committee regrets that the decision did not take account of scientific opinions in regard to tallow and tallow derivatives, whereby established manufacturing processes have been demonstrated not to present a real hazard."

15. The United States shares this concern, and urges the Commission to review and modify the Decision to ensure that it is based on the best available scientific advice and does not have an unnecessary detrimental impact on public health or international trade.

Notification Procedures

16. Annex B of the SPS Agreement provides, inter alia, that notifications "… shall take place at an early stage, when amendments can still be introduced and comments taken into account" and that members "shall … allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account". While the Commission's adoption of Decision 97/534/EC on 30 July does not appear to have been consistent with this requirement, the United States welcomes the subsequent notification and request for comments. The United States has communicated its concerns with this measure to the Commission in writing. In addition, US public health and trade officials have requested the opportunity to discuss the specific requirements in more detail. We hope that the Commission will remain open to full discussion of all the relevant issues and that the results of those discussions will be taken into account prior to the implementation of this Decision.

Conclusion

17. Commission Decision 97/534/EC fails to account for regional differences in animal disease status and other available scientific information and advice relating to the control of BSE and TSEs in products of animal origin. As a result, the Decision raises a number of concerns with respect to WTO requirements, including those set out in the SPS Agreement. The United States appreciates the notification of this measure, and looks forward to continuing discussions with the Commission on how to ensure that consumers are protected against risks associated with TSEs, without unnecessary negative consequences for other aspects of public health or unnecessary restrictions on international trade.