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IMPORTATION OF STOCKFEED AND STOCKFEED INGREDIENTS - RISK MANAGEMENT MEASURES FOR SPONGIFORM ENCEPHALOPATHIES (TSE's)

Purpose

This paper discusses measures that Biosecurity Australia believes are necessary to manage the risk of introduction into Australia of Transmissible Spongiform Encephalopathies (TSEs), in particular Bovine Spongiform Encephalopathy (BSE), in imported stockfeed and stockfeed ingredients. The scope of this paper includes:

- products imported for deliberate use in stockfeeds (including fish feeds)
- products which are imported for other uses but which may be diverted to stockfeeds eg
 - blood meal
 - dairy products
 - meat meal

The likelihood that imported stockfeed or stockfeed ingredients may contain animal-derived materials¹ are examined and recommendations are made for appropriate risk management measures for the various classes of stockfeeds and stockfeed ingredients imported into Australia.

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 and milk). 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 fish meal, is currently only permitted from New Zealand.

Australia's approach to preventing the entry of the BSE infectious agent includes strict controls on the importation of plant-based stockfeed materials to ensure that they do not contain materials derived from animals.

¹ Although this document refers throughout to risks associated with "animal-derived materials" in stockfeeds, the prime objective of risk management measures is to target materials of ruminant origin, since ruminants are the prime source of prion infectious agents.

There are sound reasons for pursuing these requirements. In the period up to 1996, potentially BSE-contaminated 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, may experience cases in the future. 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 BSE risk, such as stockfeeds and stockfeed ingredients.

Types of products imported

Australia has conditions for importation of processed stockfeed of plant origin and imports a range of stockfeed ingredients as shown in Table 1.

Table 1. Stockfeed ingredients imported in recent years

| Product | Recent Permits | Imported from |
|---|---|---|
| Range of plant meals from USA, Canada and NZ | 14 in 2 years | USA |
| Palm kernel expeller /copra meal from South Pacific Commission countries | 20 in 2 years. | PNG, Vanuatu, Solomon Islands, NZ, Marshall islands |
| Millrun of Australian origin from PNG or the Solomon Islands | 5 in 2 years | PNG |
| Plant based stockfeed pellets from New Zealand | 2 in 2 years | NZ |
| Avian blood meal from NZ | 1 in 2 years | NZ |
| Bloodmeal, meat meal, bone meal (ovine, bovine, caprine or cervine) of New Zealand origin | Nil in 2 years | |
| Dairy products from NZ for stockfeed use | 9 in 2 years | NZ |
| Fishmeal for various end uses | 66 in 2 years, of which 27 were for stockfeed use, others fish and pets | Ecuador, Peru, Fiji, New Zealand, Chile, and PNG |
| Processed stockfeed of plant origin from all countries | 1 | Indonesia |

Pathways by which animal-derived materials could enter Australia

Prior to entry into Australia, stockfeed or stockfeed ingredients could be exposed to animal-derived material 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

Each of these points is discussed below.

1 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. The likelihood of contamination of such materials may be greater if they are subject to storage or processing in proximity to MBM or materials containing MBM and where cross contamination may occur.

Plant meals are often produced in establishments dedicated to the production of that particular product. Other ingredients including animal-derived materials are not used on the establishment. In cases where there are no MBM materials used or stored on the production plant nor in storage areas, there is negligible risk of MBM contamination of the material.

Fish meal may be produced in establishments that are dedicated to the rendering of fish products only. In other cases, fish meal may be produced in establishments that also render other animal-derived materials. There are also plausible but unsubstantiated reports that fish meal may occasionally be adulterated by the addition of a small proportion of meat meal which is cheaper than fish meal but cannot easily be detected. These pathways of possible contamination indicate that the risk of contamination of fish meal should be the subject of appropriate risk management measures.

2 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 may be produced in a dedicated establishment which is never likely to have MBM or stockfeeds containing MBM 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 MBM, 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 MBM is used or stored, should be subject to appropriate risk

management measures. This would include all processed prepared stockfeeds, which incorporate multiple ingredients.

3 Contamination during packaging

Where stockfeed or stockfeed ingredients are enclosed in sealed packages such as new plastic bags, there would be no further opportunity for contamination unless the package were broken. Appropriate packaging at the point of production is an effective means of ensuring against subsequent contamination.

4 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.

5 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 and palletised would not be subject to any significant risk of contamination. However, product that is bulk packed into the container or into the hold of a ship could be contaminated by residues of 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 BSE risk are not carried on the particular ship/hold/container in question. Where such measures are not feasible however, an opportunity exists for contamination with MBM and risk management measures are warranted.

Risk management measures

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

The approach to risk management for stockfeeds and stockfeed ingredients should be based on an assessment on a case-by-case basis. The steps involved are assessment of:

- the type of product is involved
- the nature of operations in the processing establishment(s)
- packaging of the product
- transport to the point of export
- the nature of storage on board vessels for export
- cleanliness of containers/trucks/holds

It is proposed that this information be collected through a questionnaire, which would be completed by prospective exporters before issuance of an import permit. A model questionnaire is at Annex 1.

The options for risk management for TSEs with respect to importation of stockfeeds and stockfeed ingredients include:

- A. refusal of an import permit;
- B. requirement for analytical testing (using a test approved by the Australian Quarantine and Inspection Service (AQIS) - see Annex 2) on arrival but before release from quarantine to confirm the absence of MBM in the final product. A structured sampling plan should be adopted in line with Australia's Imported Food Inspection Program (see Annex 3);
- C. inspection of manufacturing and/or export premises
- D. inspection on arrival and release if documentation and product are satisfactory.

None of the recommendations shown here should impede the imposition by AQIS of discretionary inspection activities, including random sampling and testing, establishment inspection or desk audits.

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. A permit should not be issued if:

1. there is insufficient information to ascertain the nature of the product and the nature of production, processing and transport; or
2. there is significant uncertainty about the likelihood of contamination of the product based on laboratory results on prior shipments.

B. Analytical testing for animal-derived materials should be required in any of the following cases²:

1. the product is a prepared stockfeed or a mixture of ingredients from any source country; or
2. the product contains fish meal; or
3. the material is transported in bulk and the cleanliness of containers or ships holds before export cannot be guaranteed to the satisfaction of AQIS eg through a pre-approved arrangement; or
4. the material is transported in bulk but at inspection on arrival, the cleanliness of containers/holds is not confirmed; or
5. the material is packaged but is packed in other than new and unused bags; or
6. at inspection on arrival, the integrity of packaging is found to be deficient.

C. Desk audit or inspection of manufacturing and/or export premises should be required in the following circumstances:

1. A desk audit involves looking at all information received from the questionnaire and the quality control manuals. Depending on the TSE status of the source country and the nature of the commodity to be imported, a physical inspection may not be required. The following table forms the basis for these requirements.

| | | Category of commodity (See Annex 4) | | |
|--------------------------------------|---|--|--|--|
| | | A | B | C |
| Category of country (See Annex 4) | A | Mandatory inspection | Desk audit and inspection likely | Desk audit and inspection if appropriate |
| | B | Desk audit and inspection likely | Desk audit and inspection if appropriate | Desk audit |
| | C | Desk audit and inspection if appropriate | Desk audit | Desk audit |

² Certain approved products may intentionally include ingredients of ruminant origin. Examples are stockfeeds from New Zealand for use in poultry/pig rations or stockfeeds that include dairy products such as colostrum. In cases where such ingredients would give a positive result to the test, there is clearly no purpose in requiring the test.

D. Product may be released after passing inspection on arrival if:

1. the product is a single ingredient plant meal which has been bulk packed in containers/holds the cleanliness of which is acceptable to AQIS; or
2. the product is a single ingredient plant meal which has been packed in new plastic bags and the general integrity of packaging is confirmed at inspection on arrival; or
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 stockfeed; or
4. the product is dairy product of NZ origin for use in stockfeeds; or
5. it has been tested and has passed all relevant requirements.

QUESTIONNAIRE FOR USE WITH IMPORTED STOCKFEEDS AND STOCKFEED INGREDIENTS

This questionnaire should be completed and submitted with the application for a permit for import any stockfeed or stockfeed ingredient into Australia. The information is intended to help convey to AQIS staff just what is in the product, where and how it is produced, how it is transported from the production establishment to the point of export, and how it is packed on board ship.

Name of exporter:

Exporting country:

Name and address of importer:

Name of Australia-based contact person for importer:

Phone:

Fax:

Product to be imported:

List all raw ingredients in this product?:

Where is the product produced?:

Address of establishment:

What other products does the establishment produce?:

List all raw ingredients for all products produced at this establishment:

What means of transport is used to transport the product from the point of production to the point of export?:

In what way is the product packed:

- 1 packed in bags that are new and unused in kg sizes, then shipped in shipping containers
- 2 bulk packed into shipping containers at the production establishment
- 3 bulk packed into shipping containers elsewhere
- 4 bulk packed directly into the ship's hold
- 5 other (please specify):

Is the product ever stored at any location other than at the production establishment and the wharf at the point of export? (if so, give details):

Does the producing establishment have a Quality Assurance scheme that has been approved by AQIS? (Please attach photocopy of approval):

Polymerase chain reaction (PCR) test for ruminant material in stockfeed

The Australian Government Analytical Laboratories (AGAL) has developed a test capable of detecting low levels of ruminant DNA in animal feeds. The test is based on polymerase chain reaction (PCR), a technique for amplification and detection of DNA. In this application, the PCR technique is used to detect the DNA present in ruminant material. Confirmatory studies indicate that ruminant material, including meat meal, which has been denatured by heat during rendering processes, can be consistently detected in animal feed at an adulteration level at least as low as 0.5% by weight. DNA from other sources does not trigger a false positive result.

Gene sequencing can be conducted on samples that show measurable amounts of animal material, to confirm the species of origin of the DNA detected.

SAMPLING PLAN FOR TESTING AND CORRECTIVE ACTION

In the first instance, every shipment of the product will be subjected to testing. When a sufficient body of evidence shows consistent compliance, the rate of sampling may be reduced. This principle follows the "switching rules" incorporated into AQIS's Imported Foods Inspection Programme. The rate of sampling for ruminant material will be increased for product of unknown status and history. The criteria will follow the following guidelines:

Tightened level = 100 % of shipments sampled and tested.

Under the tightened level, each consignment is tested.

Five consecutive passes must be achieved at this level before inspection drops to the normal rate of inspection.

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

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

Twenty consecutive passes must be achieved at this level 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 ruminant 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 or AQIS inspector;
- liaison with the overseas government certifying authority;
- visit to the overseas manufacturing facility and government regulatory authority to investigate the likely source of the contamination.

In the case of significant deficiencies or lack of compliance with requirements, the import permit will be revoked.

Any consignment found to be contaminated with ruminant derived 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 AQIS 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 AQIS is satisfied that the history of negative results warrants a reduction to the normal level.

RISK MATRIX

| Country | Category of country |
|--|----------------------------|
| Countries with Geographical BSE Risk ³ (GBR) category III or IV | A |
| Countries with GBR Category I or II but questionable veterinary control | B |
| Countries with GBR Category I or II and a high level of veterinary control | C |

| Commodity | Category of commodity |
|---|------------------------------|
| Fishmeal for various end uses | A |
| Bloodmeal, meat meal, bone meal (ovine, bovine, caprine or cervine) products of NZ origin | B |
| Dairy products from NZ for stockfeed use | B |
| Processed fish feeds from all countries | B |
| Processed stockfeed of plant origin from all countries | B |
| Avian blood meal from NZ | C |
| Millrun of Australian origin from PNG or the Solomon Islands | C |
| Palm kernel expeller/copra meal from South Pacific Commission countries | C |
| Plant based stockfeed pellets from NZ | C |
| Range of plant meals from USA, Canada and NZ | C |

³ Category I and II countries are highly unlikely or unlikely to present a BSE risk (see http://www.europa.eu.int/comm/food/fs/sc/ssc/out243_en.pdf). Category III and IV countries are likely or confirmed to have BSE present. The system of categorisation of BSE status of countries is in a state of flux and certain countries have not been categorised at all. AQIS and other Australian authorities may deem a country to be within one of the categories shown here based on the information at their disposal.