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04-021ANPR
04-021ANPR-17
Daniel R. Dwyer

August 12, 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA Docket No. 2004N–0257

Regulatory Analysis and Development, PPD
U.S. Department of Agriculture
Animal and Plant Health Inspection Service,
Station 3C71
4700 River Road, Unit 118
Riverdale, MD 20737–1238

Re: APHIS Docket No. 04–047–1

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW, Room 102 Cotton Annex
Washington, DC 20250

Re: FSIS Docket No. 04–021ANPR

Federal Measures To Mitigate BSE Risks: Considerations for Further Action: Advance Notice of Proposed Rulemaking (69 Fed. Reg. 42288; July 14, 2004)

Comments of the Gelatin Manufacturers of Europe

To Whom It May Concern:

The Gelatin Manufacturers of Europe (GME) is a trade association representing the nine largest European gelatin manufacturers. GME hereby submits the following comments in response to the above-referenced Advance Notice of Proposed Rulemaking:

1. In response to various questions by the agencies on what scientific standards to use in evaluating BSE issues, we recommend that, because OIE standards are globally accepted and the US is a member of the OIE, the US government should rely primarily on OIE standards rather than developing new standards of its own.

Importantly, reliance on OIE standards will foster global harmonization of standards, which will benefit US consumers who receive cattle products from sources worldwide. We note particularly that the OIE recommends standard processing conditions for gelatin produced from bovine bones originating from BSE countries.

2. The following comments respond to FSIS questions 34-36:

34. Should FSIS provide an exemption for "BSE free" countries or countries with some other low-risk BSE designation?

Response: FSIS should exempt BSE-free or low-risk countries from its requirements regarding prohibited materials (which prohibit SRMs and non-ambulatory disabled cattle for use in human food). Based on currently available scientific information, prohibited materials from BSE-free or low-risk countries present a significantly lower BSE risk – a risk that may be essentially zero – as compared to such materials from countries where BSE is present at significant levels. Therefore, in order to ensure that foreign sanitary measures are equivalent to those in the US, it is necessary to consider the level of BSE risk presented by a foreign country. Cattle materials from lower risk countries – even when they contain prohibited materials – may present a sufficiently low BSE risk that the importation of such materials would be considered equivalent to the sanitary measures in place in the US. This is consistent with OIE standards which do not provide a list of SRMs for BSE free or provisionally BSE free countries.

FDA's Interim Final Rule on the use of materials derived from cattle in human food and cosmetics is based on FSIS' Interim Final Rule in that it applies to all countries equally, irrespective of their BSE risk status. The implementation of FDA's Interim Final Rule has immediately prohibited the importation of gelatin manufactured with bovine bones produced after July 14, 2004 from BSE free countries (Argentina, Brazil, Australia, New Zealand, and others). The implementation of FSIS' Interim Final Rule has done the same with respect to the raw materials themselves. However these raw materials can be considered among the safest in the world according to OIE standards. These BSE free and low-risk countries should be exempt from both FDA's and FSIS' Interim Final Rules, consistent with OIE standards. (We will be providing a comment to this effect in response to FDA's Interim Final Rule.)

Note that this would be also consistent with European practice: EU Regulation No. 999/2001 as amended by No. 1139/2003 excludes GBR I countries (Geographical BSE Risk 1: the presence of one or more cattle clinically or pre-

clinically infected with the BSE agent is highly unlikely) from the requirement to remove SRM.

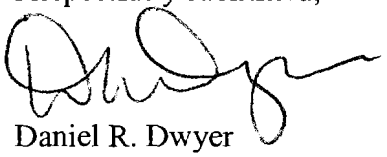
35. If FSIS were to exempt "BSE free" countries from the provisions of the SRM rule, what standards should the Agency apply to determine a country's BSE status?

Response: FSIS should apply OIE standards. Just as FDA and USDA have harmonized their approach to regulation of prohibited cattle materials in the US food supply, harmonized standards must be used worldwide to ensure consistent safety of products traded globally. In particular, the USDA should complete its rulemaking process that would permit importation of ruminant and ruminant products from BSE "minimal risk" regions, taking care to ensure that the definition of "minimal risk" is consistent with that of the OIE. 68 Fed. Reg. 62386 (Nov. 4, 2003). Note that there is precedent for the use of OIE standards in the US; for example, the FDA's earlier Guidance to Industry on gelatin referred to OIE standards. In addition, we understand that the European Commission is currently considering the replacement of its GBR classification by the OIE classification.

36. How would FSIS determine that a country meets such standards? For example, should it rely on third party evaluations, such as the OIE, or conduct its own evaluation?

Response: As discussed above, FSIS should rely primarily on OIE evaluations, though it may also evaluate countries on its own as a means of ensuring that it consistently implements OIE standards.

Respectfully submitted,



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