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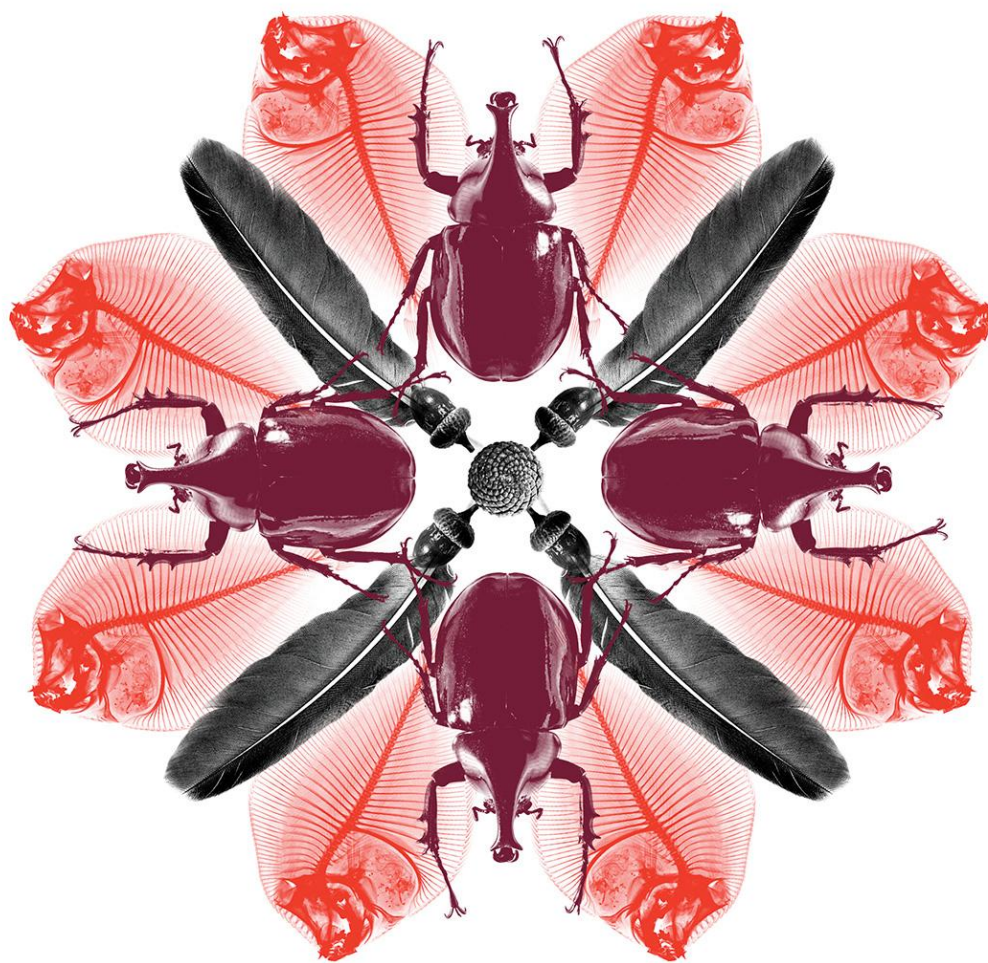
Department of Agriculture

# Importation of stockfeed and stockfeed ingredients

Finalised risk management  
measures for transmissible  
spongiform encephalopathies

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September 2015



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# Purpose

Stockfeeds and materials that may ultimately be incorporated into stockfeeds are imported into Australia in many different forms. Stockfeeds represent a high animal biosecurity risk due to their potential to be contaminated with extraneous material such as dirt, faeces or even animal derived tissues (for example, meat and bone meal) and the direct pathway to livestock. This paper discusses measures that are necessary to manage the risk of introduction into Australia of transmissible spongiform encephalopathies (TSEs), in particular bovine spongiform encephalopathy (BSE) and scrapie, in imported stockfeed and stockfeed ingredients (including fishmeal) and stockfeed additives of plant, animal and microbial origin. The scope of this paper includes:

- products imported for intentional use in stockfeeds
- products that are imported for other uses but which may be diverted to stockfeed use, or have by-products suitable for use in stockfeeds.

Examples are:

- prepared plant-derived stockfeeds
- plant meals
- whole grains
- fish meal
- blood meal
- dairy products
- meat meal
- stockfeed additives
- fish feed intended for aquarium, aquaculture or hatchery use
- pet food with significant potential to be diverted to stockfeed use.

The likelihood that imported stockfeed or stockfeed ingredients may contain animal-derived materials is examined and recommendations are made for appropriate risk management measures for the various classes of stockfeeds and stockfeed ingredients imported into Australia. Although this document refers throughout to risks associated with 'animal-derived materials' in stockfeeds, the prime objective of the risk management measures of this policy is to target materials defined as restricted animal materials (RAM).

Between now and 2025 several broad trends will change the way Australia makes, distributes and consumes food. These trends will present opportunities and challenges for businesses, consumers and the community. Predicting how our economy and society will look in 2025 is challenging, but one thing is certain—it will change. Everyone in the food system has a role to play in planning for these changes.

**This TSE stockfeed policy only relates to TSE controls. Risk management measures to address biosecurity risks other than TSEs are not covered in this document. All other quarantine import policies and requirements relevant to a specific product and/or its ingredients must also be complied with.**

# Background

Concerns over TSEs generally, and BSE in particular, have led to a range of measures designed to manage the risk of cases occurring in Australian livestock. Any incursion of BSE into Australia would have serious consequences in terms of export trade and local reaction. In March 2001, the Agricultural and Resource Management Council of Australia and New Zealand (ARMCANZ) agreed to further extend the existing ban on feeding ruminant-derived materials to ruminants, to include all animal material (excluding gelatine, tallow, oil and milk products).

The present position is that the only animal material that may be fed to ruminants is tallow, gelatine and milk or milk products of Australian or New Zealand origin. The importation of stockfeed derived from animal material, other than fishmeal, is currently only permitted from New Zealand for stockfeed use as there is no policy and a formal import risk analysis (IRA) has not been conducted.

The risk of transmitting TSEs via veterinary vaccines and other in vivo veterinary products is managed by the 2012 *Guidelines for managing the risk of transmitting transmissible spongiform encephalopathies (TSEs) via veterinary vaccines and other in vivo veterinary products* (referred to as 2012 TSE veterinary therapeutics policy in the rest of the document). This policy allows certain materials of animal origin to be imported into Australia based on exporting country's TSE risk, tissue risk category, susceptibility of the species of origin, susceptibility of target species, manufacturing method and degree of processing, method of administration of the veterinary therapeutics and other factors (for example, age of the source animal, testing at slaughter and dilution).

In addition to veterinary vaccines, cell lines and microorganisms for in vivo use, the scope of the 2012 TSE veterinary therapeutics policy includes the following biological materials that may also be used in producing stockfeed additives, probiotics, veterinary vaccines and other in vivo veterinary products:

- neural material
- milk and milk derivatives
- gelatine and collagen
- lanolin, derivatives of lanolin and wool derivatives
- lecithin (phosphatidyl choline, phosphatidyl serine, phospholipids)
- peptones and other tissue extracts
- amino acids, proteins and peptides
- tallow and tallow derivatives (for example glycerol or stearates)
- blood products used for cell lines and vaccine production
- enzymes
- hormones.

Animal-derived materials that are not covered under the restricted animal material (RAM) definition, fermentation derived products (for example, amino acids, enzymes) and others of animal origin may be allowed from certain countries in accordance with the 2012 TSE veterinary therapeutics policy as stockfeed additives. Import applications must be subject to a case-by-case risk assessment that would ensure import controls applied minimise the TSE risks associated with the specific product to an acceptable level. Examples include gelatine of porcine origin as a carrier for vitamins; and amino acids and other veterinary therapeutics as stockfeed additives.

The importation of bulk products derived from terrestrial animals for use as stockfeed (for example, meat meal, bone meal, blood meal, tallow, gelatine, terrestrial animal based oils, etc.) from any country, other than New Zealand, is not permitted until a formal import risk analysis (IRA) is conducted and a policy decision is undertaken.

Australia's approach to preventing the entry of the TSE infectious agent via plant-derived products also includes strict controls on the importation of multi-ingredient and single-ingredient plant-derived stockfeed materials to ensure that they do not contain materials derived from animals. Some products imported for other uses but which may be diverted to stockfeed use, or have by-products suitable for use in stockfeeds, are also subject to similar import controls.

There are sound reasons for pursuing these requirements. In the period up to 1996, potentially BSE-contaminated meat and bone meal (MBM) was imported by a number of countries throughout the world, some of which have experienced indigenous cases of BSE. In view of the extent of trade in MBM before effective controls were instituted, it is possible that countries currently considered free of BSE, may experience cases in the future. Many countries were also slow to implement or do not have effective ruminant feeding bans. Any contamination of imported stockfeed with material of ruminant origin would thus present an unacceptable risk of BSE if it found its way into stockfeeds in Australia.

The consequences of any incursion of BSE into Australia would be very serious. Apart from the human health consequences, consumer reaction, not only amongst Australians but also among our trading partners, could be expected to be severe. An example occurred in 2001 when Japan reported its first case of BSE. A reduction of at least 25% in demand for beef ensued as a direct result of this case, a reduction not only for Japanese beef but also for imported beef. The case illustrates the scale of potential damage to consumer confidence through BSE.

Australia takes appropriate measures to protect itself from the risks of BSE through controls on the importation of animals and products that present a potential BSE risk, such as stockfeed, stockfeed ingredients (including fishmeal), stockfeed additives, and other products with diversion risks such as fish feed intended for aquariums, hatcheries and aquaculture, pet food kibble and fertiliser.

Classical scrapie is another TSE which is exotic to Australia and potentially spread via contaminated stockfeed. Scrapie occurs in most major sheep producing countries other than Australia, New Zealand and South Africa. It would have devastating consequences if introduced into Australia. Although Australia's import measures are primarily focused on BSE, they should be equally effective in managing the risk of transmitting scrapie via contaminated stockfeed.

# Types of products imported

Australia has conditions for importation of processed stockfeed of plant, animal and microbial origin and imports a range of stockfeed, stockfeed ingredients (including fishmeal) and stockfeed additives. Examples of imported stockfeed of plant origin are palm kernel expeller/copra meal, sugar beet pulp pellets, millrun of Australian origin, sorghum and soybean meal. Examples of imported stockfeed of animal origin include fish meal, dairy products (New Zealand) and avian and ruminant blood meal (New Zealand). Examples of imported microorganisms for stockfeed use include microalgae and probiotics. Examples of imported stockfeed additives include enzymes, vitamins, gelatine and amino acids.



# Definitions

For the purpose of this revision, the definitions based on the following have been used:

- Draft Australian Feed Standard for Food Producing Animals (March 2013)
- Ruminant Feed-ban National Uniform Guidelines Version 3 (2010)
- Official Publication, Association of American Feed Control Officials (2000)
- EU Regulation (EC) No 183/2005.

## Stockfeed

Any single material, or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food producing species (including horses, poultry and for aquaculture) for the maintenance of life, normal growth, production, work and reproduction. It includes a pre-mix, block, lick or loose lick. A stockfeed comprises one or more stockfeed ingredients and may also contain one or more stockfeed additives.

## Stockfeed ingredient

A nutritive component, part or constituent of any combination or mixture making up a feed. Ingredients may be of plant, or animal (including aquatic animal) origin, or other organic or inorganic substances. It includes fishmeal, fish oil and other fish feed ingredients intended for hatchery, aquarium and aquaculture use as well as for stockfeed.

## Stockfeed additive

Any intentionally added component of feed *not normally consumed as a stockfeed ingredient*, which affects the characteristics of feed or animals fed with it. It includes a pre-mix which consists only of feed additive components. Microorganisms, enzymes, acidity regulators, trace elements, vitamins, preservatives, colouring agents, binders, dust suppressants, carriers, flavours and other products fall within the scope of this definition depending on the purpose of use and method of administration.

## Pre-mix

A uniform mixture of one or more stockfeed additives with diluents and/or carriers.

## Food producing animals

A species of animal that produces food for human consumption or is used as food for human beings, and includes but is not limited to buffalo, cattle, deer, goat, kangaroo, pig, poultry, rabbit, sheep, crocodile, horse, bees, crustaceans, molluscs, and fish (other than ornamental fish).

## Restricted animal material

Any material taken from a vertebrate animal, other than tallow, gelatine, milk products or oils. It includes rendered products such as blood meal, meat meal, meat and bone meal, fishmeal, poultry meal, feather meal, and compounded feeds made from these products (Ruminant Feed Ban National Uniform Guidelines 2012). Although RAM is defined as 'any material taken from a vertebrate animal other than tallow, gelatine, milk products or oils', 'fishmeal' also includes meals from other aquatic animal meals under the RAM definition.

# Pathways by which animal-derived materials could enter Australia

Prior to entry into Australia, stockfeed or stockfeed ingredients could be exposed to animal-derived materials that are defined as RAM under the Australian Ruminant Feed Ban National Uniform Guidelines through:

- contamination or substitution of raw materials
- contamination during production/processing
- contamination during packaging
- contamination during transport to the point of export
- contamination on board ship.

## Contamination or substitution of raw materials

Many raw materials in their original 'pure' form are generally not likely to be contaminated with animal-derived materials defined as RAM. The likelihood of contamination of such materials may be greater if they are subject to storage or processing in proximity to animal-derived material or materials containing animal-derived material and where cross contamination may occur.

However, even if animal-derived material or materials containing animal-derived material are stored in the facility, aspects of manufacturing processes such as using separate equipment, and segregation of animal-derived material and others into separate areas may reduce the contamination risks to acceptable levels. In these instances, effective quality assurance systems designed to address contamination risks could provide confidence that the risks are minimised to an acceptable level. There may also be a significant risk of deliberate contamination where this is an economic or trade advantage to adding terrestrial animal derived material to product.

Plant meals and whole grains are often produced in establishments dedicated to the production of that particular product. In cases where there is no animal-derived materials used or stored on the production plant nor in storage areas, there is negligible risk of RAM contamination of the material at the facility.

Stockfeed additives are generally produced in dedicated processing establishments. Other ingredients such as animal-derived fermentation media may be stored in the same establishments. In such cases, effective risk management measures to reduce contamination need to be implemented.

'Fishmeal' is produced in several different forms:

- fishmeal derived from whole fish—produced in dedicated facilities typically in Peru, Chile, Ecuador, South Africa, the European Union, United States, Iceland, Mexico and Thailand from whole wild caught fish
- rendered 'by-product' fishmeal—typically produced from the by-product of fisheries cannery operations
- fishmeal analogue—a blended product of various ingredients designed to mimic the nutritional status of fishmeal.

In cases where fishmeal is produced purely from fish and is not subject to contamination during bagging, transport or storage, there is negligible risk of contamination of fishmeal from mammalian derived material.

In other cases, fishmeal may be produced in establishments that also render other animal-derived materials. Fishmeal analogue may contain a variety of ingredients including mammalian protein. These products constitute a high risk.

Some crustacean meals and other aquatic animal-derived meals (for example, squid meal) are currently included in the definition of fishmeal. These products are also likely to be produced in dedicated facilities. In cases where crustacean meal/aquatic animal meal is purely produced from crustaceans and other aquatic animals and not subject to contamination during bagging, transport or storage, the likelihood of contamination with mammalian derived material is negligible.

Fish feed intended for aquariums, hatcheries and aquaculture are generally multi-ingredient products. They may contain plant-derived ingredients, fishmeal, or other animal-derived material. Fishmeal also may be substituted with cheaper mammalian derived material in these multi ingredient products. Thus, whether they are imported in bulk or bagged they constitute a high risk.

It is also plausible that stockfeed including fishmeal may occasionally be adulterated by the addition of a small proportion of meat meal or other animal derived protein especially if cheaper than and/or could increase the protein level of the stockfeed. Where there is a risk of contamination, stockfeed including fishmeal should be the subject of appropriate risk management measures.

## **Contamination during production/processing**

The type of production or processing establishment has a strong bearing on the risk of contamination with animal-derived materials. As already mentioned, plant meals, fishmeal, crustacean meals and other meals of aquatic animal origin and whole grains may be produced and processed in a dedicated establishment which is unlikely to have animal-derived material or stockfeeds containing animal-derived material on the premises. On the other hand, establishments where a range of stockfeeds is produced or stored are more likely to provide opportunities for contamination with animal-derived materials. Pathways of contamination could include incorrect identification of lots, contamination from transport or production lines previously used for feeds which incorporate animal-derived material, contamination from material left in storage areas, or inadequate cleaning of lines and equipment. Stockfeeds and ingredients, which have been processed or stored in plants where animal-derived material is used or stored, should be subject to appropriate risk management measures. This would include all processed prepared stockfeeds, which incorporate multiple ingredients.

Some stockfeed additives derived from microbial/fermentation products may use fermentation culture media containing animal-derived materials. Some stockfeed additives may contain animal-derived carriers that consist of RAM or plant-derived carriers that could potentially be contaminated with animal-derived material. These products will require appropriate risk management measures with regard to TSEs.

## **Contamination during packaging**

There may be potential for contamination during packaging if the same equipment is also used for animal derived material. Also, contamination could occur if bags are reused that have previously been used for animal derived material. Where stockfeed or stockfeed ingredients are enclosed in sealed packages such as new plastic bags, drums or glass containers, there would be no further opportunity for cross-contamination unless the packages were broken. Appropriate packaging at the point of production is an effective means of ensuring against subsequent contamination.

## **Contamination during transport to the point of export**

Transport from the point of production to the point of export provides opportunities for contamination with animal-derived materials. If the product is packed in bulk and the transport vehicles/containers are not clean, there is a risk of contamination because such

vehicles/containers may have been previously used for products containing animal-derived materials.

Another point at which contamination might occur is at storage depots, which may be used before loading for export. Where the security of containers is inadequate, there may be opportunities for cross-contamination of product, or errors in the identification of lots.

Where the cleanliness of such transport stores, vehicles, or containers cannot be verified, and the product is handled in bulk, there is a need for appropriate risk management measures.

## **Contamination on board ship**

Shipping containers and ships' holds that are used for transport to Australia may also present opportunities for contamination with animal-derived materials. In the case of shipping containers, product that is prepacked in impervious bags would not be subject to any significant risk of cross-contamination. However, product that is bulk packed into the container or into the hold of a ship could be contaminated by residues of stockfeeds or animal-derived materials left over from previous trips. It may be feasible to ensure holds or containers are properly cleaned of residues of previous loads. Alternatively, it might be feasible to maintain a system where materials capable of presenting a TSE risk are not carried on the particular ship/hold/container in question. Ships' records of previous loads may assist in maintaining such a system. Where such measures are not feasible however, an opportunity exists for contamination with animal-derived material and risk management measures are warranted.

# Risk management measures

Taking into account the likelihood of the TSE infectious agent being present in animal-derived material from an unknown source and the severe consequences of any case of TSE in Australia, the risk associated with contamination of imported stockfeed with restricted animal material is unacceptable and requires management. Risk management measures should align with the measures used within Australia to manage similar risks.

The approach to risk management for stockfeed and stockfeed ingredients should be based on an assessment on a case-by-case basis. The following aspects of the product should be assessed to estimate the risks involved:

- 1) Product (including sourcing, agricultural production methods and processing)
  - a) The type of product involved (multi-ingredient plant-derived stockfeed, single-ingredient plant-derived stockfeed, plant-derived high protein meals, stockfeed additive)
  - a) Ingredients in the final product, and
    - i) if animal-derived tissue is included, the tissue risk category, and susceptibility of the species of origin, and/or
    - ii) if product undergoes microbial fermentation using animal-derived media, and/or
    - iii) if animal products that are not RAM are included: gelatine, tallow and milk products and oil (including fish oil) from vertebrate animals
  - b) Treatments (for example, chemical, heat, etc.) used in the production of raw ingredients
  - c) Controls on raw ingredient sourcing such as supplier declarations, QA systems applicable to raw ingredients, independent verification audits and official government certification
  - d) Agricultural production system applicable to each ingredient (for example, small-scale, broad acre, intensive, mechanised, etc.)
  - e) For each ingredient, the animal health status of the country of origin in relation to relevant TSEs including BSE status
  - f) Raw materials sourced from countries with undetermined BSE status may be considered medium-high risk
  - g) Where the country of origin of the product may be one of a number of countries, the requirements for that product will be that applicable to the country in the highest risk category.
  - h) Confidence in the animal health systems and competent authority in the country of origin.
- 2) The nature of operations in the processing establishment(s)
  - a) Manufacturing process including flow-charts and processing treatments
  - b) Regulatory controls of the operations by relevant national and other authorities
  - c) Adequacy of QA systems including HACCP in the processing facility
  - d) Standard operating procedures (SOP) and good manufacturing practices (GMP)

- e) Storage or use at the establishment of any animal derived products
  - f) Effectiveness of separation, segregation, security of product in the processing facility and other controls to avoid contamination pre, post and during production with RAMs.
- 3) Product labelling and packaging
- a) RAM/non-RAM labelling as per Australian requirements
  - b) Type and size of packaging
  - c) Use of new vs. used packaging.
- 4) Transport controls
- a) Transport to the point of export
  - b) The nature of storage on board vessels for export
  - c) Cleanliness of containers/trucks/holds
  - d) Third-party audits
- 5) End use
- a) The end use of the product
  - b) Target species
  - c) Diversion risks.

It is proposed that this information be collected through a questionnaire, which would be completed by overseas manufacturers before an import permit is issued. A model questionnaire (which is not meant to be prescriptive) is at [Appendix E: Questionnaire for imported products in relation to transmissible spongiform encephalopathies](#). Operational areas should request further information (for example, QA manuals) if the information provided by the applicant does not provide sufficient evidence to make a decision regarding the management of risks associated with each product.

The options for risk management for TSEs with respect to importation of stockfeeds, stockfeed ingredients and stockfeed additives include one or more of the following:

- Refusal of an import permit
- Analytical testing before release from quarantine to confirm the absence of restricted animal-derived material in the final product. Refer to Appendix C for approved tests and Appendix D for a structured sampling plan in line with Australia's Imported Food Inspection Program
- Inspection of manufacturing and/or export premises
- Inspection on arrival and release if documentation and product are satisfactory
- Release on documentation alone.

None of the recommendations shown here impede the imposition by the Department of discretionary inspection activities, including random/additional sampling and testing, requesting additional detailed information from the importer, desk audits and/or site audits if determined necessary based on the assessment of the import application.

Any change to ownership, management or construction of the establishment may require increased level of inspection or testing, re-audit or re-approval of the establishment.

## **A. An import permit should not be issued**

- 1) For plant based stockfeed, if restricted animal material is handled or stored at either the facility processing and/or storing the stockfeed and the country has a 'not approved' BSE status.
- 2) For fishmeal and other meals of aquatic animal origin, if mammalian or avian material is handled or stored at either the facility processing and/or storing the stockfeed and the country has a 'not approved' BSE status.
- 3) The quarantine assessment determines that the product does not meet Australia's quarantine import requirements for stockfeed (not just this TSE policy).  
or
- 4) The quarantine assessment determines that the product represents an unacceptable risk to Australia.  
or
- 5) There is insufficient information to ascertain the nature of the product and the nature or security of production, processing and transport (the Department of Agriculture can request additional information from the importer where necessary).  
or
- 6) If, during on-site audit, it is found that TSE risks are not addressed to the satisfaction of the department.  
or
- 7) There is significant uncertainty about the likelihood of contamination of the product based on laboratory results on prior shipments and history of non-conformance.

## **B. Analytical testing for the presence of restricted animal materials (as applicable)**

### **All stockfeed**

- 1) In general, refer to Appendix A: Transmissible spongiform encephalopathy risk matrix and Appendix B: Risk parameters for audit for guidance on analytical testing and to identify products requiring testing for RAM. Appendix C details approved tests.
- 2) If required, testing for products will be on a sliding scale as specified in Appendix D: Sampling plan for testing product for the presence of restricted animal material and corrective action.
- 3) Exceptions to a testing requirement may be made on a case-by-case basis. Factors to be considered include raw material sourcing (i.e. BSE negligible and controlled risk countries); manufacturing of the product that provides confidence that there is unlikely to be any contamination with animal material; product where no animal materials stored in the establishment; effective HACCP and QA systems. Also, ingredients specifically assessed and approved in accordance with the 2012 TSE veterinary therapeutics policy may be exempt.
- 4) Testing should be undertaken if product is transported in bulk and the cleanliness of containers or ships holds before export cannot be guaranteed to the satisfaction of the Department (for example, through a pre-approved arrangement).
- 5) Testing should be undertaken for product transported in bulk but at inspection on arrival, the cleanliness of containers/holds is not confirmed and there is a risk of contamination with animal-derived materials.

- 6) Testing is mandatory for product if, at inspection on arrival, the integrity of packaging is found to be deficient due to deliberate tampering. However, the decision to test in other cases where integrity of packaging is deficient or where bags have been reused should be based on a case-by-case assessment. The reason for bag breakages and the number of packages affected should be considered. The options for risk management include: destroy broken bags and contents as quarantine waste if it is due to accidental breakage, or conduct analytical testing.
- 7) Analytical testing should also be applied to a product if the desk audit and/or site audit raises sufficient concern or identifies additional risk of product cross contamination with animal derived material.
- 8) Product may be exempt from testing if the assessment determines that the risk of cross contamination is negligible. Examples include little economic advantage in adding additional protein sources, and sourcing and manufacturing of the product that provide confidence that there is unlikely to be any contamination with animal material. Similarly, testing would not be necessary if all ingredients of animal origin are assessed under the 2012 TSE veterinary therapeutics policy.

### **Stockfeed of animal origin**

- 1) Testing is not applicable to certain approved products which contain ingredients of ruminant origin.
- 2) Note: Examples are animal derived stockfeed from New Zealand for use in poultry/pig rations (includes dairy product). In cases where such ingredients would give a positive result to the test, there is clearly no purpose in requiring the test.
- 3) Testing for the presence of mammalian and avian material is mandatory for product containing fishmeal and other meals of aquatic animal origin if the facility processing and/or storing the product also handles or stores mammalian or avian material.
- 4) Note: Importation should not be permitted if the country also has a 'not approved' BSE status. For all other product, there must be clear evidence, confirmed by both desk audit and on-site audit, that the fish/aquatic product is handled in separate areas and with separate equipment at the processing plant from the mammalian/avian material.
- 5) Testing for the presence of mammalian and avian material is mandatory for product containing fishmeal and other meals of aquatic animal origin (in bulk or bagged) other than fish and other aquatic animal meal products described in section D. Products not requiring site audit or analytical testing. Refer to Appendix C: Tests for the presence of restricted animal material in stockfeed.

### **Stockfeed of plant origin**

- 1) Testing stockfeed of plant origin for the presence of restricted animal material (RAM, i.e. mammalian, avian or fish material) is mandatory if:
  - a) RAM is handled or stored at either the facility processing and/or storing the plant based stockfeed  
  
Note: Importation should not be permitted if the country has a 'not approved' BSE status. Also, there must be clear evidence, confirmed by both desk audit and on-site audit, that animal and plant materials are handled in separate areas and with separate equipment at the processing plant.
  - b) The product has a TSE risk rating of 1 (refer Appendix B: Risk parameters for audit) and the country has a 'not approved' or 'controlled' BSE status



- c) The product has a TSE risk rating of 2 (refer Appendix B: Risk parameters for audit) and the country has a 'not approved' BSE status
- 2) Testing of other plant based stockfeed and related products for the presence of RAM is detailed in section D. Products not requiring site audit or analytical testing and Appendix A: Transmissible spongiform encephalopathy risk matrix and Appendix B: Risk parameters for audit.

### **Multi-ingredient stockfeed and premixes**

- 1) Testing for the presence of RAM of a prepared multi-ingredient stockfeed or a premix is mandatory if one or more of its ingredients is determined to require testing.
- 2) Note: Includes feed additives on a plant-derived or animal-derived carrier; and multi-ingredient products such as fish feed for aquaculture, hatchery or aquariums (bulk or bagged). It excludes premix consisting of stockfeed additives only.

## **C. Site audit of manufacturing and/or export premises will be required in the following circumstances**

A desk audit is undertaken on all applications to import stockfeed and stockfeed ingredients and involves assessment of all information received from the questionnaire and the QA manuals. Depending on the TSE status of the source country and the nature of the commodity to be imported, a site audit of the manufacturing facility and any other associated premises may be required. The TSE risk matrix in Appendix A: Transmissible spongiform encephalopathy risk matrix forms the basis for these requirements. The matrix also incorporates mandatory testing requirements but does not include testing to be applied at the border if integrity of the product is lost. The matrix relates to TSE risk and this TSE stockfeed policy. Additional requirements including site audit may be required under other relevant quarantine import policies for stockfeed and related products.

## **D. Products not requiring site audit or analytical testing**

The following products do not require site audits unless specific concerns are identified in the desk audit. They also do not require analytical testing unless the desk audit, site audit or inspection on arrival identifies specific biosecurity concern.

- 1) The product consists purely of plant meal(s) or whole grain(s) or single-ingredient prepared plant product with low TSE risk rating (refer Appendix B: Risk parameters for audit) which has been produced and stored in dedicated establishments  
and
  - a) bulk packed in containers/holds the cleanliness of which is acceptable to the Department of Agriculture
  - or
  - b) integrity of packaging is confirmed at inspection on arrival.
- 2) The product is
  - a) Fishmeal, derived from whole fish, which has been produced in a dedicated plant that does not process or store other stockfeed ingredients
  - or
  - b) fishmeal prepared as a by-product of fish processing which has been produced in a dedicated plant which does not process or store other stockfeed ingredients

or

- c) unprocessed fish for use as bait or aquaculture feed

or

- d) other aquatic meals (crustacean meal, krill meal) produced in a dedicated plant which does not process or store other animal-derived stockfeed ingredients

or

- e) 100% fish oil or oil of aquatic animal origin with maximum level of impurities of less than 0.15% which has been produced in a dedicated plant which does not process or store other animal-derived stockfeed ingredients.

- 3) The product is, or incorporates, meat meal, meat and bone meal, or blood meal imported from New Zealand under existing import conditions for use in products other than ruminant stockfeed.
- 4) The product is dairy product of New Zealand origin for use in stockfeed.
- 5) The product is, or incorporates product of animal origin that was assessed and approved under the 2012 veterinary vaccine policy (for example, vitamins, amino acids and other veterinary therapeutics for subsequent use as stockfeed additive).
- 6) Fish feed for aquarium use imported in packages less than 5 kg.
- 7) Fish feed imported for aquarium/aquaculture/hatchery use in bags greater than 5 kg if the likelihood of diversion to ruminants is considered negligible based on an assessment of the following:
  - a) The more specialised the feed, the less likely to be diverted (such as formulated for specific target species and stage of development (i.e. age) of the fish).
  - b) Product in larger bags is more likely to be diverted than small bag sizes.
  - c) The product label including the ingredient list should be examined carefully to assess the level of specialisation and to ensure no product of terrestrial animal origin is in the formulation.

## **E. Inspection on arrival and release if documentation and product are satisfactory**

Imported stockfeed represents a potential significant biosecurity risk to Australia for the introduction of a range of pests and diseases due to its direct pathway to animals and agricultural systems in general. All stockfeed requires an import permit and examination of documentation on arrival. Most stockfeed will also require a physical inspection on arrival (see section F. Product released on documentation alone for those not requiring inspection). Thorough examination of documentation and physical inspection of the product on arrival, if required, to ensure compliance with import conditions is critical.

Where inspected on arrival, compliance with the national labelling requirements for stockfeed (i.e. Australian Ruminant Feed Ban (ARFB) National Uniform Rules (NURs)) should be verified prior to release of the product. Refer [Appendix F: National Uniform Rules labelling requirements for NUR labelling requirements](#).

## **F. Product released on documentation alone**

Stockfeed additives derived from synthetic material, highly processed and purified derivatives of fermentation (for example, vitamins, amino acids, minerals), highly refined plant stockfeed

additives and pre-packaged, ready for retail sale pre-mixes need not be subject to physical inspection on arrival and may be released on documentation alone subject to compliance with import permit conditions.

Bulk plant based oils and molasses need not be subject to physical inspection on arrival subject to meeting other pre-determined risk mitigation measures and compliance with import permit conditions. Also, bulk fish oil imported in sealed containers (for example, isotanks need not be subject to physical inspection on arrival providing the department has assessed the likelihood of cross contamination through re-use of containers and applied appropriate conditions to manage this risk.

# Appendix A: Transmissible spongiform encephalopathy risk matrix

Table A1 Transmissible spongiform encephalopathy risk matrix

		Risk category of commodity (see Appendix B)			
		High (1)	Medium (2)	Low (3)	Very low to negligible (4)
Bovine spongiform encephalopathy (BSE) status of country (see Appendix B and Department of Agriculture BSE country list)	Negligible	Desk audit, site audit and analytical tests on a sliding scale may (a) be required based on risk on a case-by-case basis (b)	Desk audit, site audit and analytical tests (a) on a sliding scale may be required based on risk on a case-by-case basis (b)	Desk audit	Desk audit
	Controlled	Desk audit, mandatory site audit and analytical tests on a sliding scale	Desk audit, site audit and analytical tests (a) on a sliding scale may be required based on risk on a case-by-case (b)	Desk audit and site audit and analytical tests (a) on a sliding scale may be required based on risk on a case-by-case basis (b)	Desk audit
	Not approved	Desk audit, mandatory site audit and analytical test on a sliding scale	Desk audit, mandatory site audit and analytical tests on a sliding scale	Desk audit, site inspection and analytical tests (a) on sliding scale may be required based on risk on a case-by-case basis (b)	Desk audit

**a** Site audit and/or analytical testing on a sliding scale (see Appendix D: Sampling plan for testing product for the presence of restricted animal material and corrective action) may be required if on desk assessment the production facility is deemed not to have satisfactory controls over sourcing of products from countries with undetermined bovine spongiform encephalopathy (BSE) status, and manufacturing of the product does not provide confidence that there is unlikely to be any contamination with animal material at the facility (see Risk management measures). **b** See Risk management measures for factors to be considered (for example, use of raw materials are sourced from countries with undetermined BSE status).

**Note 1:** Even if not required by the TSE risk matrix (Table A1), site audit may be required by other biosecurity policies; for example, the 1999 importation of stockfeed of plant origin policy (as reviewed 2011).

**Note 2:** The importation of plant based stockfeed will not be approved if restricted animal material is handled or stored at either the facility processing and/or storing the stockfeed and the country has a 'not approved' BSE status.

**Note 3:** The importation of fish or other aquatic meals will not be approved if mammalian or avian material is handled or stored at either the facility processing and/or storing the fishmeal and the country has a 'not approved' BSE status.

## Appendix B: Risk parameters for audit

The Department of Agriculture’s bovine spongiform encephalopathy (BSE) country list should be used to determine the risk category of the country of origin for the purpose of determining audit requirements.

**Table B1 Bovine spongiform encephalopathy country classification**

Category of country	Country
Negligible	Countries listed as Negligible BSE country status in Department of Agriculture’s BSE country list.
Controlled	Countries listed as Controlled BSE country status in Department of Agriculture’s BSE country list.
Undetermined	Countries with Undetermined BSE status are those not listed as either controlled or negligible BSE status in Department of Agriculture’s BSE country list.

**Table B2 Transmissible spongiform encephalopathy product classification**

Item	Product	End use	TSE risk rating
<b>Feed additives</b>			
<b>Material of animal origin as stockfeed additives</b>			
1	Stockfeed additives of animal origin assessed, approved and imported in accordance with the 2012 TSE veterinary therapeutics policy	Stockfeed	na <b>(b)</b>
2	Stockfeed additives of microbial fermentation (animal-based) origin assessed, approved and imported in accordance with the 2012 TSE veterinary therapeutics policy	Stockfeed	na <b>(b)</b>
3	Stockfeed additives containing animal material as a carrier origin assessed, approved and imported in accordance with the 2012 TSE veterinary therapeutics policy	Stockfeed	na <b>(b)</b>
<b>Material of plant origin as stockfeed additives</b>			
4	Stockfeed additives of microbial fermentation (plant origin)	Stockfeed	very low to negligible
5	Stockfeed additives containing plant material as a carrier – includes corn cob carriers	Stockfeed	low
6	Stockfeed additives of plant origin (purified/refined) (no carrier) e.g. pastes , liquid	Stockfeed	very low to negligible
7	Stockfeed additives of plant origin other than specified in items 4, 5 or 6	Stockfeed	low
<b>Material of mineral origin as stockfeed additives</b>			
8	Minerals (more than 2 metres below ground)	Stockfeed	na <b>(a)</b>
9	Minerals and other residue above 2 metres from ground	Stockfeed	very low to negligible
<b>Material of synthetic origin as stockfeed additives</b>			
10	Stockfeed additives not of biological nor mineral origin	Stockfeed	na <b>(b)</b>
<b>Fishmeal (c)</b>			
11	Fishmeal for aquaculture, aquarium and hatchery use in a dedicated plant which does not process or store other stockfeed ingredients	Aquaculture, aquarium and hatchery use	very low to negligible

Transmissible spongiform encephalopathies stockfeed policy

Item	Product	End use	TSE risk rating
12	Fishmeal for aquaculture, aquarium and hatchery use not in a dedicated plant	Aquaculture, aquarium and hatchery use	low
13	Fishmeal or fishmeal analogue other than as specified in 12 to 15 from any country for stockfeed end use	Stockfeed	high
14	Fishmeal prepared as a by-product of fish processing which has been produced in a dedicated plant which does not process or store other stockfeed ingredients	Stockfeed	low
15	Fishmeal, derived from whole fish, from a dedicated plant which does not process or store other stockfeed ingredients	Stockfeed	very low to negligible
16	Unprocessed fish for use as bait or aquaculture feed	Stockfeed	low
17	Fish oil	Stockfeed	low
<b>Microalgae</b>			
18	Microalgae	Stockfeed	low
<b>Microorganisms as probiotics</b>			
19	Probiotics assessed, approved and imported in accordance with the 2012 TSE veterinary therapeutics policy	Stockfeed	na <b>(b)</b>
<b>Animal material from New Zealand</b>			
20	Stockfeed of NZ animal origin (Includes fishmeal, fish oil, blood meal, meat meal, bone meal, feather meal, dairy products for stockfeed use, dicalcium phosphate (animal-derived), gelatine, etc.)	Stockfeed	very low to negligible
<b>Plant-derived stockfeed and aquaculture feed</b>			
21	Processed root crops commodities including sugar beet pulp products, tapioca pellets	Stockfeed	low
22	Millrun of Australian origin (from Papua New Guinea)	Stockfeed	very low to negligible
23	Palm kernel expeller/copra meal	Stockfeed	low
24	High protein grain-based meal products (e.g. soybean meal, corn gluten meal, cotton seed meal) – Produced in a dedicated facility – Not produced in a dedicated facility	Stockfeed	low medium
25	Highly processed and refined, high protein, grain-derived concentrates (e.g. concentrates produced by further processing and refining of grain-based meals into a concentrate using extensive alcohol or acid wash processes)	Stockfeed	low
26	Other high protein, grain-derived concentrates (e.g. protein concentration based on heat denaturation and water wash process)	Stockfeed	medium
27	High-fibre feeds derived from hulls (i.e. used as roughage substitute or forage extender, e.g. soybean hulls, rice hulls, cottonseed hulls)	Stockfeed	medium

Transmissible spongiform encephalopathies stockfeed policy

Item	Product	End use	TSE risk rating
28	Low/medium protein, processed plant products (e.g. corn gluten feed, linseed meal, peanut meal, safflower meal, other by-product feeds (e.g. screenings, bran, middlings, shorts, and other feed plant based processed by-products not previously covered)) – Produced in a dedicated facility – Not produced in a dedicated facility	Stockfeed	medium high
29	Unprocessed whole grains, dry roughages (e.g. hay), silage, forage crops (leaves, grasses)	Stockfeed	low
30	Brewers/distillers grains and other products derived from plant based fermentation waste	Stockfeed	low
31	Non-land based and other non-crop based products e.g. seaweed	Stockfeed	low
32	Processed multi-ingredient stockfeed of plant origin	Stockfeed	<b>(d)</b>
33	Highly refined plant extracts (chemical extraction)	Stockfeed	very low to negligible
<b>Fish feed for aquaculture, aquarium and hatchery</b>			
34	Processed multi-ingredient fish feeds (pellets) for aquarium, aquaculture, or hatchery use produced in a dedicated plant – containing fishmeal	Aquaculture, aquarium and hatchery use	low
35	Processed multi-ingredient fish feeds (pellets) for aquarium, aquaculture or hatchery use not produced in a dedicated plant – containing fishmeal	Aquaculture, aquarium and hatchery use	high
<b>Other</b>			
36	Herbal supplement from any country	Stockfeed	low
37	Dicalcium phosphate (DCP) – imported in bulk – as stockfeed additive – assessed as per 2012 TSE veterinary therapeutics policy	—	low na <b>(b)</b>

**a** Non-regulated product—desk audit is not required as an import permit is not required. **b** TSE risk is mitigated by compliance with the 2012 TSE veterinary therapeutics policy. **c** Note that there are specific biosecurity requirements for product containing or derived from salmon. **d** Ranking to be per the component/ingredient with the highest risk ranking.

**In addition to compliance with this TSE stockfeed policy, all other biosecurity policies and requirements relevant to the product must also be complied with.**

# Appendix C: Tests for the presence of restricted animal material in stockfeed

## Animal Health Committee has endorsed

- The Agrigen Biotech PCR Assay (Ruminant Screen) as the test for detecting mammalian and avian animal material (bovine, ovine, porcine and avian) in imported fishmeal. Evaluations have demonstrated that this can reliably detect 0.05% bovine, ovine, avian, and porcine tissue with 100% sensitivity but cannot detect piscine material at that level.
- Microscopy as the test for detecting terrestrial vertebrate animal material, poultry material and fish material in imported plant-based stockfeed.

Note: Although the Agrigen Biotech PCR assay has been demonstrated a detection level of 0.05%, the company has advised the Department that the level of reporting used is 0.1%.

## Detection of non-MBM RAM

- Substitution with blood meal or feather meal could be a viable option especially for some high value, high protein plant based stockfeed.
- In addition to striated and cardiac muscle, microscopy screening should also look for the presence of blood clumps, fibrin, leucocytes, keratin and other animal tissues or cellular structure.
- Microscopy may be inadequate to detect RAM in highly processed, purified stockfeed additives and plant extracts. For these products if testing is to be undertaken, PCR Assay remains the preferred detection method.



# Appendix D: Sampling plan for testing product for the presence of restricted animal material and corrective action

## Sampling plan

For product identified in section B under Risk Management Measures of this policy as requiring testing for the presence of restricted animal material:

- In the first instance, every shipment of the product will be subjected to testing at the tightened level for restricted animal material.
- When a sufficient body of evidence shows consistent compliance, the rate of sampling may be reduced.
- This principle follows the 'switching rules' incorporated into the Department of Agriculture's Imported Foods Inspection Programme.
- The rate of sampling for ruminant material will be increased for product of unknown status and history.

Guidelines for the sampling criteria are as follows:

### **Tightened level = 100 % of shipments sampled and tested**

Under the tightened level, each consignment is tested.

Five consecutive passes without detection must be achieved at this level before inspection drops to the normal rate of inspection. This level will apply to consignments of each type of product imported by each importer. Where there are significant changes to management or production parameters at the point of production, the sampling rate will revert to this level.

### **Normal level = 25 % or 1 in 4 of shipments sampled and tested**

Under the normal level of inspection, one in four shipments is tested on a statistically random basis where importations continue on a regular basis.

Twenty consecutive passes must be achieved at this level without a detection before inspection drops to the reduced level of testing.

### **Reduced level = 5 % or 1 in 20 shipments sampled and tested**

Under the reduced level of inspection one in 20 shipments are tested on a statistically random basis where importations continue on a regular basis.

## **Corrective action in the case of a confirmed positive result**

If a positive result for contamination with restricted animal material is confirmed, appropriate follow up action will be instituted. An initial positive result should be confirmed by subjecting the sample to re-extraction and a confirmatory PCR test as well as gene sequencing analysis. The offending consignment will be held and all further consignments will be suspended pending a full investigation, which will involve one or more of the following steps:

- desk audit of the production run including re-assessment of the standard operating procedures
- inspection of the port of import, the commodity and the ship's hold

- assessment of reports from the manufacturer, transporter, agent and/or the Department's inspector
- liaison with the overseas government certifying authority
- visits to the overseas manufacturing facility and government regulatory authority to investigate the likely source of the contamination.

The importer is liable for all costs associated with investigation of a positive result.

In the case of significant deficiencies i.e. those that would suggest other consignments could be similarly affected, or lack of compliance with requirements, the import permit will be revoked.

Any consignment found to be contaminated with restricted animal material will be destroyed or re-exported at the owner's expense.

Release of suspended consignments or reissuance of an import permit will be contingent upon the Department being satisfied that there has been an effective and thorough investigation and that appropriate corrective action has been instituted.

In the case of any positive sample being discovered, the rate of sampling will revert to the tightened level of 100% of shipments until the Department is satisfied that the history of negative results warrants a reduction to the normal level.

# Appendix E: Questionnaire for imported products in relation to transmissible spongiform encephalopathies

Note: This questionnaire is provided for guidance only. Operational areas may wish to adapt it or merge it with relevant questionnaires addressing other biosecurity issues.

## **Production questionnaire for the following imported products in relation to transmissible spongiform encephalopathies (TSEs):**

**Animal feed (stockfeed, stockfeed ingredients, additives, pet and fish food, aquarium, hatchery or aquaculture feed)**

### **Plant-derived fertilisers**

This questionnaire must be completed by the **manufacturer** of the product intended for export to Australia.

This questionnaire must be submitted with the application for a permit to import animal feed or plant-based fertilisers into Australia.

The information collected will be used to determine import conditions for these products.

Please use additional paper, if insufficient space.

### 1) **Where is the product manufactured?** (Please provide name and address of the facility)

Name			
Address			
	City	Country	
	Phone	Fax	

### 2) **Exporter's details**

Name			
Address			
	City	Country	
	Phone	Fax	

**3) Importer's details**

Name			
Address			
	City	Country	Australia
	Phone	Fax	

**4) Has there been any change of ownership or management of the manufacturing facility in the past 12 months?**

Yes     No

(If yes, please provide details)

Name			
Address			
	City	Country	

**5) Name of product(s) to be imported** (Please list all products or attach a list)

1.	4.
2.	5.
3.	6.

**6) List all ingredients in each product and country of origin for each ingredient** (Please list all raw ingredients or attach a list—please include percentages adding up to 100%)

Ingredient	Composition in product %	Origin (animal, plant, microbial, synthetic or chemical)	Country and species of origin
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**7) Are any of the ingredients derived from fermentation?**

Yes     No

If yes, please attach a separate sheet with the following details:

- a list of **all** ingredients of the fermentation broths for each ingredient in the final product
- a list of **all** microorganisms (species) used
- details of the sterilisation of the broth (i.e. temperature and duration) before start of fermentation.

**8) What is the end use (as defined) and target species**

**9) Describe the manufacturing process for the product intended for export**

Attach a flow chart detailing processing of raw material into finished product.

Attach full details of all heat, pressure and/or chemical treatments used during processing i.e. provide both processing temperatures and times and core product temperatures and times for heat treatments; concentration and exposure times for chemical treatments; and pressure and duration times for pressure treatments.

**10) Has the product been heat, chemical and/or pressure-treated?** (If yes, please provide details)

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Yes     No

Minimum processing temperature (°Celsius)	Duration (minutes or hours)
Minimum core product temperature (°Celsius)	Duration (minutes or hours)
Minimum pressure (bars or kilopascals)	Duration (seconds or minutes)
Chemical used Concentration	Duration (seconds or minutes)

**11) What other products does the facility produce?** (Please list all products or attach a separate sheet)

1.	4.
2.	5.
3.	6.

**12) List all raw ingredients for all products manufactured at this facility and the country of origin for each product** (Please list all products or attach a separate sheet)

1.	6.
2.	7.
3.	8.
4.	9.
5.	10.

**13) Provide details of Standard Operating Procedures** (Please attach copies)

1. Receiving of raw ingredients	6. Security
2. Pest control	7. Documentation
3. Cleaning and sanitation including processing equipment, transport vehicles	8. Training
4. Labelling and Packaging	9.
5. Storage	10.

**14) Does the manufacturing facility store or use any products of animal origin (including marine animals and dairy)?** (If yes, please provide details)

Yes     No

**15) If animal proteins are stored or used on site, how are they segregated (kept separate from) other materials?** (Please provide details including copy of the SOP)

- 16) **How are the raw materials transported to the manufacturing facility?** (Please provide details)
- 17) **How is the finished product transported from the point of production to the point of export?**
- 18) **Has the product been transferred in bulk from the production facility and packed into bags/containers at another facility?** (If finished product is packaged at another facility, please complete a separate questionnaire for that facility)  
 Yes     No
- 19) **Is a system in place to protect the product, during and post-production, from contamination with extraneous materials, including soil, faeces, feathers, insects, viable seeds or bark?** (If yes, please describe the system)  
 Yes     No
- 20) **Does the manufacturing facility have a certificate of Good Manufacturing Procedure (GMP) compliance and/or certificates of other Quality Assurance programs (e.g. ISO, HACCP)?** (If yes, please attach photocopies of approval)  
 Yes     No
- 21) **Is the facility inspected and approved by the relevant national or regional government veterinary service or department of animal health or department of agriculture?** (If yes, please attach photocopies of approval)  
 Yes     No
- 22) **Is the facility inspected and approved by an international, independent auditing company?** (If yes, please attach photocopies of approval)  
 Yes     No
- 23) **In what way is the product packaged?**

a.	Packaged in new packaging?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
b.	Packaged in new bags, drums or other retail/bulk packaging?	<input type="checkbox"/> Yes (please specify) ..... kg or litres	<input type="checkbox"/> No
c.	Bulk packed into shipping containers at the production facility?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
d.	Bulk packed into shipping containers elsewhere (not at the production facility)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
e.	Bulk packed directly into the ship's hold	<input type="checkbox"/> Yes	<input type="checkbox"/> No
f.	Other (please specify):		

- 24) **Is the product ever stored at any location other than at the manufacturing facility and the wharf at the point of export?** (If yes, please provide details)  
 Yes     No
- 25) **Attach a sample copy of the product label or tag (if applicable).**

## **Manufacturer's declaration**

**I declare that the information I have provided in this questionnaire is true and accurate to the best of my knowledge.**

**Signature:** \_\_\_\_\_ **Printed name:** \_\_\_\_\_

**Position:** \_\_\_\_\_

**Company name:** \_\_\_\_\_

**Country:** \_\_\_\_\_

**Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

# Appendix F: National Uniform Rules labelling requirements

The ruminant feeding ban including appropriate labelling of product is a critical biosecurity risk mitigation measure for TSEs, especially BSE.

In line with the Australian Ruminant Feed Ban (ARFB) National Uniform Rules (NUR) and in accordance with all state and territory legislation, all stockfeed sold that contains restricted animal material (RAM) must include the following label warning:

**–This product contains restricted animal material–**

**DO NOT FEED TO CATTLE, SHEEP, GOATS, DEER OR OTHER RUMINANTS**

All stockfeed sold not containing RAM must have a negative RAM statement on the label as follows:

**This product does not contain restricted animal material**

Restricted Animal Material (RAM) is any material taken from a vertebrate animal other than tallow, gelatine, milk products or oils. It includes rendered products such as blood meal, meat meal, meat and bone meal, fish meal, poultry meal, feather meal, and compounded feeds made from these products.

'Label' means a label attached to, or printing directly onto, a container or package, or for loose bulk feed a delivery docket or invoice (if the invoice is delivered with the bulk feed).