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TELEPHONE: (202) 797-3319
FACSIMILE: (202) 797-3037
E-MAIL: andrew.cupit@dfat.gov.au

1601 MASSACHUSETTS AVE. NW
WASHINGTON DC 20036-2273

AUSTRALIA

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WASHINGTON DC

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APHIS Docket Clerk Docket No. 04-047-1 Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.	FSIS Docket Clerk Docket No. 04-021 ANPR Room 102, Cotton Annex 300 12th Street, SW Washington DC 20250.	FDA Docket Clerk Docket No. 2004N-0264 Division of Dockets Management (HFA-305), Rm 1061, 5630 Fishers Lane, Rockville, MD 20852.

Dear Sir or Madam

AUSTRALIAN GOVERNMENT SUBMISSION ON –
Federal Measures to Mitigate BSE Risks: Consideration for Further Action
Docket No. 04-047-1 (APHIS)
Docket No. 04-021ANPR (FSIS)
Docket No. 2004N-0264 (FDA)
Docket No. 2004N-0081 (FDA)
Docket No. 2004N-0257 ((FDA)

Australia notes the recent invitation from US authorities to provide comment on a number of regulatory initiatives and proposals which, collectively, have the stated purpose of safeguarding animal and public health against the risks posed by the disease bovine spongiform encephalopathy (BSE). The specific regulatory initiatives and proposals are:

a. FSIS Interim Final Rules, P*rohibition of the use of specified risk materials for human food and requirements for the disposition of non-ambulatory disabled cattle*; M*eat 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*
b. FDA Interim Final Rule, U*se of materials derived from cattle in human food and cosmetics*
c. FDA Proposed Rule, *Recordkeeping requirements for human food and cosmetics manufactured from, processed with, or otherwise containing, material from cattle*
d. USDA and FDA Advanced Notice of Proposed Rule Making, *Federal Measures to Mitigate BSE Risks: Consideration for Further Action* (herein after called the ANPRM).

It is further noted that the earlier APHIS Proposed Rule, *BSE Minimal Risk Regions and Importation of Commodities* released in 2003, remains to be finalised and is a closely related and relevant development.

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Australia recognises the right of US authorities, and those of any other World Trade Organisation (WTO) Member Economy, to determine their own Appropriate Level of Protection (ALOP) for BSE risk. Important principles of the WTO's Sanitary Phyto-Sanitary (SPS) Agreement include that sanitary measures are not more trade restrictive than required to achieve a Member's ALOP, and that Members accept the measures of other Members as equivalent, if the exporting Member objectively demonstrates that its measures achieve the importing Member's ALOP.

These comments are therefore primarily directed at matters relating to the application of the principle of equivalence under these BSE regulatory initiatives and proposals. Additionally, an opportunity is taken to comment on matters relating to the auditing of record keeping requirements of the type currently proposed by FDA, by exporting country competent authorities.

EQUIVALENCE

Introduction

Australia has a strong interest in the matter of equivalence - section VI D, questions 34, 35 and 36 of the ANPRM. Australia would argue that it has in place a comprehensive range of control measures to prevent the entry and/or amplification of the BSE agent. These measures protect and maintain Australia's BSE-free status. It is Australia's view that these measures, in combination with our recognised BSE-free status, should constitute equivalent sanitary measures that provide the same level of protection as that achieved domestically in the US by the new BSE Rules. In January 2004, Australia provided a technical submission to FSIS detailing its range of BSE control measures for the purpose of equivalence assessment. In addition, we have provided detailed comments on equivalence in regard to the FSIS Interim Final Rule on BSE Measures (69 Fed Reg 1862, 12 January 2004). These comments were provided in April 2004 through the Federal Register comment process, and were also attached to a letter to Secretary Veneman from Australia's Ambassador to the US, Michael Thawley.

The comments provided below are consistent with the comments already provided to FSIS on BSE equivalence matters, and in some cases are direct extracts from those comments.

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

Australia is of the strong view that such exemptions should be catered for in the relevant USDA and FDA rules and regulations. This view applies to all BSE-related measures contained in the FSIS and FDA Final Interim Rules on BSE, and those contained in the ANPRM. The FSIS and FDA Final Interim Rules as presently drafted do not allow for an exemption for countries that do not present a BSE risk, a flexibility that exists in the comparable food-safety regimes of Canada and the European Union (EU). In the EU, this flexibility also extends to BSE-related measures concerned with animal feeding, animal identification and sanitation. It is also relevant that USDA has stated its intention to adopt, to the extent practicable, a uniform approach to BSE control measures with Canada. We understand that Canada intends to continue its policy of exemptions for countries that do not present a BSE risk in finalising proposed enhancements to animal feeding requirements, announced on 9 July 2004.

Strong precedents exist for adopting an approach to exempt "BSE-free" countries. Relevant considerations include:

1. A number of countries, including Australia, are regions free of BSE as defined under current US regulation 9 C.F.R. § 94.18. This is the situation that existed before BSE was identified in North America, and continues to be the case. By contrast, other USDA initiatives, such as the meat-borne pathogen reduction requirements introduced during the 1990s, were justifiably applied to other countries as the pathogens of concern existed in their cattle populations and beef supply. Animal products exported from countries with a recognized BSE-free status, pose no BSE-risk to animal or public health in the US. Their importation should not be restricted or prohibited on the grounds of BSE, beyond the recommendations of the World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code* Chapter on BSE.

2. The principle of the recognition of equivalent foreign food safety and animal health systems, for the purposes of importing animals and their products into the US, has been enshrined in many US rules and regulations. This principal has operated, and has been shown to operate, effectively for many years to protect the health of US livestock and US citizens. There is no justification for departing from this established principle in the case of BSE.

3. The US has previously catered for the question of equivalence in the proposed rule, *BSE Minimal Risk Regions and Importation of Commodities* released in 2003. This rule proposed measures for the importation of animals and animal products from BSE minimal risk regions, that had implemented BSE risk reduction measures that produced equivalent food safety and animal health outcomes to those that applied in the US at that time. APHIS determined that the nature of this equivalence remained unchanged despite the subsequent detection in the US of an imported case of BSE from Canada, a proposed minimal risk region defined in the proposed rule. This was detailed in both an ensuing reopening of comment and explanatory note to this proposed rule. The proposed rule also detailed a possible mechanism for the assessment of a country's BSE status that has relevance to questions 35 and 36 (see below).

4. The OIE *Terrestrial Animal Health Code* Chapter on BSE clearly differentiates between the BSE risks posed by BSE free or provisionally free countries, and those posed by other BSE risk country categories. For example, this differentiation means that risk management measures involving the removal of specified risk materials (SRMs) are only recommended for minimal, moderate or high BSE risk countries.

We believe that the US 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 US to adopt similar exemptions in its response to BSE. Furthermore, such an approach would be consistent with meeting the SPS Agreement obligations of the US as a WTO Member Economy.

Our request that provision be made for an exemption and/or recognition of equivalence is also based on the high likelihood of unreasonable current and future economic harm resulting from the burdens and restrictions imposed by the FSIS and FDA Final Interim Rules on the

Australia cattle production system. Additionally, it is based on the potential economic and environmental burden that would arise from application of the measures contained in the ANPRM, such as an inability to dispose of downer/dead-on-farm cattle through salvage for rendering and pet food use. If the ANPRM measures on enhancements to the US feed ban were to apply to Australia, it would have significant effects on Australian industries. ANPRM measures would need to be applied Australia wide, as it would not be feasible to have US-only livestock feed and animal production systems applying to part of the Australian farm and agri-food sectors. There would be significant economic and environmental consequences for Australia if, for example, SRMs had to be removed from all Australian animal feeds and no parts of downer or dead-on-farm cattle could be salvaged for stock feed or pet food use. Australia is not aware that these adverse effects are supported by any scientific or risk-based justification. Furthermore, their application to the Australian farm and agri-food sectors would not confer any additional protection for the animal or public health situation of the US, because of the most favourable BSE status of the Australian cattle herd.

Question 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?*

As stated above, strong precedents and justification exist for US authorities granting exemptions from BSE-related measures for countries which do not pose a BSE risk. This ability to grant exemptions should not be restricted to FSIS measures as implied by question 35, but should be applied across all relevant US authorities. Various options exist for standards that could be applied to determine a country's BSE status. Some of these are canvassed below.

As a matter of principle, a country, other than one that is recognised as posing a BSE risk under current US regulation 9 C.F.R. § 94.18, should not have new FSIS or FDA measures applied to it until any new determination of BSE status that may be required under other US Statutes is made. As long as they remain BSE free, these countries should be allowed to trade under pre-existing conditions that applied under USDA and FDA rules and regulations, pending the completion of any additional BSE status assessment that is required.

Some options for determining a country's BSE status include:

Option 1: An assessment of BSE status of relevant countries is already conducted under current US regulation 9 C.F.R. § 94.18. FDA and FSIS rules and regulations could recognise equivalence for countries that are recognised as BSE free under this rule, using whatever standards are already in place for these assessments.

Option 2: The US could formally adopt its own criteria. We suggest that these should be based on those promulgated by the OIE for BSE free and BSE provisionally free countries. Such an approach is consistent with that in the proposed rule, *BSE Minimal Risk Regions and Importation of Commodities*. This proposed rule suggests a list of factors that has been determined by APHIS to evaluate the BSE risk from a region and classify a region as a BSE minimal-risk. These factors appear to be largely based on OIE recommendations for this category of country or region.

As an example of how OIE recommendations can be applied, the Canadian Food and Drug regulations that entered into force in 2003 define SRMs similarly to the FSIS Interim Final Rule and prohibit the sale or importation of food that contains SRMs.[1] 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 . . . . "[2] 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.[3] 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.[4] US authorities could decide to adopt an assessment system that incorporates the Canadian (or similar) criteria. 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.
>
> 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.

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

[2] *Id.*

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

[4] 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).

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.[5]

Under this regulatory regime, Australia and several other countries are currently recognized by Canada as BSE-free. If FSIS and FDA were to amend the Interim Final Rules, and any rule to arise from the ANPRM, to be more thoroughly consistent with the Canadian regulation, the standards for a designation of BSE-free would be incorporated into the Rules. As a result, countries that do not pose a BSE risk would not have to be subject to the Rules for as long as they remained BSE-free and therefore did not pose a risk to US animal health or public health.

Similarly, Annex V of the relevant EC regulation[6] 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. EU animal feeding requirements also do not apply to these countries. 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.

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[5] *Id.*

[6] EC Regulation No. 999/2001.

Question 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?*

The mechanism by which the assessment is conducted is largely a matter for the US. However, we would suggest that where assessments need to be conducted by US authorities, that these should be conducted by a single US agency. APHIS has experience in conducting foreign animal disease status evaluations and conducting risk analyses in regard to animal diseases in countries that supply the US market with animals and their products. Such an approach would also be consistent with the method of assessment of a country's BSE status in the proposed rule, *BSE Minimal Risk Regions and Importation of Commodities.*

As a matter of principle, the US should harmonise its BSE risk assessment criteria for a country, region or zone, to the extent practicable, with the relevant international standard (viz. the OIE *Terrestrial Animal Health Code* Chapter for BSE). Furthermore, when framing legislation for this purpose, flexibility should be provided to take into account changes, over time, to this international standard and to take account of the findings of BSE risk assessments conducted by international bodies or competent authorities of other countries or economic groupings.

Auditing of record keeping requirements

Australia recognises the importance of record keeping in the verification of the BSE control measures in food and pharmaceutical processing establishments. We also recognise the importance of Government access to these records to enable auditing of compliance. We affirm that it is the responsibility of the companies involved to ensure that sourcing and BSE requirements are met and as such, submit that these records should be generated and kept by company management or relevant Quality Assurance staff/HACCP team. We trust that, in accordance with accepted international practices and standards, FDA will recognise that the Competent Authorities in countries exporting to the US can certify that systems of records verification equivalent to those required by the Interim Final Rule or the Proposed Rule are in place. We further trust that, on this basis, FDA will be able to modify the Interim Final Rule and Proposed Rule to allow FDA to accept assurances provided by Competent Authorities in exporting countries that the requirements of the new FDA BSE measures have been complied with, without the need for FDA to conduct audits at all establishments in countries exporting to the US.

This approach would not in any way preclude FDA from conducting, from time to time, verification audits of the control measures instituted by the competent authorities of exporting countries. Under such an approach, US authorities could place appropriate reliance on the certification provided by the competent authorities of exporting countries.

Conclusion

For the reasons outlined above we believe that the FSIS and FDA Interim Final Rules, and any rule that arises from the ANPRM, should ensure that there is adequate provision to allow trading partners to be granted exemption from US BSE-related measures in appropriate instances, including on the basis of BSE-free status, or in situations where exporting countries can demonstrate that their own measures achieve an ALOP equivalent to that achieved domestically in the US. Further, we are of the view that a single US agency should be

responsible for assessing the BSE status of exporting countries and should apply criteria reflective of the current international (OIE) standards for this purpose.

We would also welcome favourable consideration of more flexible record keeping verification procedures for foods and cosmetics than presently proposed by FDA.

We would be pleased to provide any further information or assistance that may facilitate more detailed consideration by US authorities of variations to these BSE-related sanitary measures.

Yours sincerely

Andrew Cupit
Agricultural Counsellor