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EMBASSY OF AUSTRALIA
WASHINGTON DC

3 May, 2004

03-038IF
03-038IF-21
Andrew Cupit

FSIS Docket Clerk
Docket # 03-025IF, 03-038IF, and 01-033IF
Room 102
Cotton Annex
300 12th and C Street, SW
Washington DC 20250 – 3700

Dear Sir or Madam

AUSTRALIAN GOVERNMENT SUBMISSION ON DOCKET NUMBERS 03-025IF, 03-038IF, AND 01-033IF, AND REQUEST FOR AMENDMENT TO INTERIM FINAL RULES

PROHIBITION OF THE USE OF SPECIFIED RISK MATERIALS FOR HUMAN FOOD AND REQUIREMENTS FOR THE DISPOSITION OF NON-AMBULATORY DISABLED CATTLE

MEAT PRODUCED BY ADVANCED MEAT/BONE SEPARATION MACHINERY AND MEAT RECOVERY (AMR) SYSTEMS

PROHIBITION OF THE USE OF CERTAIN STUNNING DEVICES USED TO IMMOBILIZE CATTLE DURING SLAUGHTER

This submission is a follow-up to recent meetings and correspondence between the Australian Government and the U.S. Department of Agriculture ("USDA") regarding the Interim Final Rules published in the *Federal Register* of January 12, 2004 by USDA's Food Safety and

Inspection Service ("FSIS"). In Particular, we are responding to the interim final rule relating to the *Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle.*[1] ("the Rule"), and also to the letter from Ms. Karen Stuck of FSIS to Dr. Ann McDonald of the Australian Quarantine and Inspection Service ("AQIS") of March 26, 2004. In that letter, Ms. Stuck advises AQIS that under the Rule, "an FSIS equivalent determination of Australia's BSE surveillance is not applicable at this time."

Australia is a region free of BSE as defined under current US regulation 9 C.F.R. § 94.18. However, FSIS has indicated its view that, in spite of Australia's BSE freedom, the Rule as presently drafted does not allow for a derogation or exemption for products from Australia because the definition of "specified risk materials" ("SRMs") in new part 310.22 of the FSIS regulations includes material from *all* cattle 30 months of age and older, and part 309.2 pertains to *all* non-ambulatory disabled livestock. Neither part of the Rule makes an exception for enumerated materials when they come from cattle in BSE-free countries, or for livestock from BSE-affected countries. By placing all SRMs and meat from non-ambulatory disabled cattle into the category of "adulterated food," the importation of which is expressly prohibited under 9 C.F.R. § 327.3, the Rule does not allow for the flexibility that exists in the comparable food-safety regimes of Canada or the European Union ("EU").

We believe it is possible for FSIS to amend the Rule and we hereby respectfully request that FSIS do so as soon as possible in a way that would allow the importation of meat products from Australia that may include SRMs. In view of Australia's recognized status as a BSE-free country, the materials enumerated in the Rule, when derived from Australian cattle, pose no risk to public health in the United States, and their importation should not be prohibited. Such a position would be consistent with positions already adopted with respect to Australia by Canada and the EU. Our request that the Rule be amended as soon as possible is based on current and future economic harm resulting from the burdens and restrictions imposed by the Rule and a concern that Australia and other BSE-free countries should not have to remain in a position of uncertainty until a final rule is issued at an indeterminate time in the future. Australia is not aware that these adverse effects are supported by any scientific or risk-based justification.

There are, however, several important justifications that support amending the Rule in the immediate future to alter the definitions of SRMs and non-ambulatory disabled cattle so that Australian beef would not be subject to the Rule. First, we note that the scope of the materials included in the definition of SRMs in the Rule already contains at least one exemption. According to the preamble to the Rule, FSIS does not define SRMs to include certain hand-deboned meat, although FSIS acknowledges that the BSE risks of such meat are unknown.

In addition, there appears to be no legal obstacle under the U.S. Administrative Procedure Act ("APA") to the issuance by FSIS of an "Amended Interim Rule." Amending the Rule by redrafting the definition to exclude specified materials from BSE-free countries would also render the Rule more thoroughly consistent with the Canadian regime to which FSIS has explicitly indicated it wishes the U.S. Rule to be analogous. Moreover, amending the Rule would be consistent with U.S. efforts to achieve uniformity and consistency in international

[1] 69 *Fed. Reg.* 1862 (Jan. 12, 2004).

standards. We believe it is important to assure such consistency sooner, rather than later, to avoid additional adverse effects, uncertainty, and disruption to world beef markets. We discuss each of these justifications in this letter.

1. FSIS's interpretation of the Rule shows that the Rule is not unconditional because it exempts hand-deboned meat from the SRM ban.

In its preamble to the Rule, FSIS indicates that, while some hand-deboned meat may contain dorsal root ganglia ("DRG"), one of the SRMs otherwise banned by the Rule, "FSIS is not, at this time, prohibiting hand-deboned meat [from certain cattle] for use as human food."[2] As the reason for this exemption, FSIS states, "FSIS is not aware of any data on the extent to which DRG are found in hand-deboned meat." However, there is no language to effect such an exemption anywhere in the Rule. Therefore, it seems that FSIS has already taken the position that an exemption from the definition of SRMs in the new Rule is possible -- in this case, for hand-deboned meat -- and can be accomplished as simply as making an interpretative statement in the preamble.

If such an exemption can be made without recourse to explicit language in the new Rule for an SRM the capacity of which to transmit BSE is unknown, then there is a compelling argument in favor of a similar interpretative statement for products from Australia and other BSE-free countries the capacity of which to transmit BSE is both known, and *known to be zero*. Therefore, we suggest that a similar interpretative statement should be made in the *Federal Register* to exempt products from Australia and other BSE-free countries.

Alternatively, if inserting an exemption for Australian product into the explicit language of the Rule would result in a stronger legal position under U.S. law for such an exemption, then we urge FSIS to issue an Amended Interim Final Rule that defines such key terms as SRMs and non-ambulatory disabled cattle to exclude product originating in BSE-free countries, as discussed below.

2. There appears to be no legal obstacle to prohibit FSIS from issuing an "Amended Interim Rule" that would exclude from the definition in the Rule SRMs that come from cattle in BSE-free countries.

The APA[3] provides several exceptions to the statutory norm of advanced notice-and-comment rulemaking. FSIS invoked one such exception when it issued the Rule, determining that "prior notice and opportunity for public comment are contrary to the public interest" because "immediate action" was necessary to "ensure that materials that could present a significant risk to human health are excluded from the food supply" and that there was "good cause . . . for making this rule effective less than 30 days after publication in the Federal Register."[4] We understand that the Rule has the status of an "interim final rule" because, although the regulation took immediate effect, FSIS issued with it an accompanying request for public comment and in

[2] *Id.* at 1868.

[3] 5 U.S.C. § 551 *et seq.*

[4] 69 *Fed. Reg.* 1871.

anticipation of the agency's ultimately publishing a final rule after review of the public comments received.

U.S. federal departments and agencies have authority to amend an Interim Final Rule and USDA itself has exercised such authority in the past.[5] In addition, other U.S. departments and agencies have also issued Amendments to Interim Final Rules.[6] Our understanding from recent meetings is that FSIS staff have been sympathetic to Australia's position. Therefore, if there is no legal impediment to amending the Rule, we urge FSIS to proceed with amending this Rule to redefine SRMs so that the definition excludes materials from BSE-free countries.

To accomplish this, we suggest that the following new language be added to 9 C.F.R. § 310.22(a), as published in the January 12, 2004 *Federal Register*:

> (4) However, specified risk materials shall not include the materials in paragraphs (1) through (3) when such materials are derived from cattle raised in countries designated by the Secretary as free from BSE.

In addition, we suggest that new part 310.22(b) be amended to read as follows:

> (b) ***Except as provided in paragraph (a)(4) of this*** section, specified risk materials are inedible and shall not be used for human food [emphasis added].

We similarly suggest that the first sentence of amended part 309.2(b), as published on January 12, 2004, be amended to read:

> (b) All seriously crippled animals and non-ambulatory disabled livestock, ***except those raised in countries designated by the Secretary as BSE-free,*** shall be identified . . . . [emphasis added].

FSIS may also wish to consider amending the Rule to incorporate language similar to that contained in the comparable Canadian regulation, which sets forth criteria for BSE-free status.

3. Amending the Rule by redrafting the definition to exclude specified materials from BSE-free countries would render the Rule more thoroughly consistent with the Canadian regime to which FSIS has explicitly indicated it wishes the U.S. Rule to be analogous.

In its preamble to the Rule, FSIS states that the "SRMs prohibited for human food in this interim final rule are the same materials prohibited for use as human food by Canada, thus establishing a

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[5] *See*, for example, Amended Interim Final Rules issued by the Agricultural Marketing Service: 62 Fed. Reg. 58,633 (Oct. 30, 1997) (regarding certain Florida citrus); 61 Fed. Reg. 248 (Jan. 4, 1996) (regarding certain Texas melons); and others.

[6] *See*, for example, Department of the Treasury, Anti-Money Laundering Programs for Financial Institutions, 67 *Fed. Reg.* 67,547 (Nov. 6, 2002).

consistent standard in both countries."[7] Although some aspects of the Rule are similar to the Canadian regulations, in other respects the Rule is a significant departure from the Canadian approach and should be amended to be more consistent with Canada's policy.

The Canadian Food and Drug regulations that entered into force in 2003 define SRMs similarly to the FSIS Rule and prohibit the sale or importation of food that contains SRMs.[8] However, the Canadian regulation also states that the prohibition "does not apply in respect of food that originates from a country that is designated as being free from BSE . . . ."[9] Under a related provision in Canada's Health of Animals regulations, the government may utilize various criteria to designate countries which the government considers to be free from the diseases that pose certain risks.[10] Pursuant to its regulatory authority, the Canadian government issued an announcement in 2003 regarding its revised BSE import policies that sets forth the criteria by which Canada determines whether a country is BSE-free.[11] Should FSIS decide to incorporate the Canadian criteria into its Rule, these criteria could provide an exemption to both the SRM and disabled livestock parts of the Rule. As stated verbatim in the announcement, these criteria include:

> Either
>
> a. For the preceding seven (7) years, the country of origin must have reported no cases of BSE in indigenous bovines, AND
>
> b. no cases of BSE have been attributed to the country of origin from another country through epidemiological investigation, OR
>
> c all cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle from a BSE affected country and no cases of BSE have been attributed to the country of origin from another country through epidemiological investigation.
>
> AND (all of the following)
>
> d. The country of origin must have the animal health legislative authority to regulate BSE and the zoosanitary infrastructure to enforce surveillance, monitoring, eradication and import controls for BSE.
>
> e. BSE must have been made a nationally notifiable disease in the country of origin for the preceding seven (7) years.

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[7] 69 *Fed. Reg.* 1868.

[8] C.R.C., C. 870, s. B.01.047.1.

[9] *Id.*

[10] C.R.C., C. 296, s.7.

[11] Canadian Food Inspection Agency, Canadian Bovine Spongiform Encephalopathy (BSE) Import Policies (June 16, 2003), *available at* http://www.inspection.gc.ca/english/anima/heasan/policy/ie-2001-17-42.shtml (last viewed Mar. 19, 2004).

f. The country of origin must have an eradication policy for BSE that includes the investigation of suspect animals and, if confirmed positive, their slaughter and destruction and the depopulation of any bovine animal that epidemiological investigation identifies as potentially having been exposed to the disease agent or common risk factor. Animals to be disposed of must be excluded from both the human and animal food chain.

g. The country of origin must have implemented a surveillance and monitoring program for BSE in which clinically suspect cattle older than 24 months of age with clinical signs of progressive neurologic disease are subject to laboratory examination in accordance with the current diagnostic protocols recommended by the Office International des Epizooties (Manual of Standards for Diagnostic Tests and Vaccines). The BSE surveillance and monitoring system must place emphasis on risks, taking into account the guidelines in Appendix 3.8.3 of the OIE International Animal Health Code. Records of the number and results of the investigations should be maintained for at least 7 years.

h. The country of origin has performed a risk analysis of feed sources as risk factors for BSE and appropriate risk management options have been implemented and effectively enforced; eg. meat-and-bone meal feed ban, safe sourcing of raw materials and rendering specifications.

i. The country of origin has a policy that would effectively manage or prevent risks of BSE associated with the importation. This policy, at a minimum, should include but not be limited to live ruminants and other species known to be naturally affected with BSE, ruminant embryos and ova and meat and bone meal.

j. The country of origin must have on-going education programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases of neurological disease in adult cattle.[12]

Under this regulatory regime, Australia and several other countries are currently recognized by Canada as BSE-free. If FSIS were to amend the Rule to be more thoroughly consistent with the Canadian regulation, the standards for a designation of BSE-free would be incorporated into the Rule and, as a result, Australian product would not have to be subject to the Rule for as long as Australia remains BSE-free and therefore does not pose a risk to U.S. public health.

4. Amending the Rule would also be consistent with U.S. efforts to achieve uniformity and consistency in international standards.

[12] *Id.*

The EU also has a regime that, in general, requires the removal of SRMs from the food supply.[13] However, Annex V of the EC regulation effectively excludes from the definition of SRMs tissues that come from animals originating in member countries or third countries that fall within the lowest-risk range of categories of countries as prescribed by the regulation. Pursuant to this regime, Australia submitted an application for determination of its BSE status and was determined to be in "Category 1," the highest (safest) possible designation that can be made -- "highly unlikely that BSE exists in a clinical or preclinical form."[14] The detailed criteria for determination of BSE status are set forth in Annex II of the EC regulation and, for a Category 1 determination, are similar to the Canadian regulations discussed above.

We believe that the United States joins Australia in seeking consistency in international standards in these critically important areas of food safety and animal health. In view of the exemptions for BSE-free countries that have been incorporated into the Canadian and European regulations, we suggest that it makes sense for the United States to adopt similar exemptions in its response to BSE.

Although we appreciate the recommendation by FSIS that Australia submit comments on the Interim Final Rule for consideration by FSIS during its development of a Final Rule, we also understand from our discussions with FSIS that there is no definitive timetable for the publication of such Final Rule. Consistency in the international response to BSE is critically important, and should not be delayed for the up to two years that FSIS staff has indicated to us might elapse before a Final Rule is completed. While we recognize that some aspects of the Rule may require or benefit from a longer-term review, we do not believe that is the case for the amendment we are proposing. The Canadian system of exemption already in place for BSE-free countries -- part of a broader regulatory response to BSE that FSIS already regards quite favourably -- provides a ready-made model for such an amendment. For the reasons we have set forth in this letter, we most respectfully urge FSIS to issue an Amended Interim Final Rule as soon as possible.

FSIS staff have indicated that it is primarily the SRM and non-ambulatory disabled cattle issues that have preventing Australia from receiving a derogation from the new U.S. BSE measures and, accordingly, it is these issues that negotiations have focused on. However, as indicated in Australia's January submission to FSIS, we believe that Australia should be granted full derogation from all of the new U.S. BSE measures on account of the fact that Australia is a recognized BSE-free country and Australia already has measures in place that comprehensively deal with all relevant BSE concerns. Thus, for the reasons outlined above we would be grateful if, at the time FSIS considers an amendment to the Interim Final Rule to take account of the SRM and non-ambulatory disabled cattle issues, consideration could also be given to ensuring there is adequate provision to allow trading partners to be granted derogation from the other new U.S. BSE measures in appropriate instances. As indicated in our January submission, these issues would include such measures as the Advanced Meat Recovery regulations, pneumatic stunning device restrictions and the requirement for product holding pending the results of BSE testing.

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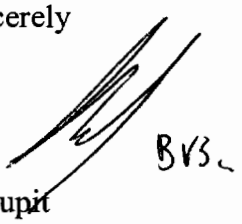
[13] EC Regulation No. 999/2001.

[14] *Id.*

As always, we would be pleased to provide any assistance necessary to FSIS in its preparation of such an amendment.

Yours sincerely



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