Chapter 2

Risk analysis processes for the importation of beef and beef products

- 2.1 On 20 October 2009 the Australian government announced a new policy, effective from 1 March 2010, which permits the importation and/or sale of certain beef and beef products under agreed conditions from countries that have reported cases of Bovine Spongiform Encephalopathy (BSE). The policy is set out in *Bovine Spongiform Encephalopathy (BSE): Requirements for the Importation of Beef and Beef Products for Human Consumption effective March 2010.* 1
- 2.2 In its first report the committee expressed the view that the decision to relax the import requirements for beef and beef products should have been preceded by a formal analysis of the import risk attached to such products. While noting the review of current scientific evidence undertaken by Professor John Mathews, the committee expressed concern that there had not been a greater attempt to confirm that our current understanding of the animal health risks posed by BSE within the current global regulatory environment is accurate. The committee also expressed concern that a thorough consideration of all likely consequences of an incursion of BSE, including the economic consequences, had not been undertaken prior to the decision to relax the policy.
- 2.3 The committee recommended that this policy and all administrative processes for the assessment of applications from countries seeking to import beef and/or beef products be suspended pending the outcome of a formal overarching import risk analysis modelled on the expanded import risk analysis process provided for in the Import Risk Analysis Handbook 2007 (update 2009).²
- 2.4 On 8 March 2010, the Minister for Agriculture, Fisheries and Forestry announced that he had written to the Secretary of the Department of Agriculture, Fisheries and Forestry to request that Biosecurity Australia (BA) conduct an Import Risk Analysis (IRA) on the importation of fresh beef and beef products (chilled or frozen) for human consumption from countries other than New Zealand. The Minister said:

There are three differences between the decision I have taken today and the process available since March 1.

Food Standards Australia New Zealand, http://www.foodstandards.gov.au/_srcfiles/BSE%20Policy%2025%20September2009.pdf accessed 15 June 2010

² Rural and Regional Affairs and Transport References Committee, *The possible impacts and consequences for public health, trade and agriculture of the government's decision to relax import restrictions on beef*, First report, March 2010, p. 49

This is a formal review process with specified time lines, guaranteed opportunities for community engagement and consultation as well as the added assurance of review by the Eminent Scientists Group.³

2.5 Prior to this announcement, BA had announced that it would consider market access requests on a country-by-country basis through an import risk analysis conducted inline with the Import Risk Analysis Handbook, but outside the regulated IRA process.⁴

Assessment by the Australian BSE Food Safety Assessment Committee

- 2.6 Under the policy which came into effect on 1 March 2010, countries wishing to export beef and beef product to Australia for human consumption can apply for a country assessment and will be assigned one of three categories:
 - Category 1 Countries assessed by Australia as meeting the 'Negligible BSE Risk' requirements of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE). Beef and beef products can be imported subject to specific requirements.
 - Category 2 Countries assessed by Australia as meeting the 'Controlled BSE Risk' requirements of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE). Beef and beef products can be imported subject to specific requirements.
 - Category 3 Countries assessed by Australia that do not meet the requirements of either Category 1 or Category 2, or countries that have not applied to be assessed by Australia. Beef and beef products cannot be imported.
- 2.7 The committee considered this risk assessment process in its first report.⁵ It noted that under the new policy, countries will submit a completed Australian Questionnaire to Assess BSE Risk. The risk assessment will be administered by FSANZ, based on the risk assessment methodology developed by the World Organisation for Animal Health (OIE) and will be reviewed by the Australian BSE Food Safety Assessment Committee. The assessment may involve an in-country inspection to verify in-country control measures.
- 2.8 Each final assessment report will be submitted to the Chief Executive Officer of FSANZ for consideration. Subject to approval, the final report will be provided to

The Hon. Tony Burke MP, Minister for Agriculture, Fisheries and Forestry, *Import Risk Analysis for Beef Imports*, 8 March 2010, DAFF 10/389B

Biosecurity Australia Advice 2010/02, Handling of market access requests and quarantine requirements for beef and beef products for human consumption, 24 February 2010

Rural and Regional Affairs and Transport References Committee, *The possible impacts and consequences for public health, trade and agriculture of the government's decision to relax import restrictions on beef*, First report, March 2010, pp. 32-38

the Deputy Secretary of the Biosecurity Services Group within the Department of Agriculture, Fisheries and Forestry and also to the applicant country.

2.9 The following flowchart sets out the assessment and certification process FSANZ will follow upon receipt of an application.

The BSE Risk Assessment Process & Certification

STEP 1 Country Applies for Assessment

A country applies for assessment to the Australian BSE Food Safety Assessment Committee (the Committee). The Committee is chaired by FSANZ, and includes an animal health expert from the Department of Agriculture, Fisheries and Forestry (DAFF) and food safety and risk assessment experts from FSANZ. The committee also prioritises applications.

Category 1 and 2 countries provide annual updates to the Committee on surveillance results, feed control, and BSE epidemiological situation. STEP 2 FSANZ undertakes a risk assessment, which is reviewed by the Committee, and a draft report with interim BSE risk category is provided to the applicant country Risk Assessment for a 60 day comment period. If required, a visit by Australian Government Process officials will be used to verify in-country control measures. Evidence obtained during the in-country inspection will be considered by the Committee prior to Assessment of completing the assessment. feeding practices, The final report including a recommended The final report animal BSE risk category (1, 2 or 3) prepared by BSE risk and imports, the Committee, once approved by FSANZ category (1, 2 or processing CEO is provided to the Deputy Secretary of 3) is provided to conditions, the Biosecurity Services Group (BSG) of Applicant training/skills, DAFF. Relevant government departments, Country. awareness. federal ministers and industry will be notification advised of the assessment outcome. requirements, surveillance and monitoring, BSE history.

STEP 3

Import Certification

FSANZ publishes the list of BSE risk categories of completed country assessments on its website.

AQIS issues an Imported Food Notice referencing the BSE risk categories, certification and requirements and implementation date.



Through the *Imported Food Control Act 1992* and subordinate legislation, AQIS implements certification for Category 1 or 2 countries as detailed in the policy document <u>Bovine spongiform encephalopathy (BSE): requirements for the importation of beef and beef products for human consumption – effective 1 March <u>2010</u>. These requirements are in addition to existing sanitary measures for beef and beef products that may apply to the Applicant Country.</u>

- 2.10 This process provides for a draft report, including an interim recommended BSE risk category, to be provided to the applicant country for comment. The process does not include provision for public consultation and there is no requirement for publication of the final assessment reports. However, the final BSE risk category of all completed country assessments, other than those categorised as Category 3, will be published on the FSANZ website. ⁶
- 2.11 The committee notes that FSANZ anticipates the assessment process will take an average of 20 weeks to complete from the time of application to the preparation of a draft report, depending on the quality and completeness of the information provided in the application and whether an in-country inspection is required.⁷
- 2.12 The committee also notes that during the 2010-2011 Budget Estimates hearings the Rural Regional Affairs and Transport Legislation Committee (the Legislation committee) was advised that:

It is still the case today that we have not had an application through to FSANZ from either the United States or Canada, but I understand one is imminent from Canada. We in Biosecurity Australia have accepted applications through letters that we had earlier from the United States and Canada, so our clock started ticking on 8 April to undertake the IRA. In that regard it has started, but we have not had an application from the United States through to FSANZ, so the planning for an in-country inspection of specific locations from which they wish to export has not been determined at this stage.⁸

- 2.13 Under the new BSE food safety policy for imported beef and beef products, countries currently allowed to trade beef products with Australia are required to submit an application to FSANZ for BSE risk status by 30 June 2011 to continue to export beef and beef products to Australia after 1 July 2011.
- 2.14 Mr Steve McCutcheon advised the committee at its 14 May 2010 hearing that one application had been lodged (by New Zealand) on 28 April 2010.

On 28 April 2010 FSANZ received an application from the New Zealand government for FSANZ to undertake a food safety risk assessment and assess its BSE risk status under the Australian government's new BSE food safety policy for imported beef and beef products. New Zealand is one of a number of countries currently allowed to trade beef products with Australia. Under the new BSE food safety policy, such countries are required to submit an application to FSANZ for BSE risk status by 30 June 2011 to

⁶ FSANZ, *The Australian assessment process to assess BSE risk*, http://www.foodstandards.gov.au/consumerinformation/bovinespongiformencephalopathybse/australianassessment4747.cfm accessed on 14 June 2010

FSANZ, *The Australian assessment process to assess BSE risk*, http://www.foodstandards.gov.au/consumerinformation/bovinespongiformencephalopathybse/a ustralianassessment4747.cfm accessed on 14 June 2010

⁸ RRAT Legislation Committee, *Budget Estimates Hansard*, 25 May 2010, p. 67

continue to export beef and beef products to Australia after 1 July 2011. Public notification of the receipt of this application was made on 7 May 2010. This is the first and only application FSANZ has received since the new BSE food safety policy came into effect on 1 March 2010. ⁹

Import risk analysis by Biosecurity Australia

- 2.15 On 8 April 2010 Biosecurity Australia announced the formal commencement of separate concurrent import risk analyses to assess the animal quarantine risks from the importation of beef and beef products intended for human consumption from the United States, Canada and Japan. These IRA processes are being conducted in parallel with the BSE food safety risk assessment being undertaken by FSANZ.
- 2.16 The IRA processes will be led by Dr Mike Nunn, Principal Scientist, Animal Biosecurity and an expert panel has been established to assist in their conduct. The expert panel comprises:
 - Associate Professor John Glastonbury, Associate Professor of Diagnostic Pathology, School of Animal and Veterinary Sciences, Charles Sturt University;
 - Dr Kevin Doyle, National Veterinary Director, Australian Veterinary Association; and
 - Dr Ron Glanville, Chief Veterinary Officer, Queensland.
- 2.17 The IRAs will be completed within 24 months from the initial BA announcement. BA will prepare draft IRA reports which will be circulated to stakeholders who will have up to 60 days to provide written comments. 12
- 2.18 The draft IRA reports will:
 - confirm the pests and diseases being assessed within the IRA and describe the major pathways for entry, establishment and spread in Australia;
 - determine the likelihood of entry, establishment or spread and the harm that could result:
 - specify whether the resulting risks exceed Australia's appropriate level of protection (ALOP) and where the risks exceed Australia's ALOP, identify potential risk management measures and determine whether application of the measures could reduce the risks to achieve Australia's

⁹ Mr Steve McCutcheon, Chief Executive Officer, FSANZ, *Committee Hansard*, 14 May 2010, p. 7

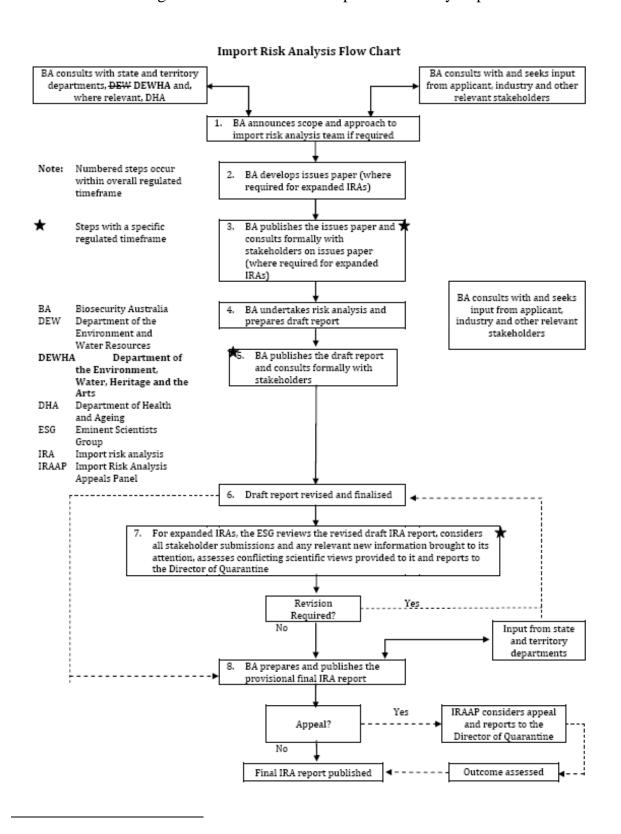
Biosecurity Australia Advice 2010/10, Commencement of IRA for the Important of Beef and Beef Products from the United States, Canada and Japan, 8 April 2010

Biosecurity Australia Advice 2010/15, Beef IRA Expert Panel, 25 May 2010

Biosecurity Australia, *Import Risk Analysis Handbook*, 2007 (update 2009), pp 18 -19

ALOP; and include a preliminary view of the preferred options for risk management. 13

2.19 The following flowchart sets out the Import Risk Analysis process.



Stakeholder consultation

- 2.20 As noted above, the process outlined in the IRA Handbook 2007 (update 2009) (the handbook), allows for formal consultation with stakeholders following completion of the draft IRA. The Quarantine Regulations 2000 provide that this consultation period must be no longer that 60 days from and including the day the invitation to comment is published. However, the committee notes that in the event that the Chief Executive BA considers that stakeholders may not have had reasonable opportunity to comment on the draft IRA report, the Chief Executive has the discretion to extend the consultation period by up to 60 days. The IRA Handbook also indicates that BA may also meet with stakeholders to discuss the draft IRA reports.
- 2.21 The committee notes that the public file of non-confidential submissions and other documentation, together with information regarding the status of each IRA, is available on BAs website and that BA maintains a data base of registered stakeholders to facilitate engagement and communication with people and organisations with an interest in the IRA throughout the process.
- 2.22 The committee insists that the draft IRA report be available for public/stakeholder scrutiny, including by the Parliament and this committee, at the commencement of the stipulated consultation period.

Parliamentary scrutiny of risk assessment processes

- 2.23 In its first report, the committee expressed concerns regarding the lack of Ministerial and Parliamentary scrutiny of decisions taken under the new policy for the importation of beef and beef products. The committee noted that the categorisation of applicant countries will be undertaken by FSANZ on behalf of the Australian BSE Food Safety Committee (ABFSA) and will be approved by the Chief Executive Officer of FSANZ. Similarly, the committee noted that any reviews of country classifications will be considered by ABFSA and any subsequent review of the policy or the questionnaire through which it is primarily administered will be undertaken at the discretion of FSANZ. ¹⁷
- 2.24 The committee has expressed concerns in previous inquiries about a similar lack of Ministerial and Parliamentary scrutiny in relation to the IRA process

Biosecurity Australia, *Import Risk Analysis Handbook*, 2007 (update 2009), p.19 and *Quarantine Regulations* 2000, Part 6A, Regulation 69D(3), p 72

¹⁴ Quarantine Regulations 2000, Part 6A, Regulation 69D(2), p 72

Biosecurity Australia, *Import Risk Analysis Handbook*, 2007 (update 2009), p.19

¹⁷ Rural and Regional Affairs and Transport Committee, *The possible impacts and consequences* for public health, trade and agriculture of the Government's decision to relax import restrictions on beef, First report, March 2010, p 51

administered by BA¹⁸ The committee notes that the completion of an IRA process is signalled by the determination of the policy framework against which decisions to grant import permits, and the extent to which conditions may be attached to a permit will be made. The committee notes that this determination is made by the Director of Animal and Plant Quarantine and that this position is held by the Secretary, Department of Agriculture, Fisheries and Forestry.

- 2.25 In making the determination the Director of Animal and Plant Quarantine considers:
 - the final IRA report and its recommendations;
 - the outcome of any appeals;
 - the report of the ESG;
 - BA's response to the ESG report; and
 - any other relevant information, including Australia's international rights and obligations.
- 2.26 The Director of Animal and Plant Quarantine notifies AQIS and BA of the policy determination and BA, in turn, notifies the World Trade Organisation Secretariat. The committee notes that this policy determination is not approved by the Minister and is not subject to Parliamentary scrutiny. The committee also notes that the only avenue for review in relation to this policy decision appears to be judicial review under the *Administrative Decisions* (*Judicial Review*) *Act 1977* in relation to an individual import permit decision taken by the Director of Animal and Plant Quarantine.
- 2.27 As noted in its first report, the committee accepts that the officers of FSANZ and BA are ultimately accountable to the relevant Minister. However, the committee does not accept that this is the same as Ministerial sign off on policy decisions, or parliamentary scrutiny of significant changes in policy.

Recommendation 1

2.28 The committee recommends a process whereby the relevant Minister is required to consider and rule on the recommendations provided by Biosecurity Australia, following an Import Risk Analysis, and the Australian BSE Food Safety Assessment Committee, following a country assessment. The committee also recommends that the relevant Minister report any decision to approve or reject such recommendations to the Parliament and this committee prior to a

¹⁸ See for example: Rural Regional Affairs and Transport Committee, Administration of the Department of Agriculture, Fisheries and Forestry, Biosecurity Australia and Australian Quarantine and Inspection Service in relation to the final import risk analysis report for applies from New Zealand, June 2007; Rural Regional Affairs and Transport Committee, Import risk analysis (IRA) for the importation of Cavendish bananas from the Philippines, June 2009.

determination by the Director of Plant and Animal Quarantine, in the case of an Import Risk Analysis, or the Chief Executive Officer of FSANZ, in the case of a country assessment, and prior to formal advice being provided to the applicant country.

'Stop the clock' provision invoked for IRA for beef from Japan

- 2.29 On 10 May 2010, BA announced that it had invoked the 'stop the clock' provision for the IRA for the importation of beef and beef product for human consumption from Japan following confirmation of an outbreak of foot and mouth disease (FMD) in cattle in Japan. On 20 April 2010 the Japanese Ministry of Agriculture, Forestry and Fisheries advised the detection of FMD in breeding cattle at a farm in Miyazaki Prefecture of Kyushu Island. FMD is internationally recognised as a very serious disease of cloven hoofed animals and Australia has strict quarantine measures for FMD. These measures include not permitting the importation of fresh beef and beef products from any country affected with FMD. ¹⁹
- 2.30 Under Clause 69H of the *Quarantine Regulations 2000*, certain periods of time in the IRA process may be disregarded, such as where a significant international quarantine circumstance exists that limits BA's ability to complete an IRA. Until Japan regains its former FMD-free status according to the World Organisation for Animal Health and following an evaluation by Australia, any time that elapses will not be considered as being within the regulated deadline for the IRA.²⁰
- 2.31 The committee sought clarification from BA regarding the impact of any past or future diagnosed cases of BSE within the United States or Canada on the IRA processes in relation to those countries. The committee asked whether such cases might trigger the 'stop the clock' provisions. Dr Andrew Carroll told the committee:

In relation to Canada, the answer is no. The slightly longer answer is that given their current BSE categorisation of status, there would be an expectation that they would from time to time have a case that would be taken into consideration as part of the process that they have gone through.²¹

2.32 Dr Carroll went on to state that it is not beyond BA's expectation that Canada or the United States could have another case of BSE.²² Dr Colin Grant, Chief Executive, Biosecurity Australia, explained to the committee that the IRA process was intended to assess the conditions under which product from these countries can come

¹⁹ Biosecurity Australia Advice 2010/13, Beef Japan Stop the Clock, 10 May 2010

²⁰ Biosecurity Australia Advice 2010/13, Beef Japan Stop the Clock, 10 May 2010

²¹ Dr Andrew Carroll, Chief Veterinary Officer, DAFF, Committee Hansard, 14 May 2010, p. 13

²² Dr Andrew Carroll, Chief Veterinary Officer, DAFF, Committee Hansard, 14 May 2010, p. 13

into Australia.²³ Dr Grant contrasted this with products from countries with diagnosed cases of FMD. Dr Grant told the committee:

Dr Grant—Products from countries with foot-and-mouth-disease cannot enter this country—

Senator BACK—Fresh?

Dr Grant—Fresh, and that is the end of that until such times as they are clear of that and we have reassessed the OIE assessment of their clearance. The exercise in terms of Canada is, in fact, to do precisely what you identified and that is to assess the conditions under which their product can come into Australia.²⁴

2.33 The committee finds Dr Carroll's statement regarding BA's expectations regarding Canada and the United States of concern. The committee believes that where there is an expectation that a country may continue to report cases of BSE, this should be a key consideration in the development of the IRA for that country.

Independent review by the Eminent Scientists Group

- 2.34 BA's 8 April 2010 announcement states that the IRA will be a standard IRA. The committee notes that the Import Risk Analysis Handbook distinguishes between standard and expanded IRA processes and that a key difference between a standard and an expanded IRA is the provision for Review by the Eminent Scientists Group (ESG).²⁵
- 2.35 However, the committee notes that in announcing his decision to request an IRA, the Minister stated that the IRA process would provide the added assurance of review by the Eminent Scientists Group. BA has also confirmed that the independent Eminent Scientists Group will provide external scientific scrutiny of the IRA reports after consideration of public comments.²⁶
- 2.36 The committee welcomes the inclusion of high level review by the ESG, independent of BA. The committee notes that following the independent review of Australia's quarantine and biosecurity system in 2008, chaired by Roger Beale AO, the role of the ESG was expanded to include review of whether all relevant matters relating to the likely economic consequences of a pest or disease incursion have been properly considered. Mr Roger Rose, former Chief Economist at the Australian

Dr Colin Grant, Chief Executive, Biosecurity Australia, *Committee Hansard*, 14 May 2010, p. 14

²⁴ Dr Colin Grant, Chief Executive, Biosecurity Australia, *Committee Hansard*, 14 May 2010, pp. 13-14

²⁵ Biosecurity Australia, Import Risk Analysis Handbook 2007 (update 2009), pp. 18 - 21

²⁶ Biosecurity Australia Advice 2010/15, Beef IRA Expert Panel, 25 May 2010

Bureau of Agricultural and Resource Economics was appointed to the ESG from 1 July 2009.²⁷

2.37 The ESG is now tasked with providing external scientific and economic scrutiny of IRAs.²⁸ The committee notes that the scope of the ESG's role, as set out in the IRA Handbook, is relatively wide. In performing its role the ESG is to:

take account of any relevant new information brought to its attention and assess conflicting scientific views to ensure that:

- all submissions received from stakeholders in response to the draft IRA report have been properly considered;
- all relevant matters relating to the likely economic consequences of a pest or disease incursion have been properly considered; and
- the conclusions of the revised draft IRA report are scientifically reasonable, based on the material presented.²⁹
- 2.38 The committee notes that the ESG may consult with Biosecurity Australia and with stakeholders and that the Chairman of the ESG may co-opt additional expertise or seek advice to assist the ESG in meeting its terms of reference. However, the committee notes that the ESG must complete its review within a maximum timeframe of 60 days. The ESG report will be provided to the Chief Executive of BA and will be publicly released. ³⁰

Development of effective import protocols

- 2.39 In its first report, the committee noted the fundamental importance of the development of effective import protocols for the importation of beef and beef products. The committee expressed concern that such protocols should be developed in close consultation with the industry to ensure that all concerns are considered and appropriately addressed.
- 2.40 The committee notes that the IRA process administered by BA provides opportunities for stakeholders to comment on the analysis of risk and the possible measures which might be applied to effectively manage these risks. Dr Grant told the committee:

There will be a process of assessment jointly done by FSANZ and Biosecurity Australia. The documentation for all of that in the context of the import risk analysis, the IRA, that is done will be put out for public comment for 60 days and the public, in all its guises, will be able to assess

²⁷ Biosecurity Australia Advice 2009/14, *Update to the Import Risk Analysis Handbook 2007*, 30 June 2009

Biosecurity Australia, Import Risk Analysis Handbook 2007 (update 2009), p. 19

²⁹ Biosecurity Australia, Import Risk Analysis Handbook 2007 (update 2009), p. 19

³⁰ Biosecurity Australia, Import Risk Analysis Handbook 2007 (update 2009), p. 19

what we have done in that entire risk assessment process, which will include in-country inspections and an assessment of the systems.³¹

- 2.41 In its first report the committee noted assurances that applicant countries will be required to demonstrate equivalence with the requirements currently applying to Australia's own beef industry. In particular, the committee noted that there is a clear expectation within the beef industry, BA, FSANZ and among government ministers that applicant countries will be required to meet equivalent traceability standards to those applied to Australian beef producers.³²
- 2.42 The committee notes that the country assessments undertaken by FSANZ provide for examination of animal traceability and identification systems within the applicant country. Applicant countries are required to provide the following documentary evidence to demonstrate the systems the country has in place to ensure the effective and timely identification and tracing of potentially BSE infected cattle, their birth and feed cohorts:
 - Documentation of the herd identification systems in the country, including any relevant legislation and/or industry standards.
 - Documentation of the process and timeframe whereby cattle at slaughter that are suspected to be BSE positive can be identified and traced back to the farm of origin and farms of residence.
 - Documentation of the process and timeframe whereby cattle from the same birth or feed cohort to the BSE positive cases can be identified and traced forward to the point of slaughter, death or residence.
 - Documentation of the risk management of cattle suspected to have been exposed to feed that has been cross-contaminated with *meat-and-bone meal* or *greaves* of bovine origin identification and traced forward to the point of slaughter, death or residence. ³³
- 2.43 In its first report the committee expressed concern that it was not clear how FSANZ would assess the equivalence of this evidence. However, the committee notes Dr Grant's assurance that:
 - ... without pre-empting the review itself and the assessment process, one of the issues we will be looking at is the chain of custody of the product and

Dr Colin Grant, Chief Executive, Biosecurity Australia, *Committee Hansard*, 14 May 2010, p. 10

Correspondence from the Hon Simon Crean MP, Minister for Trade, to the Hon. John Cobb, MP, Shadow Minister for Agriculture and Food Security, 25 February 2010

FSANZ, Australian Questionnaire to assess BSE risk, pp 8-9, http://www.foodstandards.gov.au/_srcfiles/Questionnaire%20to%20Assess%20BSE%20Risk%2023%20Feb%2020101.pdf accessed 15 June 2010

being able to be comfortable and being able to accept certification that is able to be demonstrably evident of containment.³⁴

Committee view

2.44 The committee considers that the ability to efficiently and confidently trace product from the point of sale to both its country and farm of origin, and to effectively identify the cohorts of the animals concerned, is fundamental to management of the human and animal health risks associated with the importation of beef and beef products. Throughout the inquiry the committee has expressed concern that such traceability systems must be capable of extending across country borders.

Recommendation 2

- 2.45 The committee recommends that unless there is full traceability across national borders (equivalent to Australia's traceability requirements) both countries must be considered to pose equal risk.
- 2.46 At its hearing on 14 May 2010, the committee sought to satisfy itself that existing mechanisms enabled beef products to be traced efficiently through the chain of production. The committee asked BA to investigate and provide the relevant 'paper trail' of certification in relation to a sample of beef product purchased in an Australian supermarket and labelled as Product of the United States of America. In particular, the committee wished to see the assurances upon which relevant quarantine officials satisfied themselves that the product did not contain US beef and that therefore they could confidently issue an import permit.
- 2.47 BA undertook to look into the committee's request but had not provided a response to the committee at the time of tabling this report.

In-country inspections

2.48 In its first report the committee noted that the assessment process to be undertaken by FSANZ does not provide for mandatory in-country inspections. The committee expressed the view that in-country inspections are necessary to ensure the adequacy of the certification and traceability systems within the exporting country. The committee recommended that FSANZ revise the Australian process to assess BSE risk, including the Australian Questionnaire to Assess BSE Risk, to include a mandatory requirement for an in-country inspection to be undertaken as part of the assessment of each application to import beef and/or beef product to Australia.³⁵

³⁴ Dr Colin Grant, Chief Executive, Biosecurity Australia, *Committee Hansard*, 14 May 2010, p. 11

³⁵ Senate Standing Committee on Rural and Regional Affairs and Transport References Committee, *The possible impacts and consequences for public health, trade and agriculture of the Government's decision to relax import restrictions on beef*, First report, March 2010, p. 51

- 2.49 The committee notes that the BSE risk assessment process remains unchanged. Under the risk assessment administered by FSANZ, the BSE Food Safety Assessment Committee can initiate an in-country inspection for an applicant country where the analysis of information provided by the applicant country, or any other relevant information, indicates this is warranted. Verification of in-country control measures may include examination of:
 - the existing systems in the applicant country to prevent the spread of BSE in the cattle population and from entering the human food chain;
 - the existing systems to prevent food for human consumption from becoming contaminated during animal slaughter and processing; and
 - any other relevant matter.³⁶
- 2.50 The committee also notes that the IRA process does not require in-country inspections. However, the committee is aware that the Agreement on the Application of Sanitary and Phytosanitary Measures, with which Australia's IRA process must be consistent, provides for exporting Members to give importing Members reasonable access, upon request for inspection, testing and other relevant procedures.³⁷ The committee is also aware that in-country inspections have been undertaken as part of previous IRA processes.
- 2.51 The committee notes evidence provided to the Legislation committee during the 2010-11 Budget Estimates that suggests in-country inspections will form part of the FSANZ and BA assessment processes for applications from Canada and the United States and will be conducted jointly by the two agencies. The committee is aware that planning for these inspections has not yet been finalised. Dr Colin Grant told the Legislation committee that the planning for in-country inspections had not commenced as applications were yet to be lodged by Canada and the United States. Dr Grant told said:

That has not been determined at this stage. There will be, as I understand it from FSANZ, four officers working on their risk assessment. We have indicated that we are putting together a team of 10 to 12 to work on that assessment. The in-country inspections will be done jointly by FSANZ and Biosecurity Australia, or DAFF, at the time that we go over.

FSANZ have indicated that their process will run for the order of six to eight months. The in-country inspections will take place during that period; so, assuming that we will get an application reasonably soon, sometime

³⁶ FSANZ, The Australian assessment process to assess BSE risk, http://www.foodstandards.gov.au/consumerinformation/bovinespongiformencephalopathybse/a ustralianassessment4747.cfm accessed on 14 June 2010

Import Risk Analysis Handbook 2007 (update 2009), Annex 2 SPS Agreement, p. 27 37

between now and the early part of next calendar year, and I would say something in the order of four or five months time.³⁸

Committee view

2.52 The committee is heartened by this apparent commitment to undertaking incountry inspections as part of the assessment of import applications received from Canada and the United States. However, the committee would prefer to see in-country inspections included as a mandatory step in both the FSANZ and BA risk assessment processes. In its first report the committee expressed the view that in-country inspections must be undertaken as a matter of course as part of the assessment of each import application. The committee stated that it did not consider that desk top analysis was an appropriate substitute for first hand assessment of the competencies and systems that underpin the management of livestock prior to slaughter and export. The committee remains of this view.

Economic impact of the new policy - consultation with Australia's current trade partners

2.53 The Australian Beef Association (ABA) expressed concern that there appears to have been no consultation with Australia's major export partners. The Chairman of the ABA, Mr Brad Bellinger told the committee that the ABA was concerned that if Australia were to allow the importation of beef from BSE affected countries, some of Australia's major export markets may impose age requirements on exports of Australian beef. Mr Bellinger told the committee:

As it stands with our major beef markets on the Pacific rim—Japan, South Korea and Taiwan—Japan imposed the 20-month rule on all US beef imports to that country and Taiwan and South Korea applied a 30-month rule. We have concerns that if we allow beef from BSE affected countries into Australia then these countries will then impose that rule onto our own beef market.³⁹

2.54 The ABA also expressed concern that if such requirements were imposed they would have a significant impact on Australian beef producers. ABA Director, Mr Athol Economou, told the committee that:

... we do not have the technical resources to segregate out the young cattle. It has taken the Americans six years to get their act together; it will take us decades. Meanwhile our cattle prices will collapse because Japan and South Korea account for more than 50 per cent of our exports. 40

³⁸ RRAT Budget Estimates Hansard, 25 May 2010, p. 67

³⁹ Mr Brad Bellinger, Chairman, Australian Beef Association, *Committee Hansard*, 14 May 2010, p.1

⁴⁰ Mr Brad Bellinger, Chairman, Australian Beef Association, *Committee Hansard*, 14 May 2010, p.5

2.55 Mr Hamish McCormack, First Assistant Secretary, Office of Trade Negotiations, Department of Foreign Affairs and Trade told the committee that all WTO members had been notified of the change in policy through the SPS committee and that no negative issues have been raised at a government level. Dr Carroll told the committee that:

We have had the new food safety policy out now for some six months in the international arena, notified through the WTO, and we received no negative feedback at all.⁴¹

2.56 Dr Carroll also told the committee that there appeared to have been no adverse effect on the trade of beef from New Zealand to North Asian markets as a result of its decision to allow beef imports from BSE affected countries and that it was his expectation that there would be no adverse effect on Australian beef exports. ⁴² Dr Carroll explained to the committee that he did not believe Australia would inherit the United States' status as a beef exporter as a consequence of allowing beef from the United States to be imported into Australia. Dr Carroll told the committee:

There is not free and open trade between us and the US. We would not be inheriting any US status. Should it get approval, there would be requirements applying to any product that came from the US into Australia. So we would not inherit the US status in any way.⁴³

Review of Country of Origin Labelling

- 2.57 In its first report the committee noted that while there are country of origin requirements for fresh pork and seafood and fresh fruit and vegetables, there is currently no such requirement for unpackaged fresh beef. The committee noted that a review panel led by Dr Neal Blewett AC is currently undertaking a comprehensive review of food labelling law and policy. The panel is due to report the Australia New Zealand Food Regulation Ministerial Council in December 2010 and to the Council of Australian Governments in early 2011.
- 2.58 Mr McCutcheon advised the committee that on 9 March 2010, the Parliamentary Secretary for Health, the Hon. Mark Butler MP wrote to the Chair of the FSANZ Board asking FSANZ to raise a proposal to review *Standard 1.2.11 Country of Origin Requirements* with a view to removing its inconsistency in application across unpackaged meat, particularly beef.⁴⁴

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⁴¹ Dr Andrew Carroll, Chief Veterinary Officer, DAFF, Committee Hansard, 14 May 2010, p. 18

⁴² Dr Andrew Carroll, Chief Veterinary Officer, DAFF, Committee Hansard, 14 May 2010, p. 15

⁴³ Dr Andrew Carroll, Chief Veterinary Officer, DAFF, Committee Hansard, 14 May 2010, p. 18

⁴⁴ Mr Steve McCutcheon, Chief Executive Officer, FSANZ, Committee Hansard, 14 May 2010, p. 7

2.59 The committee notes that in announcing the review, the Parliamentary Secretary stated that he was seeking to remove an anomaly in the country of origin laws which apply to fresh fish and pork, but which do not include beef. He also said:

In addition, we are seeking agreement from industry about a new labelling system for beef products – a labelling system that will make it easy for consumers to identify, for example, whether their meat pie contains only Australian beef. This labelling will be enforced by the Australian Competition and Consumer Commission.⁴⁵

2.60 In response to this request FSANZ prepared a proposal to consider extending country of origin labelling to unpackaged beef, lamb and chicken meat. The committee notes that the proposal provides the following explanation for the review:

Following changes to Australia's BSE food safety policy for imported beef and beef products, the Parliamentary Secretary for Health has asked FSANZ to prepare a proposal to review Standard 1.2.11 to remove its inconsistency in application across packaged and unpackaged meat, and that priority consideration be given to this work. This Proposal will consider extending country of origin labelling to unpackaged beef, lamb and chicken meat. Unpackaged pork already requires country of origin labelling. Preliminary discussions with Industry stakeholders indicate that they are generally receptive to extending country of origin labelling to other unpackaged meats. ⁴⁶

- 2.61 The committee notes that it was proposed to conduct targeted stakeholder meetings with key stakeholders during April 2010, with the assessment to be completed by mid June 2010. The proposal anticipates notification of the Ministerial Council by Mid-October 2010 and gazettal in early January 2010. 47
- 2.62 The committee's view is that all imported food product should be labelled with both the country of origin and country of processing, where this is a different country. This would provide consumers with a choice as to whether they wish to eat beef from countries that have had a BSE outbreak. The committee will watch the progress of the review with interest.

Recommendation 3

2.63 The committee recommends that all food product be labelled with both the country of origin and the country of processing, if different.

The Hon Mark Butler MP, Parliamentary Secretary for Health, Media Release, *Clear Labelling for Australian Beef*, 9 March 2010, http://www.health.gov.au/internet/ministers/publishing.nsf/Content/mr-yr10-mb-mb020.htm?OpenDocument&yr=2010&mth=3 accessed 13 June 2010

Food Standards Australia New Zealand, *Country of Origin Labelling – Unpackaged Meat Products*, Proposal – Administrative Assessment P1011, 4 May 2010, p. 1

Food Standards Australia New Zealand, *Country of Origin Labelling – Unpackaged Meat Products*, Proposal – Administrative Assessment P1011, 4 May 2010, p. 2

Current understanding of human health risks associated with BSE

- 2.64 In its first report the committee noted the observation of the National Health and Medical Research Council that there is so much about BSE and variant Creutsfeldt-Jakob Disease that is still unknown. The committee noted the unduly short time frame allocated to a review of the current scientific understanding of the disease and its risks to human and animal health and expressed concern that the resultant policy change may have been based on an incomplete understanding of the associated risks.
- 2.65 At its hearing on 14 May 2010, the committee heard evidence from Dr Alan Fahey who has recently submitted a thesis on the clinical neuropsychiatric, epidemiological and diagnostic features of Creutzfeldt-Jakob disease. ⁴⁸ Dr Fahey told the committee of his concerns regarding the lengthy incubation period for transmissible spongiform encephalopathies, the inadequacy of current tests and the limited nature of our current understanding of this group of diseases. ⁴⁹
- 2.66 Dr Fahey also told the committee that in the last two years a link has been established between forms of atypical CJD and atypical BSE. Dr Fahey said that:

They now believe that those atypical BSEs overseas are in fact causing sporadic Creutzfeldt-Jakob disease. They were not sure if it was due to mad sheep disease or a different form. If you look in the textbooks it looks like this is just arising by itself. But in my research I have a summary of a document which states that there has never been any proof that sporadic Creutzfeldt-Jakob disease has arisen de novo—has arisen of itself. There is no proof of that. The recent research is that in fact it is due to atypical forms of mad cow disease which have been found across Europe, have been found in America and have been found in Asia. These atypical forms of mad cow disease typically have even longer incubation periods than the classical mad cow disease. ⁵⁰

2.67 Dr Fahey suggested to the committee that there should be a government policy requiring veterinary examination of animals that die of suspicious diseases. Dr Fahey also suggested that post-mortem examinations and neuropathologyy should also be performed in the case of anyone who dies with any neurological or psychiatric condition. He said:

Post-mortem examinations and neuropathology are rarely done on humans. I personally would like to see them mandatory for anyone dying with any neurological or psychiatric condition. My aunt presented with psychiatric phenomena initially, and doctors thought it was psychiatric. Psychiatric

⁴⁸ Dr Alan Fahey, The clinical neuropsychiatric epidemiological diagnostic features of Creutzfeldt-Jacob disease (CJD) – dissertation to fulfil the requirement of the New South Wales Institute of Psychiatry for the degree of Master of Psychiatry, tabled 14 May 2010.

⁴⁹ Dr Alan Fahey, Committee Hansard, 14 May 2010, pp 21-23

⁵⁰ Dr Alan Fahey, Committee Hansard, 14 May 2010, p 23

phenomena are the way that mad cow disease presents in humans. Personally, I think that any humans—or cattle or sheep—dying with psychiatric or neurological disorders should have neuropathology performed. ⁵¹

2.68 The committee reiterates its concern that understanding of this group of diseases is currently limited but that research continues to explore new connections between the various forms of the disease. The committee notes the role of the National Health and Medical Research Council's Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) in providing independent and timely expert advice on measures necessary to prevent and limit the spread of vCJD and other TSEs in Australia. The committee considers that TSEAC should be formally charged with monitoring developments in the scientific understanding of transmissible spongiform encephalopathies and the associated risks to human and animal health and providing regular reports to the Minister for Health and the Minister for Agriculture, Fisheries and Forestry to enable the government to respond quickly and appropriately to new evidence as it emerges.

Conclusion

- 2.69 As the committee observed in its first report, the Australian beef industry has a hard earned reputation as a disease free exporter that has secured it entry into some of the most demanding markets in the world. The committee can understand why some members of the industry are nervous at the prospect of importing beef from countries that have reported cases of BSE.
- 2.70 In such circumstances it is essential that the assessment of applications from countries wishing to export beef and beef products to Australia under the relaxed policy introduced on 1 March 2010 must be thorough, robust and transparent. The committee considers that the Minister's announcement of a regulated IRA process for the consideration of import applications is a significant step in this direction. While the committee has expressed some concerns about the administration of the IRA process on other occasions, it notes that the regulated IRA process provided for in the Import Risk Analysis Handbook does provide key points at which stakeholders can provide comment during the risk analysis process and includes opportunities for review and appeal.
- 2.71 However, the committee remains concerned about the assessment process administered by FSANZ. In its first report the committee noted that the questionnaire that forms the basis of FSANZ's assessment of applications lacks a clear statement of the criteria against which applicant countries will be assessed and how equivalence against each of the requirements will be determined. The committee expressed the view that greater clarity needed to be provided in the questionnaire as to how FSANZ will be guided in its assessment of applications. The FSANZ assessment process

⁵¹ Dr Alan Fahey, Committee Hansard, 14 May 2010, p. 28

makes no provision for public consultation and, while the category is published there is no requirement to publish the assessment reports. It therefore appears that the committee and stakeholders must be satisfied with the assurances provided throughout this inquiry that applicant countries will be required to demonstrate equivalence with the requirements currently applying to Australia's own beef industry.

2.72 Notwithstanding these concerns, the committee recognises that both of these assessment processes are still at a comparatively early stage and the committee notes that FSANZ and BA appear to be working collaboratively to ensure an appropriate level of cooperation in relation to key areas of overlap between the two processes. The committee notes Dr Grant's advice that the two agencies have been working closely together:

The department will have its principal scientist on animal biosecurity on the FSANZ BSE food safety assessment committee. Regular meetings between FSANZ and the Biosecurity officers are being held and a steering committee for ongoing management of the assessment processes has been established and will be supported by a dedicated project manager. ⁵²

- 2.73 The committee is particularly pleased to note that BA and FSANZ appear to be planning to undertake in-country inspections as part of the assessment processes for Canada and the United States.
- 2.74 The committee remains concerned that the adequacy of traceability and certification systems is paramount in the management of risks associated with the beef from countries which have reported cases of BSE. The ability to identify and investigate possible incursions quickly and effectively and take appropriate action depends upon the robustness of these systems. The committee considers that these systems must be subject to rigorous first-hand inspection, both during the application process and on a regular on-going basis. With this in mind, the committee intends to monitor the progress of the Import Risk Analysis process closely and will inquire further into this matter if necessary.

Senator Fiona Nash Chair

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⁵² Dr Colin Grant, Chief Executive, Biosecurity Australia, Committee Hansard, 14 May 2010, p.