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ATTACHMENT B

ABPM 2002/43 - Importation of Stockfeed and Stockfeed Ingredients - Risk Management Measures for Transmissible Spongiform Encephalopathies (TSEs) -

Stakeholder Comments

Animal Biosecurity Policy Memorandum (ABPM) 2002/43 was circulated to stakeholders on 5 September 2002. It included recommendations for appropriate risk management measures for the various classes of stockfeeds and stockfeed ingredients imported into Australia to address the risk of TSEs. The following is a summary of the pertinent technical comments made in response to the discussion paper circulated with ABPM 2002/43.

Many of the comments have been incorporated into the revised paper on risk management measures.

General comments

Various suggestions to clarify/amend:

- the purpose and scope of the document,*
- that the paper is concerned with TSE risks only and that risk assessment measures and testing requirements to address other pest and disease concerns are not covered*
- widening the scope of questions in the questionnaire to obtain fuller information on the product proposed for importation*
- the table titled "Types of Products Imported" which needs expansion*
- the risk matrix in Annex 4 to reflect the range of products imported*

In cases where there is a mixture of just two whole grains in a product, this is equivalent to the "single ingredient plant meal" and analytical testing is not justified.

In cases where physical site visits have already been undertaken and processes well documented, the information should be taken into account in the assessment of the product.

Meat and bone meal is not generally transported in bulk (ie in the ship's hold) so this possibility is very unlikely. Meat and bone meal may however be transported internationally in containerised form.

Biosecurity Australia's Response: Biosecurity Australia notes the above general comments and has incorporated them into the revised paper as appropriate.

Fish meal

We should differentiate "fish meal" into several different products depending on the source of ingredients. Processed aquaculture feeds come in many forms to fill a variety of applications and should not be bundled under the heading "stockfeeds" or "bulk fish meal". Each form should have specific import conditions.

The Australian domestic aquaculture feed industry includes mammalian protein in its own fish and shrimp feeds.

The global aquaculture feed industry rejected the inclusion of MBM more than four years ago, recognising consumer resistance to fish fed a diet that contained land animal proteins; it is only the Australian aquaculture feed industry that continues to include MBM. The risk of BSE infectious agent being present in processed imported aquaculture feeds needs to be assessed before any further risk management measures are enforced.

Biosecurity Australia's Response: These issues to do with fish meal and aquaculture feeds are noted and considered further in the revised paper.

Delays for vessels and holding of bulk loads

It is not operationally possible to unload bulk containers prior to testing at the port, nor is it operationally feasible to delay the movement of vessels for testing while the stockfeed product remains on the vessel. An option might be to allow sampling of the product either prior to, or immediately after, loading by a competent authority in the exporting country.

It is commercially unviable and impractical to detain a vessel for a matter of days for test results. Once the product is discharged, there are major logistical implications if a positive result is found. Appropriate risk management measures need to be implemented at the point of origin and not the destination.

Biosecurity Australia's Response: Biosecurity Australia considers pre-export sampling of product is not a practical option. Firstly, the majority of products of this nature would not require testing under the provisions of the paper because they are inherently low risk products. Secondly, the nature of production for these bulk products and the sampling technique would ensure that virtually all such samples would give a negative result to the PCR test for ruminant DNA in any case. Post-loading contamination is the only likely source of any possible contamination with animal derived materials. The risk of contamination during loading or transport can be and is managed by AQIS on arrival as a matter of routine. If AQIS is not satisfied that ships' holds or containers are clean and there is a risk of contamination with animal derived materials, post arrival testing will be required irrespective of whether pre-export testing has already been done.

New Zealand's BSE status

Ruminant materials of New Zealand origin: Given the history of importation into NZ of dairy cattle "blood stock" from EU Member States, it would seem that any ruminant by-products from any origin should be considered a far higher risk than fish meal.

Biosecurity Australia's Response: Like Australia, New Zealand has a Geographical BSE Rating (GBR) of 1 for BSE. NZ is also unique amongst our trading partners in terms of our knowledge of its animal health status and the degree of cooperation and contact between our

respective animal health authorities. There is therefore no reason to alter Biosecurity Australia's assessment.

Impact of the measures

It is necessary to provide a more detailed assessment of the potential impacts on the sectors of the industry that are most likely to be affected significantly by the program. Although a system of accreditation is identified in the report, no measures to reduce the burden of the testing and inspection protocol are proposed to support the program.

Biosecurity Australia's Response: The risk assessments inherent in this paper attempt to categorise different products and different manufacturing situations. Higher risk products will attract more costs in terms of inspection and testing than low risk products. Although an assessment of impact on various industry sectors is desirable, the risks associated with BSE are such that the stated risk management measures are essential.

There should be consideration of new industry entrants. In its current state, the sampling plan would unfairly burden new industry entrants.

Biosecurity Australia's Response: Biosecurity Australia acknowledges this may be the case, however, the sampling plan is designed to address the quarantine risks and the best way to do this is to have 100% inspection until there is sufficient information on the product in question. Of course, not all products will require analysis.

The PCR test for ruminant DNA

The problem of possible false positive results from the PCR test for ruminant DNA.

Biosecurity Australia's Response: All presumptive positive results will be subject to confirmation as outlined in the paper.

The sampling rate should be 100% of shipments at all times.

Biosecurity Australia's Response: Biosecurity Australia considers 100% inspection as unnecessary. If a particular product is found to be consistently compliant, it is regarded as wasteful of resources to continue to test 100% of consignments. Such a product is clearly low risk. The risk management measures and the sampling plan are designed to match the level of risk.

Microscopy should be accepted as a testing method as in the UK (used in conjunction with ELISA). The turn around time for testing is a potential cost burden. Rapid assays such as ELISA should be considered for future use.

Biosecurity Australia's Response: Biosecurity Australia's experience and research suggest that ELISA tests currently available in Australia and the microscopy used in the UK is of insufficient sensitivity for application in this program. However, a suitable alternative test procedure would be considered if were shown to be of adequate sensitivity and specificity.

The PCR test is not sufficiently sensitive. It does not appear to detect porcine or ovine blood meal mixtures.

Biosecurity Australia's Response: The PCR test is highly sensitive for ruminant DNA. Porcine DNA would not be expected to give a positive result in this test. Similarly ovine blood meal would be expected to have a lower threshold for positive results because of the lower DNA content of blood as compared to muscle.

Clarification is required whether there is zero tolerance for ruminant material or whether trace amounts will be permissible.

The PCR test should be verified as accurate and repeatable for use in import testing. Lack of NATA accreditation of the test lessens its credibility.

Biosecurity Australia's Response: It should be noted that the PCR test is not a quantitative assay. It is a test for the presence or absence of ruminant DNA. The cut-off value of the test parameters have been set such that stockfeed spiked with 0.5% meat meal of ruminant origin has a 95% chance of giving a positive result. The test can be expected to detect a lower level of contamination but with a lower likelihood of giving a positive result.

Site inspection and audit

For country categories A and B, all lots of imported feeds should be subject to sampling and testing.

Biosecurity Australia's Response: The matrix pertains to site inspection and audit, not to the decision whether analytical testing is required. The latter is covered under paragraph B of the section headed "Risk Management Measures".

There should be a mandatory inspection of the production establishment in addition to random auditing.

Biosecurity Australia's Response: In higher risk cases, mandatory inspection and audit applies. Given the range of products under consideration as well as requirements as currently practised, Biosecurity Australia considers that the need or otherwise for inspection/audit aligns with the risks posed by a particular product and that this scaling approach is consistent with Australia's conservative approach to quarantine risk management.

Other issues raised

A high ALOP must be provided due to the public health and trade consequences of BSE.

Biosecurity Australia's Response: The appropriate level of protection (sometimes referred to as the acceptable level of risk) does not pertain to any particular product or disease. By definition, it cannot be raised or lowered according to circumstances. Australia maintains a very conservative approach to quarantine risk management.

There should be a requirement for each consignee to provide evidence of suitable trace forward and trace back procedures.

Biosecurity Australia's Response: A requirement for tracking of buyers of imported stockfeed already applies to processed stockfeed of plant origin. There is insufficient

justification to extend such a requirement to other products. The paper covers a very wide range of materials.

Indonesia should be included as a country with a risk of BSE owing to its history of importation of MBM from the UK. It should be assumed that meat meal was fed to ruminants.

Biosecurity Australia's Response: The requirements and testing are designed to ensure the stockfeed is free of animal material. While Biosecurity Australia acknowledges that Indonesia did import potentially suspect MBM up to 1996, there is no evidence that it was fed to ruminants. Furthermore, there is negligible likelihood that BSE, if it did gain entry to Indonesia, could have been circulated to cause indigenous cases because there are no ruminant rendering plants in Indonesia.

The questionnaire refers to Quality Assurance but should specify a Code of GMP.

Biosecurity Australia's Response: Each case will be judged in terms of Quality Assurance measures that are relevant to the quarantine risks.