Report Cover Page

ACERA Project

ACERA Project 1101F - Biologicals

Title

Relative Risk of Different Categories of Imported Biological Products of Animal Origin.

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Summary

This report addresses the first of three components of ACERA Project No 1101F, being a review of the relative risk of different categories of imported biological products of animal origin, with recommendations for appropriate risk management measures for each category. This report

- provides a brief background to the project, and to the development of biosecurity conditions for biological products.
- reviews the biosecurity conditions for biological products as they currently exist, and
- categorises biological products by risk level and perceived effectiveness of current risk management measures.

The report found that in general, import conditions were managing biosecurity well. Where problems were occurring, the review identified six main causes of concern, which either alone or in combination, contributed to the majority of the identified problems.

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Glossary

AB	Animal Biosecurity
ACERA	Australian Centre of Excellence for Risk Analysis
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
BIP	Biological Imports Program
CFIA	Canadian Food Inspection Agency
Compartment	an animal subpopulation contained in one or more establishments under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade.
DAFF	Department of Agriculture, Fisheries and Forestry (also incorporates references to AQIS – the Australian Quarantine and Inspection Service).
FMD	Foot and Mouth Disease
HPAI:	highly pathogenic avian influenza.
IBD	infectious bursal disease
ICON	the DAFF Import Conditions database. Available on internet. (http://www.aqis.gov.au/icon32/asp/ex_querycontent.asp)
in-vitro use	use other than in living animals
in-vivo use	use in living animals.
IRA	Import risk analysis
OIE	Acronym for The World Organisation for Animal Health. Website: *www.oie.int*
QC1(2,…etc)	Quarantine Containment Level 1(2,…etc)
SPF eggs	specific pathogen free eggs.
TGA	Therapeutic Goods Administration.
USDA	United States Department of Agriculture

Zone	a clearly defined part of a territory containing an animal subpopulation with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade.

Executive summary

This report addresses the first of three components of ACERA Project No 1101F, being a review of the relative risk of different categories of imported biological products of animal origin, with recommendations for appropriate risk management measures for each category.

This report

- provides a brief background to the project, and to the development of biosecurity conditions for biological products.
- reviews the biosecurity conditions for biological products as they currently exist, and
- categorises biological products by risk level and perceived effectiveness of current risk management measures.

For the purposes of this report, biological products *include animal or microbial derived products such as foods, therapeutics, laboratory materials, and vaccines*. (DAFF, 2007).

The report does NOT constitute a formal risk assessment as defined by the OIE. Conclusions reported here are based on the perceived risk arising from the import of biological products as discussed with experienced DAFF officers during the process of the review. As such, the outcomes reported here should be considered as providing an indication of the categories of biological products that should receive priority for allocation of resources for more formal and in depth review.

Review Outcomes

The review considered the range of products currently referred to as 'biological products'. These are shown in the Table at page 3.

The review found that existing biosecurity conditions for biological products were generally satisfactory. Where problems were identified, they could generally be attributed to one of a number of underlying causes. These were:

1. Problems associated with the current over reliance on Manufacturer's Declarations. These problems could be largely solved by revising the use of such documents in line with the recommendations in a separate report within this project (ACERA, in preparation).
2. Problems associated with the different risk presented by different intended end use of imported products. While it is true that the risk presented by a product can differ greatly depending on its intended end use, it is equally true that there are considerable difficulties involved in enforcing end use conditions on imported products, especially once they have been on-sold by the importer. Possible solutions to this problem include treating all imported goods to manage the risk posed by the most risky end use, or a review of the mechanisms for imposing enforceable end use conditions. The former is considered to be overly restrictive in many cases, but may be appropriate for some types of goods. The separate end use part of the ACERA Project may assist with suggestions for improving the control of end use and therefore assist in progressing the second option.

3. Problems arising from the increased likelihood that products imported in bulk are more likely to be diverted to alternative end uses than are products which are imported in finished, consumer ready form. Formal consideration of the effect of final packaging on this likelihood could lead to packaging being used as an appropriate risk management measure. Conditions applied to products packaged in a final form for use by consumers may be subject to different conditions to those applied to bulk imports.
4. Problems associated with categorising products into broad and loosely defined groups (e.g. dairy products, eggs and egg products) and treating all products in the group similarly. This inevitably leads to a situation where 'average' import conditions are applied, resulting in over-regulation of some relatively safe products and under regulation of other, riskier products.
5. Problems arising from reliance on 'dilution' of risk material in composite products to an arbitrary level, which is not supported by scientific evidence. Examples include the 5% rule for meat content in meat flavours, and the 10% rule for dairy and egg ingredients in composite products containing these ingredients.
6. Problems arising from the current system of DAFF approvals of various exporting countries, processing plants, processes, etc. It appears that there should be a review of the formal process of approvals, and of the maintenance of lists of approved premises/processes etc.
7. Problems arising from the continued use of old, existing import conditions, where changing circumstances indicate that review is required.
8. Problems arising when risk management measures are applied in some commodities but not in other commodities eg use of audits to verify manufacturing processes are not applied to all high risk commodities.

The results of the product by product review are set out in the body of the document, commencing at Page 20, and are summarised in tabular form at Appendix 2.

Manufacturer's declarations

The problems associated with the use of manufacturer's declarations are addressed in detail in a separate report within this project (ACERA, in preparation). This review highlighted that MDs were a source of concern, particularly in relation to meat flavours (page 26), egg products (page 32), dairy products (page 32), fertilisers (page 37), and aquaculture feeds (page 49). Other products where MDs are used, but where concerns are less serious, include canned retorted meats (page 24), retorted egg products (page 31), manufactured goods containing feathers (page 39), and highly processed synthetic drugs (page 42). Conditions for these products should be reviewed with particular reference to the issues raised in the separate report on use of manufacturer's declarations referred to above.

Biological products considered in the review.

Broad group	Sub-group	Product
Food products for human consumption		Kopi luwak
		Birds' nest products
	Seafood products	Finfish for human consumption
		Prawns
	Eggs & egg products	Retorted egg products
		Spray dried egg powders
		Products containing less than 10% egg
	Dairy products	Cheese
		Products containing less than 10% dairy
	Meat products	Canned retorted meats
		Uncanned chicken meat
		Uncanned pig meat
		Uncanned meat other than chicken or pig meat
		Meat flavours
		Casings
	Eggs and egg products	Retorted egg products
		Spray dried egg powders, egg pasta mooncakes
		Products containing less than 10% egg
	Dairy products	Cheeses
		Retorted dairy products
Cosmetics		Finished consumer-ready products
Soil & water samples		
Fertilisers		Chemical fertilisers
		Fertilisers derived from animal wastes
Hides, skins, feathers & wool		Hides & skins
		Feathers
		Wool
Therapeutic products		Human therapeutics
		Veterinary vaccines and master seeds
		Veterinary therapeutics (non-vaccines)
Laboratory materials		Catalogues
		Culture media
		Micro-organisms
		Diagnostic kits
Specific pathogen free (SPF) eggs		
Bioremediation agents		
Enzymes		
Animal feeds		Petfood
		Livestock feeds
		Stockfeed supplements

End use concerns

Biosecurity concerns can increase considerably when imported biologicals are used for purposes other than those for which they were originally intended. This commonly occurs when products imported for human consumption are diverted to use as stock feeds or for other purposes, or where human therapeutics which have been approved on the basis of a TGA assessment are used to treat animals. For example, milk powders can be diverted for use in supplementary feeding of calves, or prawns for human consumption can be diverted to use as bait or aquaculture feed.

Similarly, microorganisms and other laboratory materials such as culture media that are permitted entry for *in vitro* use only may be diverted to *in vivo* use, resulting in much increased risk. A separate part of the Biologicals Project (ACERA, in preparation) is specifically looking at end use issues in relation to laboratory materials in particular, and the outcomes of that part of the project will be valuable in assessing the seriousness of these concerns.

The regulatory enforcement of end use conditions is difficult in cases where the imported product has been released from quarantine, and the product has been passed on from the importer to another entity, which then uses the product in a manner not envisaged when the import conditions were set. Further review of the legislative options for end use control is warranted.

Packaging issues

Many products which are imported for human consumption pose little biosecurity risk provided that they are ultimately consumed by humans. This is because any exotic disease organisms which may be present in the product are destroyed during the preparation of the food, or are unable to survive and multiply in a human host. Therefore, if consumed by humans, these products are unlikely to be exposed to susceptible hosts.

Problems may arise, however, from the increased likelihood that products imported in bulk are more likely to be diverted to alternative end uses than are products which are imported in finished, consumer ready form. For example, a bulk consignment of milk powder which was imported for human consumption, but was no longer fit for that purpose, may be diverted to use in formulating a ration for calves, lambs or other livestock, resulting in an increased risk of exposure to susceptible animals. A similar quantity of milk powder, but imported in consumer ready form for human consumption, would likely be uneconomical to unpack, and would therefore be less likely to be diverted to this use.

Broad groupings of products

The import conditions for 'products containing dairy' and egg pasta and noodles are examples of product groupings that cover a wide range of products with an associated wide range of perceived risks.

Some of these products are highly processed so are unlikely to be contaminated with infectious material, and are intended for human consumption, so are unlikely to be exposed to susceptible animals in any case. These are therefore unlikely to justify a high risk rating. Other products may be less highly processed and some of these may be diverted to uses other than human consumption for a variety of reasons, increasing the likelihood of exposure, especially when imported in bulk rather than in consumer ready form.

As a result there is a perception that some such products are over regulated, while others are less well controlled. This leads to frustration from importers, who regularly request special consideration for products based on their belief that the product is being over regulated. This in turn leads to excessive resource use in dealing with these requests, and potentially to a degree of 'policy creep' without necessarily receiving the level of consideration required.

Review of import conditions for these broad categories of products would hopefully lead to greater consistency, decreased regulatory interventions and less intensive resource demands.

'Dilution' rules

The review identified a number of instances where dilution of a potentially risky ingredient with other materials in a composite product was considered sufficient to reduce the risk posed by the composite product to a safe level. Examples of commodities where this occurs are meat flavours, dairy products and products containing dairy, and products containing egg such as egg pasta or noodles. Retorted, shelf stable meat products containing less than 5% by weight of meat, goods containing less than 10% by weight (other than added water) of dairy products, and goods that contain less than 10% by weight (other than added water) of egg or an egg product, are all permitted entry into Australia without the need to obtain a permit (Australian Government, 2012).

While it is true that a product with a lower proportion of risk material in the raw materials used in its production is less likely to contain an infectious dose of a disease agent, the factors influencing the degree of risk reduction are complex (see page 27). However, the levels which are currently used to differentiate between more and less risky products are largely arbitrary. No supporting scientific evidence for the 5% level of meat in meat flavours, or the 10% level used for dairy or egg products was able to be found.

These concerns are exacerbated by the fact that a manufacturer's declaration is often the only evidence that a product contains less than a specified cut off value of risk ingredients in its composition. Tests to confirm the percentage composition of these goods are either not available or difficult to interpret due to the lack of clear definition of how the composition is to be measured.

Despite these concerns, no disease incursions have been attributed to biosecurity breakdowns arising from the importation of these products. It is difficult to know whether this is due to the percentage cut–off values, to other factors such as the effect on pathogen survival of the processing of the products, or the low likelihood that these products for human consumption will be exposed to susceptible animals.

It may be timely to review the percentage composition limits to ensure that they remain appropriate to current needs.

DAFF approvals

There are many instances where existing import conditions refer to countries, processes, or premises etc. being 'approved by' DAFF, or the Director of Quarantine. In many such cases, it is not clear what formal processes for obtaining approval exist, or what mechanisms are used to maintain lists of such approvals. If formal approvals do not exist, it may jeopardise future enforcement actions in cases where goods are imported other than in accordance with conditions. It would be prudent to review all cases where import conditions refer to such 'approvals' and ensure that appropriate systems are in place to gain approval, and to maintain records of approvals that have been granted.

Old conditions

The review identified two cases in particular where current conditions are based on old or out-dated, pre-existing conditions.

The import conditions for eggs and egg products where considered to be in need of review some years ago, and a formal IRA was commenced with a view to updating the conditions for this group of products. Similarly, import conditions for dairy products were considered to be in need of review. For a variety of reasons, these IRAs has not been progressed. Completion of these import risk analyses, whether by a formal IRA process or as a series of reviews of smaller groups of products, would greatly assist in reducing avoidable demands on Departmental resources, by providing clearer guidance to assessing officers and therefore minimising the need for case-by-case review of permit applications relating to eggs and egg products, or dairy and products containing dairy.

The review also found that a significant number of aquatic products had not been the subject of specific import risk analyses. A large number of previously unrecognised aquatic pest and disease organisms have been discovered in Australian waters over the past few decades. Whether this is due to an increased level of awareness and scrutiny leading to recognition of pests and diseases that have been present for some time, or whether it is due to unwitting introduction of these pests and diseases through imports of aquatic animals and aquatic animal products is unknown. It is likely to be a combination of both. The development of risk analyses for aquatic products that have not already been considered should be considered a priority.

Recommendations

A total of 30 Recommendations resulted from the review. These are presented below in isolation. Further discussion relating to each recommendation can be found in the body of the report.

Recommendation 1

BIP should consider consulting with DoHA to ensure that they have no human health concerns in relation to kopi luwak.

Recommendation 2

There is some concern that existing conditions for aquatic products may leave Australia exposed to risk of introduction of exotic pathogens. Development of risk analyses for unassessed aquatic products should be considered a priority.

Recommendation 3

For many food products including meat flavours, the nature of the packaging (whether in bulk or in consumer ready form) has an effect on the likelihood of diversion to end uses other than originally intended. It is recommended that the nature of the packaging should be considered when assessing import conditions for products which may have alternative end uses.

Recommendation 4

It is recommended that import conditions which refer to a minimum percentage of risk ingredients (such as the 5% rule) should be reviewed.

Recommendation 5

Many import conditions refer to approval of facilities, treatments or countries of origin by DAFF, or by the Director of Quarantine. However, it is not clear what systems exist for granting such approvals, nor for maintaining records of approvals once granted. It is recommended that such systems should be formalised and documented.

Recommendation 6

A comprehensive review of import conditions for eggs and egg products, whether as a regulated IRA or an informal review, should be undertaken as a matter of priority.

Recommendation 7

It is recommended that the use of Manufacturer's Declarations for ensuring compliance with import conditions for retorted egg products should be reviewed.

Recommendation 8

The use of Manufacturer's Declarations for ensuring compliance with import conditions for composite products containing egg should be reviewed.

Recommendation 9

The present informal policy on import of soil and water samples should be formalised to prevent policy creep.

Recommendation 10

The use of Manufacturer's Declarations for ensuring compliance with import conditions for fertilisers should be reviewed.

Recommendation 11

Import conditions for raw hides should be reviewed to ensure that current operational arrangements meet biosecurity needs.

Recommendation 12

The use of Manufacturer's Declarations for ensuring compliance with import conditions for feathers should be reviewed.

Recommendation 13

Import conditions for wool should be reviewed to ensure they remain appropriate to current conditions.

Recommendation 14

Procedures for assessment of human therapeutic goods should be reviewed, in cooperation with Therapeutic Goods Administration, to ensure that animal biosecurity issues are appropriately addressed in all cases.

Recommendation 15

Review of the current procedures for assessment of laboratory catalogues is warranted to determine whether more efficient methods of control can reduce the resource cost associated with this group of products.

Recommendation 16

Import requirements, and end use controls for culture media should be reviewed to ensure that they are meeting current needs.

Recommendation 17

End-use controls for microorganisms should be reviewed to minimise risk of inappropriate use of imported materials.

Recommendation 18

DAFF should continue to maintain a contact person for SSBA issues and provide input or assistance to DoHA as required.

Recommendation 19

Review of the use of manufacturer's declarations for those diagnostic kits which contain material of animal origin to ensure that this remains appropriate would be desirable.

Recommendation 20

Import conditions for bioremediations agents should be the subject of an in depth review, probably in cooperation with State EPAs, to ensure that a system of controls which meets the needs of biosecurity and environmental agencies is developed and implemented.

Recommendation 21

A review of pet food controls is warranted.

Recommendation 22

A review of the current conditions for stock feed supplements is warranted.

Recommendation 23

Reliance on Manufacturer's Declarations for ensuring that import conditions for aquaculture feeds are met, should be reviewed.

Recommendation 24

Recent events suggest that testing requirements for aquaculture feeds at the border should be reviewed to provide enhanced confidence that import conditions are being complied with.

Recommendation 25

The recommendations of the end use review (Part 3 of this project) should be considered in relation to *in vivo* approvals.

Recommendation 26

In addition to recommendations listed above relating to the use of Manufacturer's Declarations for specific products, it is recommended that a broad review of the use of Manufacturer's Declarations be carried out, in accordance with the findings of the separate report prepared as part 2 of this Project.

Recommendation 27

In addition to specific recommendations listed above relating to end use controls for specific products, it is recommended that a broad review of end use conditions be carried out, in accordance with the findings of the separate report prepared as part 3 of this Project.

Recommendation 28

A review of the relationships between packaging, end use and risk should be carried out to determine whether packaging can be effectively used as a risk management measure, and the extent of risk mitigation it might provide.

Recommendation 29

Where current import conditions refer to broad categories of products such as dairy products, or eggs and egg products, it is recommended that consideration be given to completing import risk analyses of individual products within the category to ensure that import conditions remain relevant to the level of risk posed by that product rather than to the group as a whole.

Recommendation 30

A program of formal review of existing import conditions should be implemented to identify cases where changing technologies or other factors have rendered those

conditions ineffective. In such cases, conditions should be updated to ensure continued relevance to the current quarantine environment.

Introduction

Background to the project

This report addresses the first of three components of ACERA Project No 1101F, being a review of the relative risk of different categories of imported biological products of animal origin, with recommendations for appropriate risk management measures for each category.

1. The DAFF Import Risk Assessment Handbook 2011states:

> "The level of quarantine risk is defined in section 5D of the *Quarantine Act 1908*.
>
> The definition is as follows:
>
> reference in this Act to a *level of quarantine risk* is a reference to:
>
> (a) the probability of:
>
> (i) a disease or pest being introduced, established or spread in Australia, the Cocos Islands or Christmas Island; and
>
> (ii) the disease or pest causing harm to human beings, animals, plants, other aspects of the environment, or economic activities; and
>
> (b) the probable extent of the harm."

Within this legislative context, the Australian Government Department of Agriculture Fisheries and Forestry (DAFF) has responsibility for animal and plant quarantine. The Biologicals Import Program (BIP) is part of Biosecurity Animal Division, which has an essential role in relation to animal biosecurity. Other agencies have responsibility for human quarantine, and for environmental issues. Where imported goods may pose risks to human health or the environment, DAFF staff work in consultation with other departments and agencies, including the Australian Government Department of Health and Ageing (DoHA), the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Australian Government Department of Sustainability, Environment, Water, Population and Communities (DSEWPAC). As this project was sponsored by BIP, this report will concentrate on animal biosecurity issues, while recognising that the overall biosecurity role is broader in scope.

For the purposes of this report, biological products *include animal or microbial derived products such as foods, therapeutics, laboratory materials, and vaccines*. (DAFF, 2007).

Biological products including foods of animal origin are imported into Australia for a range of *in vitro* and *in vivo* purposes. Such products range from products that are potentially of high risk (e.g. pathogens and vaccines) to those that are of extremely low risk (e.g. many processed foods for human consumption).

Known potentially high risk products include exotic agents such as microorganisms that could (if exposed to susceptible Australian hosts outside appropriately built and managed biological containment facilities) cause disease outbreaks and result in significant negative consequences (e.g. welfare issues arising from animal disease, loss of production,

productivity, trade and, in some cases, adverse effects on human and environmental health). Other biological products that are of potentially high risk include cell or tissue cultures (e.g. that may be used to make vaccines that are used on Australian animals or people) or genetic material (e.g. imported DNA can be used to study cell biology) because they may become contaminated with exotic pathogens that could rapidly lead to disease in large numbers of Australian animals over a large area. Vaccines and other therapeutic products and stock feed products also rate as high risk because of their direct exposure pathway to potentially susceptible Australian animals.

At the other extreme, some biological products are of extremely low risk (e.g. diagnostic test kits that might contain inactivated exotic agents or antigens from such agents). Between such extremes, there is a wide variety of different types of biological products from a diverse range of countries of origin (each with a different animal health status), manufacturers (each with different levels of manufacture in practice and standards of quality assurance), and methods of production.

Currently, there is a tendency to group different biological products of animal origin together rather than to differentiate them into a larger number of categories according to the potential risk they pose. This inevitably leads to a tendency over-regulate some products, while other products are under-regulated.

The review considered the range of biological products and the existing risk management measures, and categorised these products by risk level, and by the perceived effectiveness of current management measures. Risk was considered as low, moderate, or high, and risk management measures were assessed as being well managed, or not well managed.

The biosecurity system

In brief, Australian biosecurity legislation prohibits the import of goods into Australia, unless a permit to import the goods has been granted. The permit may be unconditional or may impose on the import conditions intended to manage the biosecurity risk. Such conditions may include:

- limitations on source countries, zones or compartments;
- testing or treatment of live animals ;
- requirements for control of manufacturing processes (such as quality assurance systems, codes of Good Manufacturing Practice etc);
- limitations on, or testing of, raw materials;
- requirements for the imported goods to be treated in some way to inactivate potential pathogens which may be present in or on the goods, like –
    - heating or freezing to defined temperatures for defined times;
    - radiation or other sterilization treatments; and
- other treatments considered to reduce the biosecurity risk to an acceptable level.

In cases where physical treatments such as heating, freezing, radiation or other treatment are used to reduce the biosecurity risk, Australian authorities do not (in most cases) actually

perform these treatments, but rely on others to do so. The role of Australian Department of Agriculture, Fisheries and Forestry (DAFF) staff at the border is therefore to be confident that the import conditions relevant to particular goods have been complied with. There are a number of means by which border staff can be confident that importers have complied with import conditions. These include:

- physical inspection;
- sampling and testing; and
- assessment of documentation.

However in many circumstances, DAFF staff must rely on documentation to provide confidence that biosecurity conditions have been met, because compliance with biosecurity conditions cannot be verified by physical inspection or by testing. For example, the animal health status of an exporting country cannot be verified by examination of a sample of the imported goods. Similarly, it is not possible to say, by inspection, whether a particular sample of meat has been cooked to a required temperature for a required time. Tests for cooking may exist, but they are not able to be calibrated to exactly correspond with heat treatments that are required by biosecurity conditions.

Australia is a member of the World Trade Organisation (WTO) and the World Organisation for Animal Health (OIE), and a signatory to the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). This creates both rights and obligations relating to how countries behave in relation to International trade. Of particular importance to this report are the OIE Terrestrial Animal Health Code (the Code), and the OIE Aquatic Animal Code (the Aquatic Code), which provide, *inter alia*, guidelines for international veterinary certification for products derived from terrestrial or aquatic animals, respectively. Similar arrangements also exist in relation to plant biosecurity.

The Code details '*fundamental principles of an ethical, organisational, legislative, regulatory and technical nature*', and provides guidelines on how importing countries can assess the veterinary authorities in exporting countries to ensure that international veterinary certification can be relied upon. Further details on these fundamental principles can be found on the OIE Web site (World Organisation for Animal Health, 2012).

Compliance with the guidelines for veterinary authorities and international veterinary certification provides a high level of confidence in matters certified by means of an international veterinary certificate. An international veterinary certificate, issued by an official of a veterinary authority that has been assessed as complying with the Code, is therefore the most reliable means of ensuring that biosecurity conditions have been met.

For a variety of reasons, international veterinary certification has not been available for some imported goods. Over time, in order to facilitate trade, DAFF has accepted alternative forms of documentation. These have included documents such as Manufacturer's Declarations, in which the manufacturer of the goods makes a declaration that certain treatments have been applied, or that the goods are in compliance with other conditions.

The level of confidence which can be afforded such Manufacturer's Declarations varies. Manufacturer's Declarations may be countersigned by veterinary officers from the exporting country veterinary authority – in such cases the veterinary officer is required to sign a statement to the effect that "… after due enquiry, I have no reason to doubt the statements in this declaration." While this provides a greater level of confidence than a similar Manufacturer's Declarations without the counter signature, it has to be accepted that the level of checking varies between veterinary authorities. In cases where the manufacturer's Declaration is not counter signed by the veterinary authority the level of confidence which can be placed on the matters declared is much reduced in light of significant commercial pressures in play providing an incentive to falsify these documents.

For a fuller discussion of the limitations of Manufacturer's Declarations see the separate Report within this Project on use and reliability of Manufacturer's Declarations. (ACERA, in preparation)

Development of existing import conditions for Biologicals

In July 1994, DAFF published the document 'GUIDELINES FOR THE IMPORTATION OF BIOLOGICAL PRODUCTS (the Guidelines)'. It was intended to provide DAFF staff with guidelines on biosecurity requirements for imported biological products destined for research, laboratory, therapeutic, diagnostic, analytical, environmental, industrial, medical, veterinary and related uses. The Guidelines identified categories of products that were defined as 'biologicals' for the purpose of that document. The categories of goods identified as 'biologicals' in the Guidelines are shown in Table 1.

Since the publication of the Guidelines, the considerable advancement in the science and technology of biological products has meant that Biosecurity Officers dealing with 'biologicals' are now faced with a situation where they have to assess and manage risk arising from imports of a range of products of new technologies that, while falling within the definition of 'biologicals' as considered in the Guidelines, were not themselves considered at the time of publication.

Table 1. Categories of goods defined as 'biologicals' by the Guidelines.

1.	**Micro-organisms which are differentiated into *in vitro* use, food/beverage use, bio-remediation organisms, probiotics, vaccines and other *in vivo* uses**
2.	Cell lines and hybridomas
3.	Small amounts of serum, antiserum, enzymes, hormones, antibodies and other animal products contained in *in vitro* diagnostic, analytical and immuno-chemical kits or used for the transport of specific antibodies or immuno-globulins for *in vitro* use only
4.	Animal serum, enzymes, hormones, tissue extracts and other animal products imported in bulk or destined for industrial, environmental, therapeutic or veterinary purposes
5.	Culture media containing ingredients of animal origin
6.	Serum, blood proteins, tissue and other material of human origin
7.	Special purpose therapeutics for human use
8.	Commercial veterinary and/or human therapeutics

9.	Implantables (eg catgut) of animal origin
10.	Products derived from microbial fermentation
11.	Plant extracts and biochemicals derived from plants
12.	Monoclonal and polyclonal antibodies, DNA, RNA, restriction enzymes, oligonucleotides and other molecular biology products
13.	Cosmetics containing human or animal material
14.	Preserved specimens and microscope slides and smears.

In addition, changes in the way that DAFF deals with import permit applications have led to a broader range of products than was originally considered in the guidelines being now considered as falling within the scope of 'biologicals'. As examples, food products for human consumption, soil and water samples, hides, skins, feathers and wool, and stock feed products, are now considered to be 'biologicals'.

As a preliminary exercise in preparation for the formal review project, senior officers within the Biologicals Imports Program (BIP) were asked to list the types of products that were now considered to be 'biologicals' and therefore within the scope of the review. They were also asked to rate the overall level of risk associated with each of the groups of 'biologicals', before risk management measures were applied. The output of that exercise is attached as Appendix 1.

Existing import conditions for biological products have been developed via a risk analysis. Historically, this process was informal, and much of the reasoning behind the development of existing conditions has not been recorded. More recently, and in particular since Australia became a member of the World Trade Organisation (WTO), the process has been formalised and is now conducted in accordance with Australia's rights and obligations under the SPS Agreement. More recently again, the process has been legislated in the *Quarantine Regulations 2000*, which provides for the process to be undertaken as either a formal regulated Import Risk Analysis (IRA) following the administrative steps set out in the IRA Handbook 2011 (Department of Agriculture Fisheries and Forestry, 2011), or alternatively as an unregulated review. In either case, the components of risk analysis described in the OIE Animal Health Code (OIE 2009a) are hazard identification, risk assessment, risk management and risk communication. Risk assessment is defined as the '*evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard within the territory of an importing country*'.

Risk assessment is a scientific process. For DAFF this involves consideration of the likelihood that imported goods will be contaminated with pests or diseases that can be transferred to susceptible animals in Australia. Arbitrarily, the process is subdivided into a number of stages, referred to as release (or entry) assessment, exposure assessment and consequence assessment. In making these assessments, a risk analyst considers matters such as:

- Disease prevalence in the country of origin of the goods;
- Nature of goods
    - live animals vs products,

    - species of origin,
    - degree of processing (if any), and
    - packaging of products;
- Nature of pest or disease agent
    - host specificity,
    - environmental stability of the causative organism, and
    - transmissibility of the causative organism;
- Likelihood of exposure to susceptible Australian animals
    - nature of the product, and
    - its intended end use;
- Volume of product imported; and
- The estimated consequences of a disease outbreak.

Where the risk assessment process leads to an estimate of risk which exceeds the acceptable level of protection (ALOP) risk management measures are imposed that are designed to:

- reduce the likelihood that goods destined for import into Australia will be infected or contaminated with exotic pathogens;
- reduce the likelihood that the contaminating organisms will survive in an infective state during transport to Australia;
- reduce the likelihood that the infective pathogen will come into contact with, and infect, susceptible Australian animals;
- reduce the likelihood that the infection will establish and spread in Australia following infection of the first susceptible animals; or
- reduce the consequences of an outbreak of disease resulting from introduction of an exotic pathogen.

The appropriate risk management measures then form the basis of the import conditions for the product under consideration.

Because of the rigorous scientific process used to develop import conditions, it is reasonable to assume that, *if correctly implemented*, the combination of risk management measures specified will be sufficient to reduce the risk associated with the import of products to an acceptable level, without imposing undue restrictions on trade.

However, there are potential problems with the implementation of the system, as applied currently to the broad category of products referred to as biologicals.

Firstly, as mentioned above, there is a tendency to group different biological products of animal origin together, rather than to apply a larger number of categories to allow differentiation according to the potential risk they pose. This leads to a tendency to over-regulate some products, while others are under-regulated. This mismatch of regulatory control to real biosecurity risk can lead to an inefficient use of inspection resources, as well as limiting the free movement of low risk goods and products.

Secondly, the effectiveness of the risk management measures is only guaranteed to the extent that the measures are correctly applied. Import conditions generally require that the importer ensures that particular risk management measures are applied to the goods, and DAFF requires some level of assurance that this has been done. This assurance may come in the form of official Government-to-Government certification, manufacturer's declarations, or inspection and testing requirements. In practice, successful application of conditions can vary owing to things like the sophistication of technology available in the country of origin, availability of appropriate scientific and technical skills, inadvertent failures in production processes, varying levels of commitment to best practice, and honesty of parties involved in the importation process. Other parts of this Project (ACERA Project 1101F) specifically address aspects of the paper based system providing assurance that import conditions have been effectively applied.

Thirdly, changes over time can affect the risk associated with import of specific biological products. Changes in disease prevalence in the country of origin, mutation or other evolution of pathogens, changes in environmental conditions in production areas, appearance of emerging diseases, and technological advancements in processing methods can all affect the likelihood that pathogens may contaminate imported goods.

Finally, the OIE risk assessment process described above considers both the likelihood and the biological and economic consequences of the importation of goods. This leads to a situation where, under the terms of the SPS Agreement, DAFF staff are not able to consider the 'worst case scenario', but must consider the 'likely' consequences of an import. In some cases, this can lead to problems. For example, if a microorganism is imported for *in vitro* use in a laboratory, and permit conditions are adhered to, there is very little risk of an unintended outcome. However, if the microorganism imported for *in vitro* use is subsequently used in *in vivo* trials in livestock, a disease outbreak could occur with severe consequences. For this reason, DAFF imposes end use conditions on imports. However, these end use conditions are very difficult to enforce in practice. A simple approach to this problem would be to apply import conditions that assumed that the product would be used *in vivo*, but this could be argued to be overly restrictive, and therefore inconsistent with SPS provisions, since the *in vivo* use was not a likely outcome. Similar problems arise in a wide variety of categories of biological products. Examples include prawns for human consumption being diverted to use as bait, and dairy products being diverted to use in supplementary feeds for calves. End use problems are being considered in more detail in a separate part of this Project.

A review of the risks associated with biological products is timely to ensure that risks are effectively managed without imposing unnecessary restrictions on international movement of goods, and that resources are being efficiently used while maintaining biosecurity.

Method for the review

Prior to the formal commencement of the review, and as part of a scoping project undertaken by BIP, senior officers within the Biologicals Imports Program (BIP) were asked to list the types of products that were considered to be 'biological products' and therefore within the scope of the review. They were also asked to rate the overall level of risk associated with each of the groups of 'biological products'. Officers rated the risk of different biological products on a scale from 1 to 5, with the latter indicating the highest risk. This rating reflects the nature of the disease agents that might be introduced in association with the products, the degree of processing of the product, the effect of that processing on pathogens, and the likelihood of exposure to susceptible Australian animals. It is accepted that this was largely a subjective exercise. However, the purpose of this preliminary exercise was to provide a list of products and categories of products that were considered to be within the scope of the project, and to determine which of these were considered to pose the greatest level of risk by experienced BIP officers. The outcome of that exercise is summarised at Appendix 1.

After consideration of the information presented in Appendix 1, and further discussion with officers from BIP and AB, a categorised list of products to be considered in the review was developed. The final list is shown at Table 2.

During May 2012, officers from DAFF's BIP and from Animal Biosecurity (AB) took part in a series of Commodity Risk Review meetings to discuss, in greater detail than was considered during the preliminary reviews, the risks associated with each of the identified biological products or categories of biological products, the perceived effectiveness of the current risk management measures applied, and any changes to existing import conditions that were considered necessary to address those risks. For each of the identified products or categories of products identified in Table 2, this resulted in:

- an assessment of the level of risk associated with the product; and
- an assessment of whether this risk was well managed or not.

Largely for convenience in differentiating the risk rating derived during the preliminary exercise from the more considered, final rating, following the Commodity Risk Review meetings, the final ratings were reported using the qualitative terms low, moderate, and high. There was no direct relationship between the initial numeric estimates and the final qualitative ratings because they were developed using different processes.

Where it was considered that risks were not well managed, recommendations were made to address the situation. The following product reviews reflect the thinking that was expressed during those meetings. The outcomes of the review are summarised in tabular form at Appendix 2.

This report does not constitute a formal risk assessment as defined by the OIE. A formal risk assessment of that nature is well beyond the scope of the Project. The risk levels reported are largely based on the perceived risk as reported by DAFF officers with experience in dealing with the products discussed. As a result, the outcomes reported should be used as a guide to

the priority that should be attached to reviews of existing import conditions, and not as definitive recommendations in themselves.

Table 2. Biological products considered in the review.

Broad group	Sub-group	Product
Food products for human consumption		Kopi luwak
		Birds' nest products
	Seafood products	Finfish for human consumption
		Prawns
	Eggs & egg products	Retorted egg products
		Spray dried egg powders
		Products containing less than 10% egg
	Dairy products	Cheese
		Products containing less than 10% dairy
	Meat products	Canned retorted meats
		Uncanned chicken meat
		Uncanned pig meat
		Uncanned meat other than chicken or pig meat
		Meat flavours
		Casings
	Eggs and egg products	Retorted egg products
		Spray dried egg powders, egg pasta mooncakes
		Products containing less than 10% egg
	Dairy products	Cheeses
		Retorted dairy products
Cosmetics		Finished consumer-ready products
Soil & water samples		
Fertilisers		Chemical fertilisers
		Fertilisers derived from animal wastes
Hides, skins, feathers & wool		Hides & skins
		Feathers
		Wool
Therapeutic products		Human therapeutics
		Veterinary vaccines and master seeds
		Veterinary therapeutics (non-vaccines)
Laboratory materials		Catalogues
		Culture media
		Micro-organisms
		Diagnostic kits
Specific pathogen free (SPF) eggs		
Bioremediation agents		
Enzymes		

Animal feeds	Petfood
	Livestock feeds
	Stockfeed supplements
	Aquaculture feed
***In vivo* approvals**	
Returning Australian products	

Review of relative risk level of various categories of biological products

The scoping process undertaken prior to the commencement of the formal review resulted in the broad groups of products listed at Appendix 1. It is accepted that within some of these broad groups of products there exist different products with different intrinsic risks, resulting from the different raw materials used in producing the products and the differing processes undergone during manufacture. As will be discussed further later in this project, this is not ideal as it results in some individual products being potentially over-regulated while others are potentially under-regulated. However, these groupings reflect common usage within BIP, and are maintained for that reason. Recommendations relating to further breakdown of these broad groupings are made later in this report.

Food products for human consumption

In general, human food products have a lower likelihood of exposure to susceptible animals because such exposure is largely accidental, given that the product is imported for human food. Thus usually only waste material is likely to come in contact with animals. This is especially true when products for human consumption are imported in finished, consumer ready packaging.

Products imported in bulk may pose an increased risk, through diversion to an end use different from that for which they were originally imported. This may occur, for example, where bulk products have exceeded a ‘use by date’ for human consumption, but are still suitable for use as animal food. In such cases, importers may recoup some value for the product by diverting to animal food use. This is less likely to occur with consumer ready products due to the costs involved in removing the product from its consumer packaging before incorporation in an animal feed product.

Kopi Luwak

Kopi luwak or civet coffee is made from coffee beans that have been eaten by and passed through the digestive tract of the Asian palm civet (or other related civets). Kopi luwak was rated as being of low risk when rated by senior BIP Officers during the preliminary exercise, scoring 1 on a scale with a maximum value of 5 (Appendix 1).

This coffee is widely noted as the most expensive coffee in the world with prices reaching $160 per pound (Wikipedia, 2012). As a result of its cost and rarity, it is highly unlikely that this product will be exposed to susceptible Australian animals. In addition, the fact that the product is a “gourmet” item and commands a high price will help to ensure that the product is always processed correctly in order to maintain the quality reputation of the product.

Some concern has been raised in relation to human health risks posed by the method of processing involving civet cats, which were the source of severe acute respiratory syndrome (SARS), a viral respiratory disease of humans, which first occurred in 2002-03. Human health risks are primarily the responsibility of the Australian Government Department of Health and Ageing (DoHA). BIP should consider consulting with DoHA to ensure that they have no human health concerns in relation to this product.

Conclusion 1. Kopi luwak is considered to be a low risk product from an animal biosecurity point of view. Existing policy provides appropriate management of animal biosecurity risks.

Recommendation 1. BIP should consider consulting with DoHA to ensure that they have no human health concerns in relation to kopi luwak.

Birds' nest products

Birds' nest products are an ingredient of Asian birds' nest soups, and are produced from the saliva of a particular species of bird. Birds' nest products were rated as being of low risk when rated by senior Biosecurity Officers, scoring 1 on a scale with a maximum value of 5 (Appendix 1).

As a product of live birds, birds' nest products have the capacity to carry a range of avian pathogens including in particular avian influenza and Newcastle disease. However, birds' nest is considered a delicacy in Chinese cuisine, and this fact combined with the difficulty of harvesting natural birds' nests, means that edible birds' nests are among the most expensive animal products consumed by humans (Wikepedia, 2012). As a result, birds' nest product imported for human consumption is highly unlikely to be exposed to susceptible Australian birds, which reduces the risk considerably by reducing the likelihood of exposure.

Current import conditions (see extracts from ICON database in Appendix 3) require that the product be retorted. Retorted is defined in the *Quarantine Proclamation 1998* as follows:

> ***'retorted** means in an unopened hermetically-sealed container that has been heated for a time, and to a temperature, sufficient to make the contents commercially sterile.'*

The retorting process has been shown to effectively manage all known disease risks associated with this product, if effectively implemented. However, there have been concerns in the past that these requirements have not been met. 'Dry canned' products, containing less than 30% moisture, are commonly encountered at the border. These products have been sealed in cans, but have likely not been subject to a true retorting process, due to the fact that the contents of the can were dry. Retorting processes require the presence of moisture in the can in order for the process to be effective. Dry canning processes have not been shown to manage the risk, although it is possible that some such processes may well do so, depending on the temperature reached and the time for which the temperature is maintained during the process.

The ICON entry for this product (see Appendix 3) also requires '*mandatory inspection on arrival to ensure that the product has been commercially manufactured and retorted'.* The

inspection requirements should allow for ready identification of dry canned product as described above. Such products should, at present, be rejected since they do not meet the existing import conditions, which require retorting. However, if data were presented to show that a particular dry canning process was able to manage the risk, and alternative conditions were developed based on that data, some products which currently must be rejected could be found to be acceptable. The responsibility for presentation of such data should lie with importers or manufacturers.

Conclusion 2. Birds' nest products are considered to be low risk. Current policy may lead to overly restrictive risk management.

Seafood products

Finfish for human consumption

Finfish for human consumption were rated as being of low risk when rated by senior BIP Officers during the preliminary exercise, scoring 1 on a scale with a maximum value of 5 (Appendix 1).

IRAs have been conducted for non-viable salmonid products, and for non-viable marine finfish products for human consumption. Conditions for import of finfish for human consumption developed through the IRA process include requirements for assessment of the competent authority in the exporting country prior to granting of import permits, and government certification of all shipments, which must consist of consumer ready products.

The requirement for import of consumer ready product decreases risk by limiting further processing of imported raw materials in Australia, and thus minimising the production of processing waste which could be diverted to fish food or other uses. This in turn minimises the likelihood of exposure.

Advice from staff of the Aquatics Section within Animal Biosecurity Branch is that relevant measures seem reasonably practical, and result in an acceptably low risk.

Conclusion 3. Finfish products for human consumption (in consumer ready form) are considered to be a low risk product. Existing policy provides appropriate risk management.

Prawns

Prawns for human consumption were rated as being of low to moderate risk when rated by senior BIP Officers during the preliminary exercise, scoring 2 on a scale with a maximum value of 5 (Appendix 1).

Highly processed prawns are considered to present a lower biosecurity risk than less processed prawns. This is because they are less likely (for reasons of cost, as well as useability) to be diverted from human consumption to other end uses, such as bait, which have a greater likelihood of exposure to susceptible Australian animals. Also, prawn viruses of concern are contained largely in the shells of the prawns, so processing by peeling or by removing the head largely removes the virus.

Prawns have been the subject of a recent formal IRA. Risk management measures developed from the IRA and subsequent reviews are in place. Current import conditions for highly processed prawns are attached at Appendix 4.

As a result of the decreased risk associated with highly processed prawns, the IRA concluded that highly processed prawns need not be subject to the mandatory import testing for pathogens (WSSV (White Spot Syndrome Virus) and YHV (Yellowhead Virus)). The removal of the requirement for testing represents a substantial saving to importers. This initially led to some problems, which arose as follows.

The import permit application process for highly processed prawns requires that the importer submit a manufacturer's Declaration describing the nature of the processing undergone during the manufacture of the product. The details of the manufacturing process as detailed on the manufacturer's Declaration are taken into account in determining whether or not to issue a permit. Initially, the permit conditions for highly processed prawn products were written in very general language and did not require more than a generic description of the product.

As an example, a producer could provide a manufacturer's Declaration stating that a prawn product had been prepared using a marinade including garlic, and a permit would be issued for "garlic prawns". It was subsequently discovered that up to 70% of consignments imported under similar import conditions met the generic description, but did not meet the detailed processing as specified in the manufacturer's Declaration. In fact, it was considered that importers had been washing off very low quantities of marinade and returning product to an essentially fresh state, thus avoiding the expense of import testing for fresh product.

Minor changes to permit conditions were subsequently introduced. These included a requirement that health certificates, not manufacturer's declarations, were required to specify the percentage of flavour ingredients in the marinaded product. This, together with a requirement for 25% random inspection of product to verify the marinade process, has improved the situation, to the point where staff now believe that the risk is well managed.

Existing conditions for the import of prawns, including highly processed prawns, are effective at managing the biosecurity risks associated with the product, provided there is high confidence the conditions have been effectively applied. The requirement for government certification in place of Manufacturer's Declarations together with random inspection of consignments to verify processing, has increased the level of confidence in the system. The effectiveness of Manufacturer's Declarations in improving confidence that biosecurity conditions have been effectively applied is the subject of a separate Report within this Project (ACERA, in preparation).

Conclusion 4. Prawns for human consumption, which have been processed in such a way as to make them unsuitable for use as bait or berley, are considered to be a low risk product. Existing policy provides appropriate risk management.

General comment in relation to aquatic products for human consumption

Staff from the Aquatics section of Animal Biosecurity (AB) advised that a number of previously unrecognised aquatic pest and disease organisms have been identified in Australian waters over the past few decades. An example is the recent isolation of iridovirus from Murray cod, which are considered to have been introduced in aquarium fish (Go, Lancaster, Deece, Dhungyel, & Whittington, 2006). Whether this is due to an increased level of awareness and scrutiny leading to recognition of pests and diseases that have been present for some time, or whether it is due to unwitting introduction of these pests and diseases through imports of aquatic animals and aquatic animal products is unknown. It is likely to be a combination of both.

While the example quoted above relates to the possible introduction of exotic disease agents in live aquarium fish, discussion with staff in the Aquatics section of Animal Biosecurity suggests that there are a large number of aquatic products, including some for human consumption, that have not been the subject of formal import risk analysis, and this may leave Australia open to some level of biosecurity risk. Complete risk analyses of these products are beyond the scope of the present review. However, the development of risk analyses for unassessed aquatic products should be considered a priority.

Recommendation 2. There is some concern that existing conditions for aquatic products may leave Australia exposed to risk of introduction of exotic pathogens. Development of risk analyses for unassessed aquatic products should be considered a priority.

Meat Products

Meat for human consumption, including canned retorted meats, and meat flavours, were rated as being of low to moderate risk when rated by senior BIP Officers during the preliminary exercise, scoring 1.8 on a scale with a maximum value of 5 (Appendix 1). This low rating, despite the fact that meat derived from ruminants is potentially capable of carrying many of the most serious animal diseases, is likely due to the lower likelihood of exposure of product to susceptible Australian animals, and to the internationally enforced requirements for hygienic production of meat for human consumption, including requirements for ante mortem and post mortem inspection.

Canned retorted meats

If correctly applied, the canning or retorting process will manage all biosecurity risks associated with meat products, with the exception of potential risk of introduction of BSE in beef products. Internationally recognised conditions for managing risk associated with BSE are in place and are considered adequate.

Currently, the retort process can be certified by the use of a manufacturer's Declaration which has been endorsed by an official of the veterinary authority of the exporting country. As discussed in the separate report on Manufacturer's Declarations, there is reason to doubt the efficacy of Manufacturer's Declarations alone for the reduction of biosecurity risk, although their reliability is increased by requiring that they be endorsed by a veterinary

officer as is required in this case. In the case of retorted meats there is a further safeguard in the system – correctly processed products will be shelf stable, while 'blown' cans will result from inadequately processed ones. Consequently any failure of the process is clearly evident. Canned retorted meats (imported in accordance with current import conditions) represent a moderate risk product for which risk is well managed by virtue of the effect of the canning process on microbial survival.

Some commercial canned meat products are not fully retorted, but only 'hot filled'. These products are not shelf stable so require refrigeration to ensure they remain fresh. Their processing may not be sufficient to fully manage the biosecurity risk. Such products do not meet the definition of canned retorted meats and consequently are subject to import conditions for uncanned meats (see below). Provided this remains the case, the risk is managed and no further intervention is required.

Conclusion 5. Retorted canned meat for human consumptions is considered to be a moderate risk product. Existing policy provides appropriate risk management.

Uncanned chicken meat

This product has been the subject of a recent formal IRA. Appropriate risk management measures are in place.

Conclusion 6. Uncanned chicken meat represents a potentially moderate risk product, where risk is well managed by existing conditions.

Uncanned pig meat

Uncanned pig meat has been the subject of a recent formal IRA. Appropriate risk management measures are in place.

Conclusion 7. Uncanned pig meat represents a potentially moderate risk product, where risk is well managed by existing conditions.

Uncanned meat other than chicken or pig meat

The ICON database currently advises that "*The quarantine requirements for the importation of uncanned meat and meat products from domestic stock (excluding pig and poultry) have been suspended pending a formal review.*" This suspension applies to all red meats with the exception of red meat from New Zealand and beef from Vanuatu.

Red meat policies were suspended following the discovery of imported beef from Brazil in Australia in 2004 and concerns over the risk of introduction of foot and mouth disease (FMD) under the protocol in place at the time. In response to these concerns, Animal Biosecurity Branch (ABB) has commenced concurrent standard IRAs for the importation of beef and beef products from the USA, Canada and Japan. The below extract from Biosecurity Australia Advice 2010/10 (Biosecurity Australia, 2010) describes the scope of these IRAs:

Biosecurity Australia will assess the animal quarantine risks associated with the importation of beef and beef products for human consumption that contain bovine tissue (including from cattle, buffalo and bison). This includes meat, bone and offal (chilled, frozen, dried, cured or

salted and retorted shelf-stable products), including natural casings and gelatine derived from bones, but excludes milk, dairy products, gelatine and collagen derived from bovine skins and hides (including sausage casings produced from this type of material), and edible bovine fat/tallow comprising less than 30% of a processed product. The products covered will thus align with the FSANZ definition of beef and beef products in the Australia New Zealand Food Standards Code Standard 2.2.1 Clause 11.

In the case of USA and Canada, Biosecurity Australia has requested information from the United States Department of Agriculture (USDA), and from the Canadian Food Inspection Agency (CFIA) on their respective cattle health status and beef production, inspection and certification systems. Until this information is provided, the Executive Director of BA has invoked the 'stop the clock' provisions of the *Quarantine Regulations 2000.* Work on these IRAs will recommence when the required information is provided to BA by USDA and CFIA.

The 'stop the clock' provision has also been invoked in relation to the IRA for the importation of beef and beef products from Japan, due to the detection of FMD in breeding cattle at a farm in Miyazaki Prefecture (on the eastern side of Kyushu Island, the most southern island of Japan). Although Japan has recently regained its FMD free status *(AQIS, 2012),* a decision on recommencement of this IRA has not yet been made.

Following receipt of appropriate advice from overseas country authorities, the eventual completion of the beef IRAs for USA, Canada and Japan, will clarify the requirement for beef products. These IRAs will also provide a basis for review of other countries' access requests when and if these are received.

Since the major concerns that lead to the suspension of these red meat policies were in relation to FMD, and the beef IRAs will certainly consider FMD, the completion of these IRAs should also provide a basis for reviews of policy relating to red meat from species other than beef (e.g. lamb, or venison).

Requirements for BSE (bovine spongiform encephalopathy) and other transmissible spongiform encephalopathies (TSEs) which are included in conditions for meat for human consumption are the responsibility of Food Standards Australia New Zealand (FSANZ) and will not be considered further here.

Meat flavours

Although intended for human consumption, meat flavours may be diverted to use in animal feeds, resulting in an increase in the likelihood of exposure to susceptible Australian animals. Once again, the likelihood of diversion to inappropriate end use is affected by the nature of the packaging in which the product is imported. Products imported in bulk are more likely to be diverted to use in animal food than are products imported in finished, consumer ready packaging.

Recommendation 3. For many food products including meat flavours, the nature of the packaging (whether in bulk or in consumer ready form) has an

effect on the likelihood of diversion to end uses other than originally intended. It is recommended that the nature of the packaging should be considered when assessing import conditions for products which may have alternative end uses.

Flavours are more likely to be diverted to use in pet food (for dogs and cats) than stockfeed. Consequently the risk due to this possible diversion is perhaps lower than might otherwise be the case, since dogs and cats are generally not susceptible to ruminant diseases.

As stated above, products imported in bulk are more likely to be diverted for use in animal feeds than are those imported in consumer ready form.

Current import conditions for meat flavours (see Appendix 5) require that, where the product contains greater than 5% meat, Government certification of the species of origin, processing plant approval details, heat treatment, post-processing handling to prevent contamination, packaging and transport details, is required. In addition, if the product is exported in bulk, and from a country which has foot and mouth disease (FMD), then audits of the processing plant are required before a permit is granted. Where the product is imported in bulk from a country which is free of FMD then desk audits are required prior to permit issue. These requirements mean that imports of meat flavours which contain greater than 5% of meat ingredients are well managed.

Conclusion 8. Import conditions for meat flavours containing greater than 5% meat ingredients are appropriate and the risk associated with these products is well managed.

However, for imports of meat flavours which contain less than 5% of meat, Government certification is not required. A manufacturer's declaration, covering the same facts that are covered in the Government certification for products containing greater than 5% meat is all that is required. This raises two problems. The first relates to the use of Manufacturer's Declarations as a means of verifying that biosecurity conditions have been met. This will be discussed in a separate report (ACERA, in preparation) that forms Part Two of this project.

The second problem arises from the nature of the 5% rule itself.

The 5% Rule

ICON records two Permit Conditions cases (PC0672 and PC0673, Appendix 5) containing very similar statements relating to the ingredients and the processing of meat based flavours. One of these conditions requires a Manufacturer's Declaration, while the other requires a Government Certificate. This distinction arises from the belief that a product containing less than 5% of meat products is intrinsically safer than one with greater than this concentration.

It is true that a product with a lower proportion of meat in the raw materials used in its production is less likely to contain an infectious dose of a disease agent. However, the 5% level currently used to differentiate between more and less risky products is largely arbitrary and unrelated to any scientific analysis.

In order to calculate what such a cut-off value should be, it would be necessary to know both the maximum titre of infectious agent likely to be present in the tissues of an animal at the time of slaughter, and the minimum infectious dose required to infect an exposed animal of the target species. Both of these values will vary and will be affected by a great many factors, potentially including, but not limited to:

- the species, age, sex, nutritional status and stress level of the animal which was slaughtered to produce the raw material;
- the particular pathogen involved;
- the time of slaughter relative to the time of infection of the host, and hence the level of bacteraemia or viraemia at slaughter;
- the nature of the processes to which the product is subjected during manufacture, and their effect on the survivability of the infectious agent; and
- the species, age, sex, nutritional status and stress level of the target animal to which the finished product is exposed.

In addition to the complexity arising from the factors listed above, biological systems are inherently variable, so that even if these factors could be experimentally controlled, a very great number of trials would be required in order to obtain reliable data on the titres, and minimum infectious dose of pathogens involved.

It follows that, where a particular percentage of raw materials is being considered to represent a point of differentiation between 'more risky' and 'less risky' products, the chosen level should include a reasonable 'safety factor' to account for this variability.

Is the 5% cut-off value applied to meat flavours sufficiently conservative to achieve Australia's acceptable level of biosecurity protection? This value has been in use for a considerable period of time, (at least since the entry into force of the *Quarantine Proclamation 1998*), and no disease outbreaks have been attributed to biosecurity breakdowns arising from the importation of these products. It is difficult to know whether this is due to the percentage cut–off values, or to other factors such as the effect on pathogen survival of the processing of the products, or the low likelihood that these products for human consumption will be exposed to susceptible animals. It would seem that, at least to that extent, the 5% rule is appropriate. In theory, at least, the volume of trade in products such as this could be used to calculate an upper bound on the probability of entry and establishment of associated diseases, although this may be difficult in practice due to the fact that there is no direct link between permits issued and volume of product imported.

Similar arguments apply to other products where similar conditions apply. Products containing less than 10% dairy ingredients do not require a permit, while products containing greater than 10% dairy do require a permit. Egg noodles or pasta with less than 10% egg content are treated differently to similar products with 10% - 20% egg content, while product with greater than 20% egg content are not permitted. In neither of these cases does there appear to be any record of arguments justifying the chosen levels. It is interesting that the

levels vary so widely (5% for meat flavours, 10% for dairy products, and 10% - 20% for egg in pasta).

Conclusion 9. For some composite products, depending on the processing and intended end use of the product, it appears reasonable that there should be some minimum percentage of 'risky' ingredients, below which the biosecurity conditions relating to that 'risky' ingredient cease to apply, or are less strictly enforced. However, it may be timely to review the limits to ensure that they remain appropriate to current needs.

Recommendation 4. It is recommended that import conditions which refer to a minimum percentage of risk ingredients (such as the 5% rule) should be reviewed.

Casings

The term "Casings", in this context, refers to natural sausage casings derived from the intestinal tract of animals slaughtered for human consumption. Arificial sausage casings produced from collagen or plastic do not pose a biosecurity risk and are not ocnsidered further here. Casings were rated as being of moderate risk when rated by senior BIP Officers during the preliminary exercise, scoring 2.3 on a scale with a maximum value of 5 (Appendix 1). Casings are currently being considered in the context of the beef IRAs for USA, Canada and Japan. Therefore this review will not address casings in detail. However, there are some issues relating to the current conditions for the import of casings which bear mention in this report.

Existing policy for the import of casings is attached at Appendix 6.

Amongst other things, the policy requires that the competent authority in the exporting country certifies that "***The casings were derived from animals originating in and slaughtered in the exporting country".*** Over time, there has been concern that a significant quantity of casings is imported for which this certification can be cast into doubt. This concern has arisen from the international nature of the market for this commodity, which sees casings from a wide range of countries of origin shipped to other countries for processing, and then later shipped to importing countries. Product flow controls are not necessarily fool proof and casings imported into Australia have been found to have labelling and other indications which do not coincide with the statements on the documentation accompanying the shipments, giving rise to concerns that (whether accidentally or deliberately), casings that do not meet Australian requirements have been shipped to this country. Biologicals Import Program is aware of this problem, and changes to the wording of import conditions and certification requirements have been made to address the problem.

Conclusion 10. Sausage casings are a moderate risk product which has caused problems in the past. Changes have been made to improve the situation in the short term. The current beef IRA will address beef casings, and should result in improved biosecurity outcomes for this product. Once this task has been

completed, extrapolation of the requirements to casings from other species should be relatively straight forward.

DAFF approval of premises

There is also a requirement in the conditions for casings that premises where the product is prepared or stored must have "*current DAFF approval".* It is not clear what criteria must be met for approval to be granted, or what procedures are in place to formally approve production premises in overseas countries, nor what systems exist to ensure that records of approvals are maintained and kept up to date. This issue arises in import conditions for other products also.

Recommendation 5. Many import conditions refer to approval of facilities, treatments or countries of origin by DAFF, or by the Director of Quarantine. However, it is not clear what systems exist for granting such approvals, nor for maintaining records of approvals once granted. It is recommended that such systems should be formalised and documented.

Other food products

General comment on eggs and egg products

Historically, conditions for the import of spray dried egg powders were developed using infectious bursal disease virus (IBDV) as a surrogate for other pathogens that may be contained in egg products. Over time, this was extrapolated to other product types, and this may have led to a potentially over restrictive biosecurity regime for this group of products, since it is recognised that it is highly unlikely that IBDV will be contained within an egg. Further, IBDV is much more resistant than other avian pathogens to heat and to other risk management treatments, so basing import conditions on IBD leads to a treatment which is more severe than necessary to control the risk associated with any pathogen that is likely to be present.

As a result of this overly restrictive approach, based on an inappropriate surrogate pathogen, there has been an on-going process of incremental 'policy creep' in relation to import conditions for this group of products, which has led to an overly complex and confusing situation. In turn, this has led to a resource intensive, case by case approach to assessment of permit applications for many products containing eggs, and at times, accusations of unfair and inequitable treatment of one importer when compared with another. Work was commenced on a comprehensive import risk analysis of eggs and egg products some years ago. Work on this IRA has stalled and the IRA has been removed from the priority list. There is potential for considerable saving in resources if this IRA was to be re-instated and progressed, whether as a regulated IRA or as a review, and the current overly complex situation therefore simplified.

Recommendation 6. A comprehensive review of import conditions for eggs and egg products, whether as a regulated IRA or an informal review, should be undertaken as a matter of priority.

Eggs and egg products

A search of the ICON database for existing conditions for egg products reveals that there are a relatively small number of products containing "*greater than 10% or discernible pieces of egg*" for which conditions have been developed. Importers are advised that the import of other such products is not permitted. The list of products for which conditions exist is as follows:

- Egg pasta/noodles with less than 20% egg content;
- Mooncakes containing egg and no other prohibited ingredients;
- Canned or retorted eggs (Refer to the ICON commodity "Egg products containing 10% or greater egg-Canned");
- Pasteurised egg products from New Zealand;
- Whole boiled eggs from New Zealand;
- Egg waffles;
- Spray dried egg white/albumin; and
- Whole spray dried whole egg or egg yolk products from Canada, Denmark, USA, Belgium and the Netherlands.

These different types of products will have differing levels of risk depending on the percentage of egg contained in the product, the degree of processing and the proposed end use. Whole egg products were rated as being of moderate risk, with a score of 2.5 against a maximum possible score of 5, while other food stuffs which may contain egg are considered to be relatively low risk with a score of 1.2 out of 5, when rated by senior BIP Officers during the preliminary exercise (Appendix 1).

More recently, a meeting of officers of Biologicals Imports Program and Animal Biosecurity discussed the perceived risk associated with various types of egg products.

Retorted egg products

The meeting agreed that retorted whole egg products would pose little risk as the retort process, if correctly applied, would be sufficient to ensure destruction of all pathogens. Doubts remained about the efficacy of the manufacturer's Declaration process at ensuring that the treatment had been properly applied. It was considered that all treatments that relied on retorting should be subject to Government certification rather than to MDs. With this change, this category of egg products would be appropriately managed.

Conclusion 11. Retorted egg products are well managed provided there is confidence that the retort process is effectively applied.

Recommendation 7. It is recommended that the use of Manufacturer's Declarations for ensuring compliance with import conditions for retorted egg products should be reviewed.

Spray dried egg powders, egg pasta, mooncakes

The meeting also considered that spray dried egg powders were well managed since these were all now subject to Government certification rather than MDs. Egg pasta and mooncakes were also considered to be well managed under current import conditions.

Conclusion 12. Spray dried egg powders, pasta and mooncakes, are considered to be well managed under current conditions.

Products containing less than 10% egg

For egg products 'containing less than 10% egg and no discernible pieces of egg' ICON advises that

> *"1. An Import Permit is not required for products containing less than 10% egg ingredients by dry weight and containing no discernible pieces of egg.*
>
> *2. Each consignment must be accompanied by a manufacturer's declaration to indicate the product contains less than 10% egg ingredients (by dry weight) and contains no discernible pieces of egg."*

This presents problems similar to those discussed above in relation to meat flavours. The 10% level is arbitrary and without strong scientific justification. In addition, a manufacturer who is prepared to sign a declaration that the product contains less than 10% egg can avoid the cost of government certification, or perhaps even gain access to the Australian market for a product which would not otherwise be permitted. Given the legal difficulties associated with regulation of the manufacturer's declarations discussed in the separate report on MDs, it seems that this leaves an opportunity for biosecurity security to be severely compromised.

Conclusion 13. Reliance on Manufacturer's Declarations in relation to the percentage of egg in composite products is of concern.

Recommendation 8. The use of Manufacturer's Declarations for ensuring compliance with import conditions for composite products containing egg should be reviewed.

Dairy products

Dairy products were rated as a moderate to high risk product, scoring 3.8 on a scale with a maximum value of 5, when rated by senior biosecurity officers (Appendix 1). This rating was qualified by the comment that processed products are less risky than raw products.

In contrast, meat and meat products scored only 1.8 on the same scale. Meat and meat products are derived largely from animals of the same species as are dairy products, and carry the risk of the same diseases. In the main, these products are imported for human consumption, and therefore in general terms the likelihood of exposure to susceptible Australian animals is similar. This significantly higher rating for dairy products seems to be related to the increased likelihood that the products may be incorporated into animal feeds after importation, especially when imported in bulk. In particular, dairy products may be legally fed tp pigs, while meat products may not. This increases the likelihood of exposure with a consequent increase in the overall level of risk.

Another possible explanation arises from the fact that the term “dairy products” represent a very broad range. Some possible products that fall into this category include:

- whole milk;
- cheese;
- butter;
- milk powders;
- coffee whiteners;
- milk drinks;
- flavours; and
- a broad range of so-called composite products which contain at least some percentage of dairy ingredients.

Some of these products are highly processed and are intended for human consumption, so are unlikely to be contaminated with infectious material, and are unlikely to be exposed to susceptible animals in any case. These are therefore unlikely to justify a high risk rating. Other products may be less highly processed and some of these may be diverted to uses other than human consumption for a variety of reasons, increasing the likelihood of exposure, especially when imported in bulk rather than in consumer ready form. This sub-group of dairy products therefore represents a greater risk.

Biologicals Imports Program (BIP) has identified a number of issues that cause significant problems for their day to day work. These have been referred to Animal Biosecurity for resolution (See Appendix 7). The specific issues which have been identified are as follows, in order of priority as identified by BIP:

1. Cheese aging and pH;
2. Dairy products sourced from Australia or New Zealand but further processed and/or dry blended in countries not considered free from FMD (relates to the interim dairy policy);
3. The ten percent dairy rule;
4. Current wording on import conditions;
5. Third country certification of dairy products;
6. Retorting dairy products; and
7. Dairy, sourced from FMD approved countries, processed in non-FMD approved countries (also relates to the interim dairy policy).

Cheeses

Cheeses from FMD infected countries are subject to Government certification only and MDs are not used. Permit conditions at present make reference to the ageing process, and to the final pH of the finished product. However, there has been some confusion in the minds of staff assessing import permit applications, over whether the ageing process itself makes a contribution to the risk management or whether the pH is the major mitigation measure. This matter should be clarified and the permit conditions updated.

Cheeses from FMD free countries are imported with Government certification only. There are no restrictions on species of origin. Manufacturer's declarations are not used. BIP staff members consider they represent a low residual risk.

There is also reference to the difference between pasteurised and unpasteurised cheeses. Currently non-pasteurised cheeses are referred to imported foods or assessed in line with FSANZ lists, as the pasteurisation is considered to be a matter for human health. However, it could also contribute to the biosecurity risk mitigation and should be considered. These products were considered to present a high residual risk, casting doubt on the perceived effectiveness of the current system of regulation for these products.

The interim dairy policy

The increasingly global nature of international trade leads to further complexity. In particular, products may be sourced from Australia or New Zealand (or other approved FMD free country) and may be further processed or blended in countries not free of FMD. The interim dairy policy provides for the importation of product originally produced in Australia or New Zealand and subsequently processed or blended in other countries.

The questions raised by BIP with ABB in relation to the interim dairy policy relate to priorities 2 and 7 from the list above. In particular, BIP claims that the requirement for auditing of production facilities would place unsustainable demands on BIP resources. BIP has requested advice as to whether a change to biennial audits of the competent authority in the exporting country, and a sample of production plants would be sufficient, rather than the more rigorous audit program currently required by the interim policy.

Further the interim dairy policy allows only product from Australia or New Zealand to be further processed overseas in countries not considered free from FMD. However, there have been requests for product from approved FMD free countries other than Australia or New Zealand to be further processed in non FMD free countries under the same conditions as for Australian or New Zealand product

The ten per cent dairy rule

Problems arising from the ten per cent rule arise in a number of ways. While it is accepted that dilution will reduce the risk of introduction of exotic disease agents to some extent, there is little scientific justification for assuming that products containing ten per cent or less of dairy products are safe, while products containing higher levels of dairy are not. However, the Quarantine Proclamation 1998, and presently exempts any dairy products containing less than ten per cent of dairy ingredients, from the requirement to obtain an import permit. Unfortunately, as pointed out in a minute from Biological Import Operations and Marine Pests Branch to Animal Biosecurity, (see Appendix 7), "it is not possible to verify the percentage of dairy in a product by inspection and no reliable, recognised quantitative test for dairy content is available".

This provides unscrupulous importers with an incentive to falsely declare that their product contains less than ten per cent of dairy ingredients, thus avoiding costs associated with obtaining an import permit, and complying with conditions which may be imposed if the

product was declared to contain a higher percentage of dairy ingredients. This presents the same problems as were discussed above in relation to meat flavours, and egg products. A separate report (as part of the Biologicals Project) addresses problems arising from the use of Manufacturer's Declarations (ACERA, in preparation).

Current wording on import conditions

This problem appears to be related simply to the published conditions not keeping pace with changes in the international animal health situation. Rectification of the wording would ease operational difficulties.

Third country certification of dairy products

The difficulties identified here relate to the increasingly global nature of international trade. When product is imported from one country to another for further processing, and is then to be further exported to Australia, it is difficult for the final exporting country to provide certification to a level that will satisfy Australian requirements. This is an administrative problem that should not be insurmountable in theory. However, it may lead to increased costs for importers who have to ensure that appropriate certification and product separation, are maintained at all points in the export chain. Critically, Australian standards should not be compromised in order to facilitate individual importers' trade needs.

Retorted dairy products

For dairy products from FMD infected countries, only retorted products are currently allowed. However, the retorting process can be certified by government certification or by way of a manufacturer's declaration. Given the low level of confidence that can be placed on information provided by way of manufacturer's declaration only, and the disease status of the exporting country, these products should be considered to have a high residual perceived risk, despite the fact that the retort process, if correctly applied, will effectively manage the real risk. In particular the use of manufacturer's declarations needs to be reviewed. Increased biosecurity confidence can be gained by requiring government certification in all cases, or by implementing a program of audits to ensure that retorting processes are effectively applied at all stages.

In many of the cases identified above, it appears that the high risk rating attributed to dairy products arises not from the intrinsic risk associated with the product itself, but from administrative difficulties associated with the risk management measures applied to this group of products. Addressing the issues raised in the separate report on manufacturer's declarations (ACERA, in preparation) will go some way towards redressing these problems.

Correction of some of the wording issues and anomalies in the current interim dairy policy will also assist in reducing operational difficulties.

However, to fully address it will require a refinement of the category into more and less risky sub-categories, and the development of conditions for the sub-categories that more accurately reflect the real risk associated with these products. This will allow a much more targeted risk-return approach to this category of biological products.

To some degree, this approach is already in use. For example, there are different conditions currently in place for generic dairy products from FMD infected and FMD free countries. Similarly, there are different conditions in place for cheese based on the FMD status of the source country. Examples of the different level of requirements for these products are outlined below, based on recent discussions with officers of Biological Imports Program and Animal Biosecurity.

When dairy products are imported from FMD free countries, current conditions require that the product not be used for stock feed. This is an appropriate requirement and, if complied with, would largely reduce the likelihood of exposure to susceptible Australian animals, and therefore decrease the biosecurity risk. However, enforcement of end use conditions has proven to be difficult. In addition, only products from bovine sources are permitted. In particular, imports of bulk dairy products pose a risk of deliberate, or inadvertent, diversion to an inappropriate end use, and should be further considered. Government certification is required and MDs are not used. With the exception of the possible diversion of bulk products to animal feed use, this is considered to present a low residual biosecurity risk.

In addition to providing advice to BIP on the questions raised above, some broader issues need to be addressed. In particular, BIP and ABB should consider:

- What basis exists for sub-dividing the large group generally referred to as "dairy products" into smaller subgroups based on intrinsic risk? and
- What risk management measures are appropriate to each of these smaller sub-categories, including clarifying the role of ageing, 'dilution' of the dairy component with other ingredients, and pasteurisation, as discussed above?

Conclusion 14. Identified operational problems with dairy products are the subject of requests for advice from BIP to AB. Review of the dairy policy by AB as requested by BIP, together with implementation of recommendations from the separate report on manufacturer's declarations, should assist in minimising administrative problems with assessment of permit applications, and improve biosecurity in relation to this class of goods.

Cosmetics

Fully finished manufactured cosmetics

Cosmetics include a wide range of products. Some (such as lip sticks) that are generally imported as finished consumer-ready packaged items are of little concern. However, the raw materials included in other forms of cosmetics are varied, and bulk imports are of potential concern.

The following extract from the "GUIDELINES FOR THE IMPORTATION OF BIOLOGICAL PRODUCTS" describes the current DAFF thinking on cosmetics.

"Most fully manufactured cosmetics, by nature of their processing and end use, are unlikely to represent a significant quarantine risk despite containing animal proteins. A small quarantine risk may exist with waste as there are no controls ensuring safe disposal of

cosmetics by the end users especially if the product contains a large amount of material of animal origin.

Some cosmetics contain human placental material or other products of human origin. The (then) *Department of Human Services and Health (DHSH)* (now Department of Health and Aging (DoHA)) *has advised that this is not a human quarantine issue and is adequately regulated by the Therapeutic Goods Administration (TGA) and/or Trade Practices Act.*

Conclusion 15. Fully finished consumer-ready cosmetic products are low risk and are appropriately managed by existing conditions.

Raw or semi-processed ingredients for cosmetics

Raw or semi-processed ingredients of animal origin destined for further processing or incorporation into cosmetics in Australia can represent a significant quarantine risk and therefore an import permit is required."

These "raw or semi-processed ingredients" are subject to individual assessment according to the nature of the material involved, such as animal serum, animal tissue extracts, etc, and will be further discussed under these separate headings.

Soil and water samples

There is currently no formal policy for the import of soil and water samples. These are currently managed in accordance with an informal policy. Soil and water samples are generally imported for environmental studies, and there is generally no intention to attempt to isolate microbial contaminants. In accordance with the informal policy, such studies are undertaken in Quarantine Containment level 1 (QC1) facilities. Where there is an intention to isolate microbes, Quarantine Containment level 2 (QC2) conditions are required. However, there is currently no account taken of the disease status of the originating country. Overall, the risk is considered to be well managed at present but there is a view that the existing informal policy should be formalised to ensure that policy creep does not occur and lead to inadvertently increasing the risk.

Recommendation 9. The present informal policy on import of soil and water samples should be formalised to prevent policy creep.

Fertilisers

Fertilisers were rated as being of high risk when rated by senior BIP Officers during the preliminary exercise, scoring 4.1 on a scale with a maximum value of 5 (Appendix 1).

Fertilisers can be further sub-divided into chemical fertilisers and materials derived from animals. Those derived by chemical means are of relatively low risk.

Fertilisers derived from untreated animal wastes such as manure and guano are potentially of very high risk due to the likelihood of contamination with micro-organisms derived from the animal source and the likelihood of direct contact with susceptible animals in the environment. For this reason, fertilisers of animal origin are generally not permitted.

As is discussed in the separate report on the use of Manufacturer's Declarations, there are issues with these products arising from the reliance on MDs. Products which were declared to not contain animal material have been found to be contaminated, thus presenting a potentially high risk.

Conclusion 16. Fertilisers are considered to be potentially high risk products. Reliance on manufacturer's declarations for ensuring compliance with import conditions is of concern.

Recommendation 10. The use of Manufacturer's Declarations for ensuring compliance with import conditions for fertilisers should be reviewed.

Hides, skins, feathers and wool

Hides, skins, feathers and wool were collectively rated as being low risk when rated by senior BIP Officers during the preliminary exercise, scoring 1.5 on a scale with a maximum value of 5. However, the risk varies within, and between these broad categories.

Hides and skins

Because of the severity of the process involved in tanning, fully processed and partially processed hides (wet whites, wet blues), tanned skins, and new leather goods present little risk of introduction of exotic pathogens.

Used equestrian or other animal handling equipment where direct exposure to susceptible animals is possible present a higher risk.

Raw hide and products containing raw hide (including artefacts such as drums) have a variable risk profile. The likelihood of exposure of many of these to susceptible animals is low, so risk is proportionally less than for cases where direct exposure is likely. These are well managed by current conditions.

Hides for taxidermy purposes, and raw hides for tanning, may present a risk of introduction of pathogens, especially when the tanneries or taxidermy premises to which they are consigned are in rural areas. In recent years, this has become increasingly the case, as metropolitan tanneries have closed down. There is a need to review the conditions for import of hides for taxidermy purposes, to ensure that they remain appropriate to the risk.

Conclusion 17. Processed or partially processed hides, skins and new leather goods are low risk items, well managed by current conditions.

Conclusion 18. Used leather goods such as equestrian equipment present a slightly higher risk, but are appropriately managed under current conditions.

Conclusion 19. Raw hides for further processing and taxidermy skins present a higher risk.

Recommendation 11. Import conditions for raw hides should be reviewed to ensure that current operational arrangements meet biosecurity needs.

Feathers

Conditions for the import of manufactured goods containing feathers, or for the import of bulk feathers, are attached at Appendix 8.

Feathers that are imported as a component of finished products such as pillows and doonas should pose little risk. For commercial imports, sourced from countries where highly pathogenic avian influenza (HPAI) is present, ICON advises that

> *"Consignments must be accompanied by a consignment specific Government Certificate, or a consignment specific manufacturer's declaration endorsed by a Government Officer, stating that the feathers in the product have received one of the following treatments:*
>
> *i) gamma irradiation at 50 kGray (5 Mrad); or*
> *ii) ethylene oxide treatment (T9020); or*
> *iii) heated to a core temperature of at least 100°C for a minimum of 30 minutes; or*
> *iv) heated to a temperature of at least 120°C for a minimum of 30 minutes; or*
> *v) washed thoroughly in detergent followed by formaldehyde fumigation (10% formalin) for 4 hours."*

These treatments will effectively manage the risk of introduction of disease in feathers, if correctly applied. Reliance on Manufacturer's Declarations is of concern, although at least in this case the MD is required to be countersigned by a Government Officer, providing a higher degree of confidence than is afforded by a manufacturer's Declaration that has not been endorsed by a Government Officer.

However, for commercial imports from countries where HPAI is not present, the option exists for an importer to provide a manufacturer's Declaration that the feathers have been *"cleaned and are free of all animal tissue and other extraneous matter"*. Other options including provision of a government certificate, or a pre-shipment ethylene oxide treatment certificate from a DAFF approved offshore treatment provider, exist. It would be preferable if the option to provide a MD was removed.

For bulk feathers with no attached animal tissue, from countries where HPAI is present, importers may supply "consignment specific documentation" attesting to either ethylene oxide or radiation treatment. While it is not clear from the wording of the ICON case, it is assumed that this is similar to the "treatment certificate from a DAFF approved offshore treatment provider" referred to above. It would be preferable if the wording of the ICON case were to be updated to remove any ambiguity. Other options listed in the ICON case include government endorsed manufacturer's Declaration, or treatment on arrival. These options are appropriate.

If HPAI is not present in the exporting country, importers may elect to comply with the conditions outlined above for HPAI countries. However, the option exists to rely solely on inspection at the border. If inspection reveals contamination with animal tissue, the consignment must be sent for treatment at the importers expense. Again, this seems

appropriate, provided that operational instructions relating to methods of inspection exist and are followed.

Feathers may also be incorporated in artefacts (such as decorations, face masks etc.). These pose little risk due to low likelihood of exposure to susceptible animals.

Conclusion 20. Feathers are considered to be relatively low risk. Overall, current conditions for import of feathers are appropriate, if correctly implemented. Reliance on manufacturer's declarations for ensuring compliance with import conditions is of concern,

Recommendation 12. The use of Manufacturer's Declarations for ensuring compliance with import conditions for feathers should be reviewed.

Wool

Scoured wool should pose little risk if properly processed. Conditions for the import of scoured wool are attached at Appendix 9. For scoured wool imported from countries where FMD is absent, existing conditions require government certification of the scouring process used. Wool imported from countries where FMD is present requires government certification that the wool has been heat treated to a level set by DAFF in order to manage the risk of transmission of FMD. Despite these requirements for government certification, wool that was imported as fully scoured has been discovered to be heavily contaminated with faecal material, indicating that the control measures have been ineffective.

Unscoured wool may be the vehicle for introduction of a range of serious animal diseases and / or zoonoses. The import of this commodity is only permitted from a range of approved countries where FMD is not present. These countries include Fiji, New Caledonia, New Zealand, Norfolk Island, Papua New Guinea, Samoa (Western), Solomon Islands, Tonga, Vanuatu. All unscoured wool is inspected on arrival to determine whether it meets acceptable standards. If standards are not met, the consignment is subject to scouring at a DAFF approved facility.

There is a need to review the conditions applying to this entire group to ensure that required risk management measures are appropriate and that DAFF overview is adequate to ensure that risk management objectives are met.

Conclusion 21. Wool is considered to be a relatively low risk product. However, despite requirements for government certification, consignments which do not meet existing conditions have been found at import inspection.

Recommendation 13. Import conditions for wool should be reviewed to ensure they remain appropriate to current conditions.

Therapeutic products

Human therapeutics including animal- and fungal- based complementary medicines

Human therapeutics were rated as being low risk when rated by senior BIP Officers during the preliminary exercise, scoring 1.6 on a scale with a maximum value of 5 (Appendix 1).

The low risk rating derives from the fact that the likelihood of direct exposure to susceptible Australian animals is relatively low. However, some human therapeutic goods do have the potential to be used for veterinary purposes (either under direct veterinary supervision or by animal/pet owners treating their animals without veterinary advice). Fully finished product in final packaging and intended for human therapeutic use receives little attention from DAFF and is largely considered by a rapid assessment process, on the basis that the import of these products is regulated by Therapeutic Goods Administration (TGA) within the Department of Health and Ageing. However, some of these products can be assigned by TGA to a category which is considered relatively safe for human use but does not address animal biosecurity concerns. The role of TGA is to ensure efficacy and safety of these products for human use and the level of biosecurity risk may not be a factor in TGA decision-making. This can result in some products being imported with little animal biosecurity assessment.

Recommendation 14. Procedures for assessment of human therapeutic goods should be reviewed, in cooperation with Therapeutic Goods Administration, to ensure that animal biosecurity issues are appropriately addressed in all cases.

Veterinary vaccines and master seeds

Veterinary vaccines and master seeds were considered to be very high risk when rated by senior BIP Officers during the preliminary exercise, scoring 4.9 on a scale with a maximum value of 5 (Appendix 1). This was the highest rating given to any group of biological products. Vaccines are considered intrinsically risky products due to the fact that direct exposure to large numbers of susceptible animals is highly likely (virtually certain). In addition, for live vaccines, the products are intended to preserve the antigenic agent and so could potentially also preserve any contaminating agents. Despite this intrinsic high risk, veterinary vaccines are considered to be well managed under the current biosecurity regime. This is because there is a well-established policy for the importation of vaccines and master seeds that has been the subject of extensive consultation with industry. The policy takes account of the fact that the international vaccine industry is highly regulated, and that major vaccine manufacturers have a vested interest in ensuring that vaccine contamination does not occur. Anecdotally, it has been stated that industry self-regulation practices are sound and that, at least in some cases, manufacturers draw DAFF attention to issues that may arise before DAFF has recognised that a potential problem exists.

Assessment staff report that they have appropriate reference material to draw upon in their assessments from Animal Biosecurity and / or AAHL. There is also provision in the policy for DAFF to audit the production plants. DAFF is currently working on development of a policy on audit procedures and frequency, which may in turn impact on vaccine assessment processes.

Conclusion 22. Overall veterinary vaccines and master seeds are considered to be products with a high intrinsic risk, which is well managed by current procedures.

Veterinary therapeutics (non-vaccines)

Veterinary therapeutics (non-vaccines) were considered to be very high risk when rated by senior BIP Officers during the preliminary exercise, scoring 4.5 on a scale with a maximum value of 5 (Appendix 1). Arrangements for control of veterinary therapeutic goods other than veterinary vaccines are generally similar to those described above for the vaccines.

However, the category does cover a wide range of products from highly refined semi-synthetic products to relatively unrefined animal extracts. Fermented products such as some anti-microbial drugs are considered reasonably safe, while some reproductive treatments such as hormones (often derived from urine) are less so.

Current DAFF work instructions divide the conditions applied to veterinary therapeutic import permits into two categories:

a) Products containing highly processed or low risk animal material, into a low risk target species – veterinary therapeutics in this category are imported accompanied by a manufacturer's declaration;
b) Products containing higher risk animal material – veterinary therapeutics in this category are accompanied by official government certification.

In addition to the assessment undertaken by BIP officers in DAFF, there is a concurrent assessment undertaken by the Australian Pesticides and Veterinary Medicines Authority (APVMA). All vet medicines used in Australia are subject to APVMA registration, which includes a requirement for manufacturers to be approved to a code of Good Manufacturing Practice (GMP). Many overseas manufacturers are audited directly by APVMA GMP auditors, or by the overseas competent authority. The APVMA has a mutual recognition arrangement in place for manufacturers in North America and some European countries whereby GMP approval issued by is recognised by the APVMA as meeting Australian requirements. While there are some problems associated with the use of manufacturer's declarations, the additional confidence provided by the APVMA assessment and their requirements for GMP approval means that the products falling into category (a) above are well managed in this case. Further discussion of the use of MDs is contained in a separate report within this project (ACERA, in preparation).

Conclusion 23. Overall veterinary therapeutics are considered to be products with high intrinsic risks which are well managed by current procedures. Reliance on Manufacturer's Declarations for some lower risk categories is of concern, but balanced by other requirements such as GMP.

Laboratory material

Catalogues (excluding micro-organisms)

Historically, laboratory supply companies have applied for an import permit to cover the range of materials contained in their catalogues, rather than applying for separate permits for each of the items included in the catalogue. The range of materials represented is very broad, and includes a wide variety of materials of animal origin as well as materials which do not

contain animal derived ingredients. The level of risk associated with such products also varies widely. For the majority of the items referred to in the catalogues, there is little if any biosecurity risk. The assessment of applications for biological material catalogues takes up considerable resources, as assessing officers must work through the vast number of individual items contained in them. This leads to delays, and significant costs for importers.

Senior officers from BIP and Animal Biosecurity expressed a view that it may be possible to develop a system of management of these catalogues based on an "Approved Quarantine Arrangement". Under this system, BIP would still do an initial assessment and maybe an audit. Then the company would not need to supply all the documentation at the border every time they import a batch. This would save time for the importer as well as our border staff as they spend considerable time at each importation checking documentation.

This seems to be a sensible suggestion and should be followed up. At a minimum, administrative procedures for this category should be reviewed in order to take resources from a relatively low risk area and use them more effectively on higher priority issues.

Conclusion 24. Catalogues may include both low risk and high risk products. Current procedures are resource intensive and potentially inefficient.

Recommendation 15. Review of the current procedures for assessment of laboratory catalogues is warranted to determine whether more efficient methods of control can reduce the resource cost associated with this group of products.

Culture media

A growth medium or culture medium is a liquid or gel designed to support the growth of microorganisms or cells (Wikepedia, 2013). These may contain a wide variety of animal derived material including blood, serum, and animal cells, as well as hormones or growth factors. As a result, culture media as a group were considered to be very high risk when rated by senior BIP Officers during the preliminary exercise, scoring 4.2 on a scale with a maximum value of 5 (Appendix 1). The risk associated with individual culture media varies depending on the source country, raw materials, quantity imported (whether in bulk or smaller packages), nature and degree of processing, and the intended end use of the product.

The major categories of culture media which are imported involve selective or differential media which are designed to grow (or inhibit) particular microorganisms. This type of diagnostic material is intrinsically low risk in itself, but could be used to isolate and grow microorganisms for later use in autogenous vaccine production, for example. Any contaminants in the culture media could then be inadvertently included in the vaccine and transferred from there to susceptible Australian animals. This could lead to a higher level of risk. Current conditions do not require government certification, nor are there restrictions on source country, and there are no volume restrictions. However, it was considered that it may be more efficient to look at improving end use controls than to impose stricter import conditions.

Import conditions for bulk dehydrated media are stricter than those applying to selective and differential media. They require that all materials are treated at 100°C for 30 minutes, and

that no TSE risk material be used in the production of the media. In addition, a Government certificate must be provided. The certificate must state the country of origin, the species of animals from which the material was derived, and that all animals used in the production of the raw materials were subject to ante and post mortem inspection.

The stricter controls on bulk dehydrated media reflect a higher risk level, derived from these products being one step closer to the final step in production of vaccines or other therapeutic goods than are the selective and differential media. In both cases, the risk is associated with contaminants in the culture media being included in a finished product that is later administered to animals. However, bulk media are used in the production stages, so contaminants in these media are more likely to be carried through into the final product.

During a risk categorisation review meeting, officers of BIP and AB expressed the view that there may be an unintended consequence arising from the difference in conditions between bulk media and smaller quantities (< 20ml/20gm). The bulk quantities are more closely regulated, while these are more likely to be used by major vaccine manufacturers, who are relatively tightly regulated in any case. Small quantities may be used in experimental vaccine development or in production of small batches of 'one off' or autogenous vaccines, which are less tightly controlled. Therefore the smaller quantities of culture media may pose a higher risk than larger quantities.

Conclusion 25. There are concerns that culture media, which are considered high risk products, are not appropriately managed at present.

Recommendation 16. Import requirements, and end use controls for culture media should be reviewed to ensure that they are meeting current needs.

Micro-organisms (includes bacteria, viruses and fungi)

Microorganisms as a group are considered as slightly above average risk, scoring 3 out of a possible 5 (Appendix 1).

There is a well-established micro-organisms policy that is considered to be working well and effectively managing risks. The DAFF "Policy for the importation of microorganisms for *in vitro* use" (Department of Agriculture Fisheries and Forestry, 2001) provides guidance for staff on other conditions which apply to this category of microorganisms. All applications for import permits for microorganisms such as this are subject to careful scrutiny.

Clearly, the risk level varies from species to species, with some organisms presenting little if any risk and others far more risk. For example, starter cultures for human food or beverage production, such as baker's or brewer's yeast, wine cultures, sausage cultures, and cheese or yoghurt cultures present extremely low risk, provided that they are not in a milk based carrier, and are not intended for *in vivo* use other than in defined laboratory animal species.

For other, more risky microorganisms, permits are issued only to restricted laboratories such as the Australian Animal Health Laboratory (AAHL) and only from selected known and respected sources. End use conditions are in place, so that these organisms are only able to be legally used for *in vitro* studies in secure laboratories. Concerns have been raised by

biosecurity staff that organisms may be used in contravention of end use conditions. The extent to which this is happening will be further explored by the 'end use' part of the Biologicals Project and will be reported separately.

The biosecurity security of the system could be improved by a program of audits to verify the species of imported cultures, and this process could be considered in the context of controls on end use. A limitation of this approach is the acknowledged difficulty of enforcing end-use conditions when the end user is not the importer.

Conclusion 26. Overall, microorganisms represent a high risk, but the procedures in place are generally appropriate to ensure that imports are well managed. There are residual concerns relating to inappropriate use of organisms post-import.

Recommendation 17. End-use controls for microorganisms should be reviewed to minimise risk of inappropriate use of imported materials.

Potential bioterrorism agents

Potential bioterrorism agents

Consideration of microorganisms also raises the possibility of import of bioterrorism agents. Potential bioterrorism agents include endemic and exotic pathogens. The deliberate release of harmful biological agents such as viruses, bacteria, fungi and toxins has the potential to cause significant damage to human health, the environment and the Australian economy. However, the potential for an agent to be used as a bioterrorism agent is not a biosecurity issue and is not within the scope of the *Quarantine Act*. The biosecurity risks associated with potential bioterrorism agents are managed through an import permit and the conditions that apply.

Potential bioterrorism agents are regulated under the *National Health Security Act 2007*and the *National Health Security Regulations 2008*, which are administered by DoHA. Part 3 of the *National Health Security Act 2007* establishes the regulatory scheme for entities and facilities that handle suspected or known Security Sensitive Biological Agents (SSBAs) and legislates the regulatory scheme. DAFF participated in the process that lead to the establishment of the (SSBA) Regulatory Scheme and continues to have a contact person.

Recommendation 18. DAFF should continue to maintain a contact person for SSBA issues and provide input or assistance to DoHA as required.

Diagnostic kits

Diagnostic kits are addressed in the "GUIDELINES FOR THE IMPORTATION OF BIOLOGICAL PRODUCTS", and are considered to be unlikely to be intentionally exposed to animals. Accidental exposure is possible, although in most cases the kits do not contain viable organisms. Some kits are entirely synthetic in nature and do not contain any animal or microbiological material. These are considered to present little biological risk and may be imported without permit, although they are subject to random audit by Customs and Biosecurity officers, and importers should therefore ensure that each shipment is accompanied by sufficient information to determine its synthetic nature.

Where diagnostic kits contain material of animal or microbial origin, manufacturer's declarations relating to the animal health of all products contained in, or used in the production of, the kits is required. In addition, labelling is required that the product is for *in vitro* use only.

Because diagnostic kits are low risk products, these controls are considered to be sufficient to ensure that the biosecurity risk posed by diagnostic test kits is adequately managed. For consistency with other recommendations it would be prudent to review the use of manufacturer's declarations in relation to kits which contain material of animal origin, but this is considered to be a low priority.

There has been a belief in the past that control should be maintained over the import of diagnostic kits for exotic pathogens. This was to ensure that only official laboratories could perform tests for these exotic pathogens, to guard against the possibility that unauthorised laboratories could make a positive diagnosis (whether real or due to a false positive reaction) and report it internationally before the appropriate state or federal regulatory agencies were aware. This could lead to international embarrassment, and potential loss of export markets. While this is considered to be a real risk it is considered that this should not be a part of biosecurity consideration. Other legislation should be used to control this possibility.

Conclusion 27. Diagnostic kits generally present a low biosecurity risk, which is well managed by current conditions. However, some residula concerns remain over the use of Manufacturer's Declarations.

Recommendation 19. Review of the use of manufacturer's declarations for those diagnostic kits which contain material of animal origin to ensure that this remains appropriate would be desirable.

Conclusion 28. There is a degree of 'political' or 'commercial' risk associated with use of diagnostic kits by unapproved persons, and unauthorised reporting of positive results (whether real or false positive). The Quarantine Act is not the appropriate legislative instrument for control of this risk.

SPF eggs

Australia currently has only one producer of SPF eggs. Current import policy allows the import of SPF eggs only for contingency use, when the Australian producer is unable to meet demand. SPF eggs are used for a variety of purposes, including vaccine production, laboratory testing, production of sentinel birds for post-arrival quarantine testing of imported birds and/or hatching eggs, and other purposes. The existing sole supplier arrangements often lead to a need to arrange for imports of SPF eggs to occur at short notice, and with a degree of urgency, and consequently lead to hurried decision making.

SPF flocks are required to meet the European Pharmacopoeia requirements which include weekly testing for a wide range of avian diseases and a twelve month history of testing of the source flock prior to egg collection. The current contingency policy imposes requirement over and above those set out in the European Pharmacopoeia and this results in a very well managed risk, which would not be appreciably greater if the contingency clause were

removed. Issues which have been raised in the past to justify the continuation of the contingency policy are arguably not biosecurity related and are more to do with ensuring an on-going Australian based supply of SPF eggs. While this is a reasonable concern, it is not a biosecurity issue and the *Quarantine Act* should not be used for this purpose. Other policy approaches would be better suited to this purpose. It would be highly desirable for this policy to be further reviewed to simplify the arrangements.

Conclusion 29. SPF eggs are relatively low risk products, which are potentially over regulated at present.

Bioremediation agents

Bioremediation agents were rated as being high risk when rated by senior BIP Officers during the preliminary exercise, scoring 3.9 on a scale with a maximum value of 5 (Appendix 1). Bioremediation agents represent a broad category of products that are often not completely defined with respect to their individual components. They are generally microbial, but often consist of a mixed microbial flora, with only the main component(s) identified. The microbial fraction of the bioremediation agent is subject to the micro-organisms policy, but when the microbial mix is incompletely defined, application of the policy can pose some difficulty. In addition, the 'carrier' in which the microbial portion of the agent is contained is often organic in origin and may in itself pose biosecurity concerns.

The assessment of applications for import permits for these products is usually desk based, and may include an assessment of the producers' Quality Assurance manuals. However, there is at present no formal requirement for this to be the case. There is little regulatory oversight of the industry in many exporting countries, and there is at present no requirement for on-site auditing of the production process.

In addition to any animal biosecurity concerns that might arise from the import of these products, there are possible adverse environmental outcomes that could result. If DAFF staff assess there may be a risk of environmental damage arising from the import of a bioremediation agent, they may refer to Environment Protection Agencies for advice. However, if DAFF is not fully aware of the nature of the material, this assessment can be flawed.

Conclusion 30. Bioremediation products represents a cause of serious concern to DAFF staff.

Recommendation 20. Import conditions for bioremediations agents should be the subject of an in depth review, probably in cooperation with State EPAs, to ensure that a system of controls which meets the needs of biosecurity and environmental agencies is developed and implemented.

Enzymes

Enzymes were rated as being moderate risk when rated by senior BIP Officers during the preliminary exercise, scoring 3.2 on a scale with a maximum value of 5 (Appendix 1). The risk associated with enzymes varies depending on the source country, raw materials, quantity imported (whether in bulk or smaller packages), nature and degree of processing, and the

intended end use of the product. These products are not generally considered to be a high risk due to the high level of dilution involved in their production and use.

Some types, such as porcine pancreatic enzymes are unable to be treated with any common biosecurity risk mitigation treatment without destroying the enzymes activity. These are only permitted to be imported from countries which are free of all diseases listed in Annex 1 to the Veterinary Vaccine policy (Australian Quarantine & Inspection Service, 1999). Government certification attesting to the disease status of the country, and species of origin, and processing are required in these cases.

Conclusion 31. Overall, enzymes are considered to be a moderate risk product and are well managed by current conditions.

Animal feeds

Pet food

Pet foods are often produced from animal material, and there is a direct pathway of exposure to Australian animals. Therefore, these products pose a relatively high level of biosecurity risk, scoring 4 out of a possible 5 when rated by senior DAFF officers (Appendix 1). This is slightly lower than for stock feeds (4.5), because pet foods are largely fed to carnivores, which are not generally susceptible to the major diseases of the livestock species from which the pet foods are largely derived

In accordance with the existing import conditions, all pet food imports that contain animal material are subject to government certification of treatments applied during the processing of the raw material. Pet food production plants are either audited by DAFF staff, or are audited by competent authorities from the exporting country, in accordance with an MOU. This should provide a relatively high level of biosecurity confidence.

However, the range of products falling under this heading is large, and ranges from fresh meat and meat products (from a limited number of countries), to semi-dried and dried pet foods, raw hide products (chews), dried pigs' ears, and other items. Due to the very large global market and intense competition, the international pet food companies are continually trialling new technologies and biosecurity policy has not always kept up with advances in the market. The ability to assess the effect of heating at high pressure and temperature (but for very short times) such as used in extrusion processes, and the biosecurity safety of flavour enhancers such as meat digests used as a coating on kibble products are examples of the problems associated with these products.

Officers from BIP and Animal Biosecurity have advised that there have been recent problems with imported pet food being contaminated with *Salmonella* spp. This contamination has not yet been fully investigated but it appears that it may be related to one or other of the problems referred to above (i.e. that the heat treatment resulting from the extrusion process was insufficient to fully inactivate any possible contamination in the raw material used in production of the kibble itself, or that there was contamination in the flavour-enhancing coating on the kibble pieces.

Further investigation of this incident will hopefully shed some further light on this matter. However, it is an indication that the current system of control over this category of products is not infallible.

Conclusion 32. Pet foods are a potentially high risk product. Recent problems suggest that this group of products is not well managed at present. Rapid changes in the technology used in the production of pet food may be contributing to the observed problems.

Recommendation 21. A review of pet food controls is warranted.

Livestock feed (animal/microbial based — fishmeal, meat and bone meal etc)

Stock feeds were rated as being high risk when rated by senior BIP Officers during the preliminary exercise, scoring 4.5 on a scale with a maximum value of 5. As a result of this high risk, the import of stock feed of animal origin (with the exception of dairy based stockfeed from New Zealand) is not currently permitted. Meat and bone meal from New Zealand is permitted, but State legislation prohibits the feeding of meat and bone meal to ruminant species. Plant-based stockfeeds are imported and are subject to testing to ensure that contamination with animal based protein supplements such as meat and bone meal are not included.

Conclusion 33. Stock feeds are high risk products due to the direct exposure pathway to susceptible Australian animals. They are well managed by current conditions.

Stock feed supplements

There is a wide range of products that fall under the broad heading of 'stock feed supplements'. These include, but are not limited to, fermentation derived additives, amino acids, micro algae, milk powder and lactose based additives, gelatin and lanolin based carriers etc. These products can present a similar level of intrinsic risk as those classified as veterinary therapeutics, in that they are biologically derived, and have a direct route of exposure to susceptible Australian animals. They are therefore considered to be high risk. They are generally not subject to the same level of regulatory oversight in the producing country as are other therapeutic goods. There are currently no restrictions based on country of origin applicable to these products.

Conclusion 34. Stock feed supplements are potentially high risk products which do not appear to be subject to the same level of control as other, similar products.

Recommendation 22. A review of the current conditions for stock feed supplements is warranted.

Aquaculture feed/fish food

Aquaculture and fish foods present different levels of biosecurity risk. Aquaculture foods are likely to be used in large quantities and exposed directly to the environment, while aquarium fish foods are used in smaller quantities and direct exposure to the environment is less likely, although still not impossible. Livestock may have access to ponds which are also used for

aquaculture, or sludge removed from ponds after harvesting may be applied to pasture as fertiliser.

As was discussed in a separate report within this project (ACERA, in preparation), there is a reliance on Manufacturer's Declarations for control of some of these products. This can be a serious concern and should be reviewed in line with the recommendations from the Project's Report on Manufacturer's Declarations.

In addition, ruminant protein may be used as an ingredient in fish foods and this may also lead to problems if used in the environment especially where terrestrial animals have access to water bodies used for fish farming or where runoff from aquaculture enterprises contaminates water sources. To combat this risk there is a requirement to test certain imported aquaculture feeds for the presence of ruminant protein. Positive ruminant DNA test results in the past have led to concerns that the use of ruminant derived products in these feeds is possible (J. Cupit, 2012 *pers. comm*.).

This case also presents an instructive example of the unintended consequences of 'policy creep'. The policy states that bags over 16 kgs in weight should be subject to testing. However, for some reason, (possibly concerns raised by industry about the costs associated with testing), the requirement to test is now limited to those cases where the product is imported in bags of greater than 30 kg in weight. Due to industry standards, and to occupational health and safety requirements, much of this type of product is now imported in bags of less than 22 kg, resulting in a situation where the product is rarely tested (J. Cupit, 2012 *pers. comm*.).

As aquaculture develops there is also a concern that as with pet foods, technological progress will lead to development of innovative processes and products that will also require assessment for their biosecurity risk. BIP has advised that the current policy is under reconsideration by AB.

Conclusion 35. Aquaculture feeds represent a potentially high risk product.

Recommendation 23. Reliance on Manufacturer's Declarations for ensuring that import conditions for aquaculture feeds are met, should be reviewed.

Recommendation 24. Recent events suggest that testing requirements for aquaculture feeds at the border should be reviewed to provide enhanced confidence that import conditions are being complied with.

In vivo approvals

Discussion of *in vivo* approvals refers not to a particular group of biological products, but to the establishment of permit conditions that restrict the use of particular high risk products in live animals. In general, once a product has been permitted to be imported, its use is unrestricted. In some cases of high risk products however, use in live animals is only permitted under controlled circumstances such as in a laboratory. The risk associated with the product will determine what level of laboratory facilities is required in order to allow such *in vivo* use, and any other conditions which may be placed on that use, such as requirements for waste disposal and disposal of animals which have been exposed to the product. Because of

the nature of the products involved, these approvals present a relatively high level of risk which must be managed. Discussion with senior managers from BIP suggested that the system for *in vivo* approvals is, overall, working relatively well. These are high risk products but with good management in place. The real problem lies with the diversion of products that were given *in vitro* approval to *in vivo* use after arrival (high risk products poorly managed). This will be addressed more fully in a separate part of this project relating to 'end use' of imported biologicals.

Conclusion 36. *In vivo* approvals are high risk but well managed under current conditions, subject to appropriate control of end use. End use issues are being addressed separately.

Recommendation 25. The recommendations of the end use review (Part 3 of this project) should be considered in relation to *in vivo* approvals.

Returning Australian Products

Senior officers have expressed concerns over the not infrequent requests for import permits for product which had been exported, that for a variety of reasons, the exporter later wants returned to Australia. Such products create problems when industry needs to return goods, but where the goods may not be able to be appropriately certified, and hence not necessarily in compliance with Australian regulations.

DAFF has a web site with detailed instructions on the processes to be followed in such cases (DAFF, 2011). In addition to detailing the procedures to be followed, the web site provides information on the increasing level of risk associated with returning Australian goods, depending on the state of the product at the time of re-import. At present the information is heavily biased towards food products, but the general principles would apply equally to non-food commodities as well. As the product progresses further down the export chain, and therefore further from the last point at which it was subject to supervision by Australian authorities, the risk increases. The following list describes various steps in this progression.

- container seals are intact (container unopened)
- container seals broken but product (eg. meat) intact in original container
- container seals broken and product (eg. meat) samples withdrawn
- containers unpacked under foreign quarantine supervision
- containers unpacked but not under foreign quarantine supervision, and/or
- container cleared quarantine and currently not under quarantine supervision.

This web site is in the process of being updated (Carol Sheridan, *pers. comm.*, 2012). Changes from the information shown on the current web site are minimal, but the revised version does include a flow diagram which depicts the processes to be followed by staff assessing applications for returning Australian products.

The information supplied on the web site, particularly when the proposed amendments are finalised, provide an appropriate means of dealing with this problem, in accordance with Australia's current biosecurity policies.

Conclusion 37. Returning Australian products present a variable risk depending on the particular product involved. Current conditions are appropriate.

General Comments

This review has identified a number of problems that have affected the perceived risk associated with various categories of imported goods. These problems can be broadly classified into seven groups, and are listed below, together with general recommendations relating to each.

1) Problems associated with the current over reliance on Manufacturer's Declarations. These problems could be largely solved by revising the use of such documents in line with the recommendations in a separate report within this project (ACERA, in preparation).

Recommendation 26. In addition to recommendations listed above relating to the use of Manufacturer's Declarations for specific products, it is recommended that a broad review of the use of Manufacturer's Declarations be carried out, in accordance with the findings of the separate report prepared as part 2 of this Project.

2) Problems associated with the different risk presented by different intended end use of imported products. While it is true that the risk presented by a product can differ greatly depending on its intended end use, it is equally true that there are considerable difficulties involved in enforcing end use conditions on imported products, especially once they have been on-sold by the importer. Possible solutions to this problem include treating all imported goods to manage the risk posed by the most risky end use, or a review of the mechanisms for imposing enforceable end use conditions. The former is considered to be overly restrictive in many cases, but may be appropriate for some types of goods. The separate end use part of the ACERA Project may assist with suggestions for improving the control of end use and therefore assist in progressing the second option.

Recommendation 27. In addition to specific recommendations listed above relating to end use controls for specific products, it is recommended that a broad review of end use conditions be carried out, in accordance with the findings of the separate report prepared as part 3 of this Project.

3) Problems arising from the increased likelihood that products imported in bulk are more likely to be diverted to alternative end uses than are products which are imported in finished, consumer ready form. Formal consideration of the effect of final packaging on this likelihood could lead to packaging being used as an appropriate risk management measure. Products packaged in a final form for use by consumers may be subject to different conditions to those applied to bulk imports.

Recommendation 28. A review of the relationships between packaging, end use and risk should be carried out to determine whether packaging can be effectively used as a risk management measure, and the extent of risk mitigation it might provide.

4) Problems associated with categorising products into broad and loosely defined groups (e.g. dairy products, eggs and egg products, meat flavours) and treating all products in the group similarly. This inevitably leads to a situation where 'average' import conditions are applied, resulting in over-regulation of some relatively safe products and under regulation of other, riskier products.

Recommendation 29. Where current import conditions refer to broad categories of products such as dairy products, or eggs and egg products, it is recommended that consideration be given to completing import risk analyses of individual products within the category to ensure that import conditions remain relevant to the level of risk posed by that product rather than to the group as a whole.

5) Problems arising from reliance on 'dilution' of risk material in composite products to an arbitrary level, which is not supported by scientific evidence. Examples include the 5% rule for meat content in meat flavours, and the 10% rule for dairy and egg ingredients in composite products containing these ingredients. This problem has been addressed at Recommendation 4 above.
6) Problems arising from the current system of DAFF approvals of various exporting countries, processing plants, processes, etc. It appears that there should be a review of the formal process of approvals, and of the maintenance of lists of approved premises/processes etc. This problem has been addressed at Recommendation 5 above.
7) Problems arising from the continued use of old, existing import conditions, where changing circumstances indicate that review is required.

Recommendation 30. A program of formal review of existing import conditions should be implemented to identify cases where changing technologies or other factors have rendered those conditions ineffective. In such cases, conditions should be updated to ensure continued relevance to the current quarantine environment.

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Appendices

Appendix 1. Initial risk estimate by Senior BIP officers of commodities in the program (2010).

(Range from 1 to 5: 1 is lowest risk, 5 is highest likely risk)

In preparation for the start of the formal review project, senior officers within the Biologicals Imports Program (BIP) were asked to list the types of products that were considered to be 'biologicals' and therefore within the scope of the review. They were also asked to rate the overall level of risk associated with each of the groups of 'biologicals', before risk management measures were applied. The outcome of that exercise is summarised below.

Commodity	**Rating**	Comments
Birds' nest products	**1**	
Cosmetics	**1**	(fully finished risk < bulk)
Fin fish (for human consumption**)**	**1**	
Soil and water samples	**1**	volume cut off?
Foodstuffs (excluding dairy, fish, prawns, and herbal products)	**1.2**	
Hides, skins, feathers and wool	**1.5**	
Human therapeutics (including animal- and fungal-based complementary medicines)	**1.6**	TGA
Meat (including canned/retorted meat products)	**1.8**	
Laboratory material and catalogues (excluding micro-organisms)	**2**	diagnostic kits <
Prawns products - human consumption	**2**	
Casings	**2.3**	
Uncanned chicken meat	**2.3**	
Whole egg products	**2.5**	
Pig meat	**2.6**	
Micro-organisms (including bacteria, viruses and fungi)	**3**	0691 <
Enzymes	**3.2**	
Aquaculture feed / fish food	**3.8**	
Dairy products	**3.8**	(processed risk < raw)

Bioremediation agents	**3.9**
Pet food	**4**
Fertilisers	**4.1**
Culture media	**4.2**
Livestock feed (animal/microbial based — fishmeal, meat and bone meal etc.)	**4.5**
Veterinary therapeutics (non vaccines)	**4.5**
In vivo approvals	**4.8**
Veterinary vaccines and master seeds	**4.9**

Appendix 2. Risk rating of biological products derived from the review process (2012).

Initial commodity	Initial Risk Rating	Sub-group	Final Risk Rating	Comments
Food products for human consumption				
Kopi luwak			Low risk. Well managed.	Expensive specialist gourmet product for human consumption. Very low likelihood of exposure to susceptible animals.
Birds' nest products	1		Low risk. Well managed.	Expensive specialist gourmet product for human consumption. Requirement for inspection at border to ensure proper processing. May be over regulated.
Fin fish (for human consumption)	1		Low risk. Well managed.	IRA established current conditions. Competent authority assessment. Government certification required. Consumer ready product. Low likelihood of exposure.
Prawn products for human consumption	2		Low risk. Well managed.	Recent IRA established current conditions. Testing of fresh product, or highly processed product. Government Certification required
Other aquatic products	Not considered		Management for some (incl oysters) but not all. Effectiveness and risk varies. Risk unknown for some but potentially high. .	The large number of aquatic products which have not been the subject of formal import risk analysis leave Australia open to significant biosecurity risk. Recommend priority be given to development of risk analysis for the bulk of aquatic products not already subject of IRAs.
Meat (canned/retorted meat products)	1.8		Moderate risk. Well managed	Canned retorted meats currently require Government endorsed manufacturer's declaration. **For consistency with other similar products, needs to be changed to Government Certification only**.

Initial commodity	Initial Risk Rating	Sub-group	Final Risk Rating	Comments
Uncanned chicken meat	2.3		Moderate risk. Well managed.	Recent IRA established current conditions. Government Certification only.
Pig meat	2.6		Moderate risk. Well managed.	Recent IRA established current conditions. Government Certification only. Approved countries only.
Uncanned red meat	1.8			Currently, conditions suspended pending finalisation of beef IRAs.
Meat flavours			Risk varies with percentage of meat in the product, source country, and final packaging. **High Residual risk for <5% conditions.** Low risk for >5% meat conditions.	**<5% meat currently requires manufacturer's declaration**. This leaves open the possibility of fraudulent declarations allowing some products to enter with less than optimal risk management treatments. >5% meat, consumer ready packaging, Government certification required. >5% meat, bulk packaging, FMD affected country, requires on-site audit of processing plants, Government certification required. >5% meat, bulk packaging, FMD free country, requires desk audit, Government certification required.
Casings	2.3		Moderate risk. Well managed.	Government Certification only. Approved countries and species. Can only be sourced and exported from one country to Australia.
Eggs and egg products	2.5		Broad range of products involved. Potential for some to be used in bird feeds, so potential high risk, while others are low risk.	Use of IBD as a surrogate pathogen leads to unrealistic risk estimates. However, reliance on manufacturer's declarations leaves open the possibility of fraudulent declarations allowing some products to enter with less than optimal risk management treatments. Completion of an import risk analysis in relation to egg products has the potential for considerable savings in resources.
		Retorted egg products	Conditions are appropriate	Reliance on manufacturer's declarations of concern

Initial commodity	Initial Risk Rating	Sub-group	Final Risk Rating	Comments
		Spray dried egg powders, pasta & mooncakes	Well managed.	
		Products with less than 10% egg		Reliance on manufacturer's declarations of concern
Dairy products	3.8		Broad range of products involved. Potential for some to be used in animal feeds, so potential high risk, while others are low risk.	Risk varies with: - source country (FMD affected > FMD free); - degree of processing (processed risk < raw); - packaging (bulk > consumer ready); - %age of dairy ingredients in product (reliance on manufacturer's declarations for <5% is inappropriate); and - end use (dairy products not to be used for stock feed but this is difficult to enforce). Biologicals Imports Program (BIP) has requested advice from ABB on a range of problems relating to this group of products. Reliance on manufacturer's declarations of concern
Cosmetics	1	Fully finished consumer ready cosmetics	Low risk. Well managed	
		Bulk products for use in	Possible moderate risk	These should be assessed according to the conditions for the

Initial commodity	Initial Risk Rating	Sub-group	Final Risk Rating	Comments
		cosmetics		material itself, not as cosmetics.
Soil and water samples	1		Low risk. Well managed .	The present informal policy should be formalised to prevent policy creep. The formal policy should consider a volume limit.
Fertilisers	4.1	Chemical fertilisers	Low risk. Well managed.	.
		Animal manure derived fertilisers	High risk. Generally prohibited, which is an appropriate management measure.	Reliance on manufacturer's declarations increases the risk. These should be reviewed
Hides, skins, feathers and wool	1.5			
		Processed and partially processed skins	Low risk. Well managed by current conditions.	
		Skins for taxidermy	High risk especially when transported to rural areas for processing.	Conditions for import of hides for taxidermy need review
		New leather goods	Low risk. Well managed by current conditions.	
		Used leather goods	Moderate risk. Well managed by	

Initial commodity	Initial Risk Rating	Sub-group	Final Risk Rating	Comments
			current conditions	
		Manufactured goods containing feathers	Moderate risk from HPAI infected countries; Well managed by current conditions. Low risk from HPAI free countries, but option for manufacturer's declarations of concern.	Consider removing option for use of manufacturer's declarations for HPAI free countries.
		Bulk feathers – tissue absent	Low risk. Conditions provide good management if appropriately applied.	Ensure inspection procedures are well documented and are correctly applied.
		Bulk feathers – tissue present	Moderate risk. Well managed.	
		Artefacts containing feathers	Low risk. Well managed	
		Wool	Low to Moderate risk. Conditions provide good risk management, if appropriately applied.	Experience suggests that there may be problems with application of existing conditions.
Therapeutic				

Initial commodity	Initial Risk Rating	Sub-group	Final Risk Rating	Comments
products				
Human therapeutics including animal and fungal based complementary medicines	1.6		Moderate risk, due to possible use in animals.	Reliance on TGA assessment potentially overlooks animal biosecurity issues. Review of assessment procedures is warranted.
Veterinary vaccines and master seeds	4.9		High risk. Well managed by current conditions.	
Veterinary therapeutics (non-vacines)	4.5	Highly processed synthetic drugs	Low risk. Well managed by current conditions.	Reliance on manufacturer's declarations of potential concern.
		Animal extracts (eg hormones)	Potential High risk.	
Laboratory material				
Laboratory material catalogues (excluding microorganisms)	2		Generally Low risk. Well managed by current conditions.	Potentially over regulated Consider an "Approved Quarantine Arrangement" process to allow resources to be diverted to more productive use.
Culture media	4.2	Selective and differential media	High risk mainly related to inconsistent endues controls	Could cause problems if used for example to isolate organisms which are subsequently used for vaccine production. Consider improved end use control.

Initial commodity	Initial Risk Rating	Sub-group	Final Risk Rating	Comments
		Bulk dehydrated media	High risk mainly related to inconsistent end use controls	Small quantities may be riskier than large considering industry structure. Larger, better regulated companies use large quantities; smaller, potentially less well regulated companies use smaller quantities.
Microorganisms	3		Moderate risk. Import conditions appropriate but concerns remain over end use controls.	Consider discussions with other agencies on handling of potential bioterrorism threats.
Diagnostic kits	Not considered		Low risk for most; Where there is a risk it is well managed by current conditions.	Consider "trade risk" arising from use of test kits for exotic pathogens by non-official laboratories. This is not a biosecurity problem *per se* and should be managed under other legislation.
SPF eggs	Not considered		Low risk. arguably over regulated.	Policy concerns relate to continuity of supply of Specific Pathogen Free (SPF) eggs, not Biosecurity.
Bioremediation agents	3.9		Potentially high biosecurity and environmental risk; not well managed at present.	Need to review in cooperation with environmental agencies.
Enzymes	3.2		Moderate risk. Well managed by current conditions.	
Animal feeds				
Pet food	4		Moderate to High risk. Despite strong biosecurity controls in	Some issues arise due to technological advancement and new products in the pet food industry. Recent contamination incidents suggest treatments are not infallible. On-going review

Initial commodity	Initial Risk Rating	Sub-group	Final Risk Rating	Comments
			place, occasional problems occur	required.
Livestock feed	4.5	Stock feed of animal origin	High risk. Well managed under current conditions.	Animal based stock feeds are essentially prohibited except for dairy based stock feed from NZ.
Stock feed supplements			Variable risk due to broad range of products. Some have potential moderate to high risk	Consider controls on country of origin & Government certification
Aquaculture feed / Fish food	3.8		Potential High risk. Potential management problems.	Consider - reducing reliance on manufacturer's declarations; - reducing package size that requires testing to less than 23 kgs due to OHS&S issues; and - possible future technological advances as aquaculture develops.
***In vivo* approvals**			High risk but well managed.	End use issues may lead to problems. This is being addressed in a separate part of the ACERA Project No: 1101F - Biologicals.
Returning Australian products			Variable risk depending on product. Well managed by current conditions.	

Appendix 3. **Extracts of current import conditions for birds' nest products**

Non-Commercial

1. An Import Permit is not required for the importation of personal consignments of commercially manufactured and retorted moist birds' nest products. The products must be moist retorted in cans, jars or retort pouches and must not require refrigeration.

2. Importers should be advised that raw product and dry retorted product are currently not permitted.

3. Consignments will be subject to mandatory inspection on arrival to ensure that the product has been commercially manufactured and retorted and are shelf stable. Consignments that do not comply must be re-exported or destroyed at the importers expense.

Commercial

1. A valid Import Permit must be obtained prior to importation. Permit applications must be sent to DAFF Canberra office for assessment.

2. Importers should be advised that Import Permit conditions currently only permit products that are moist retorted. The minimum requirement is that all products are heat treated to a minimum core temperature of 100°C in a retort process, obtaining an Fo of at least 2.8. Dry retorted products are currently being assessed on a case by case basis. Raw product are currently not permitted.

3. Consignments will be subject to mandatory inspection on arrival to ensure that the product has been commercially manufactured and retorted. Hermetically sealed products that have not been retorted do not comply. The inspection includes checking that the product is shelf stable and does not require refrigeration until opened.

4. Consignments that do not comply with the Import Permit conditions or are found to be not properly canned / retorted and commercially manufactured, or are not shelf stable must be re-exported or destroyed at the importer's expense.

a) 'Retorted' means heated in an unopened hermetically sealed container for a time, and to a temperature, by superheated steam under pressure, sufficient to render the contents commercially sterile.

b) 'Hermetically sealed' means airtight; completely sealed from the atmosphere, so that when sealed it does not allow micro-organisms or any other material to enter it.

Appendix 4. Import conditions for highly processed prawns

1. A valid copy of this Import Permit (or a method of identifying the Import Permit such as the Import Permit number) and all required documentation must accompany each consignment. Alternatively, necessary documentation will need to be presented to DAFF at the time of clearance. In order to facilitate clearance, airfreight or mail shipments should have all documentation securely attached to the outside of the package, and clearly marked "Attention Quarantine". Documentation may include Import Permit (or Import Permit number), manufacturer's declaration and invoice. The importer must meet all costs associated with the importation of this product.

These conditions apply to uncooked prawns that are highly processed, i.e.: the head and shell removed (last shell segment and tail fans permitted) and coated for human consumption by being breaded or battered, marinated in a wet or dry marinade, marinated and placed on skewers or processed into dumpling, spring roll, samosa, roll, ball or dim sum-type product:

Manufacturer's Declaration

2. Each consignment of highly processed prawns and/or prawn products must be accompanied by a manufacturer's declaration, stating that for relevant products listed in PC0600:

a) the method of manufacture has not altered since information was supplied to DAFF with the application.

b) the permitted flavour components of the wet marinades are no less than 12% of the total weight of the product; and/or

c) the permitted flavour components of the dry marinades clearly coat the product; and/or

d) the permitted flavour components for prawns placed on skewers clearly coat the product; and/or

e) the raw prawn meat has been processed into permitted breaded or battered product; and/or

f) the raw prawn meat has been processed into permitted dumpling, spring roll, samosa, roll ball or dim sum type product.

Note: Marinade components such as rice flour and maltodextrin are not considered flavour components as they do not add flavour to the product.

3. The manufacturer's declaration must be:
.from «name of manufacturer»

. where the manufacturer is not specified above, the declaration must be issued by the individual manufacturing site or by the manufacturer's head office within the country of export.
. on manufacturer's letterhead including company address and country.
. written in English.
. signed by a designated representative whose name, position and title also appear.
. identify the date of issue.
. issued and dated within the last 6 months (unless otherwise specified in this import permit).
. free from erasures and non certified alterations (all erasures and alterations must be endorsed by the issuer of the document. The only acceptable endorsement is a company stamp or seal and the signature of the company officer responsible for signing the declaration applied adjacent to the alteration).
. contain the correct statement/s as required by the import conditions (all prescribed information on the certification must be legible and appear above the signature).
. specific to the product(s) listed on this permit.
. have a unique identifiable link to the consignment such as one of the following: container number, bill number, commercial invoice number, preferential tariff certificate number, health certificate number, packing list number or letter of credit number, batch/serial number or date of manufacture.

Competent Authority Certification

4. Each consignment must be accompanied by batch and/or carton specific certification issued by the Competent Authority of the country of export. (A batch is defined as a population from a different pond population or fishing period population) The certificate must state that the prawns:

a) have been processed, inspected and graded in premises approved by and under the control of the Competent Authority; and

b) are free from visible signs of infectious disease.

Government certification must be:
.on official government letterhead.
. written in English.
. signed by a Government Officer whose name, position and title also appear
. identify the date of issue.
. issued and dated within the last 6 months (unless otherwise specified in this import permit).
. free from erasures and non certified alterations (all erasures and alterations must be endorsed by the issuer of the document. The only acceptable endorsement is a government stamp or seal and the signature of the Government Officer responsible for signing the certificate applied adjacent to the alteration).
. sealed with the stamp/seal of the issuing National Competent Authority.
. contain the correct statement/s as required by the import conditions (all prescribed

information on the certification must be legible and appear above the signature of the Government Officer).
. specific to the relevant product(s) listed on this permit.
. have a unique identifiable link to the consignment such as one of the following: container number, bill number, commercial invoice number, preferential tariff certificate number, health certificate number, packing list number, letter of credit number, batch/serial number or date of manufacture.

All documentation must meet the requirements of the Minimum Documentary Requirements Policy. For full details of the DAFF minimum documentary requirements, please refer to http://www.daff.gov.au/DAFF/import/general-info/documentary-requirements.

Inspection Requirements

5. a) Consignments will be subject to random inspection by DAFF to ensure the imported commodity complies with the product description on this permit and the competent authority certificate.

b) Where consignments are not covered by a valid manufacturer's declaration or are covered by a manufacturer's declaration with an incorrect statement and/or products are not listed in PC0600, the entire consignment must be:

i) re-exported; or

ii) destroyed; or

iii) sampled with all batches directed to a Quarantine Approved Premises (QAP) and be tested for White spot syndrome virus (**WSSV**) and Yellowhead virus (**YHV**).

If option 5.b.iii is selected the Testing Requirements under point 6 apply.

If all of the Documentation provided meets the above conditions then the goods may be released from quarantine, subject to random verification inspections.

Testing Requirements

6. a) All consignments of prawns will be held under quarantine control in Australia, at a QAP, where they will be sampled for testing. Prawns will remain under quarantine control until the results of the tests are available. Batches that return positive results must be re-exported, destroyed or further processed in a facility approved by DAFF for that purpose. Importers wanting to further process batches that return positive results must contact the DAFF Biological Imports Program for further information.

b) Each consignment must be accompanied by documentation from the exporter, supplier or competent authority verifying the number of batches in the consignment. This documentation

must clearly detail the labelling of each batch in the consignment. If the number of batches cannot be determined from documentation, a full unpack and inspect may be required in order to determine the number of batches.

c) The importer or authorised agent is required to sign a declaration form stating the number of batches in the consignment, and the laboratory they wish to conduct the testing, prior to sampling.

d) All costs associated with testing (including sampling, transport, and testing) are to be borne by the importer.

Packaging Requirements

7. The product should be packaged in a manner that facilitates inspection. This does not include whole block form.

8. Prawns that are not packaged in a manner that facilitates inspection (eg in whole block form) need to be re-exported or destroyed, or the importer will be required to arrange for the frozen blocks to be sawed open under quarantine supervision to facilitate inspection while the product remains frozen.

Post Entry Requirements

9. The product is for sale in its imported form for cooking without removal of the coatings and is not for further processing or repackaging without written approval from DAFF.

Appendix 5. Permit conditions relevant to meat flavours

PC0672

DOCUMENTATION REQUIREMENTS

1. Each consignment must be accompanied by a manufacturer's declaration, written in English, stating:

a) the meat based flavour ingredient contained in this product has been heated in the country of export to a minimum core temperature of 100°C for a minimum of 30 minutes; and

b) the product contains less than 5% meat; and

c) the product contains no discernible pieces of meat; and

d) the product does not contain bovine meat; and

e) i) the product contains less than 10% dairy ingredients by dry weight; OR

ii) the product does not contain dairy or dairy derived ingredients;

AND

f) i) the product contains less than 10% egg ingredient by dry weight and the product contains no discernible pieces of egg; OR

ii) the product does not contain egg or egg derived ingredients.

PC0673

CERTIFICATION REQUIREMENTS

2. Each consignment must be accompanied by an Official Government veterinary certificate from the country of origin which states:

a) Species from which the meat was derived; and

b) The product does not contain bovine meat; and

c) Date(s) on which the meat was heat processed; and

d) Identification/veterinary control number(s) of the establishment(s) where the meat was heat processed; and that these establishments have current approval; and

e) That the animals from which the meat was derived were subjected to ante- and post-mortem veterinary inspection and were found to be free from contagious or infectious disease; and

f) That the meat has been treated with heat so that the core temperature of the meat exceeded 100°C for not less than 30 minutes; and

g) That the product contains no discernible pieces of meat. (Note: This point can be confirmed by physical inspection of the product if required).

h) That the meat based flavour has been packed in clean, new bags, wrappers or packing containers. Also, the identification/veterinary control number of the establishment where the meat was heat processed must be readily visible on the outer wrapping or package and numbers must not be able to be removed without damage.

i) That the meat based flavour has not been exposed to contamination before export.

j) That the meat based flavour is being shipped to Australia in a clean container the seal of which was intact at the time of export.

k) For products containing ovine and caprine (sheep and goat) meat, that the consignment does not contain offal and protein products derived from the offal, from sheep and goats over 12 months of age originating from countries or zones not considered free from scrapie. Offal includes skulls including brains and eyes, spinal cord, tonsils, thymus, spleen, distal ileum, proximal colon, lymph nodes, adrenal gland, pancreas, liver or bone marrow.

PC0565

DOCUMENTATION/CERTIFICATION REQUIREMENTS

2. Each consignment must be accompanied by New Zealand Food Safety Authority (NZSFA) certification stating:

a) That the meat based flavours has been processed in establishments operating in accordance with New Zealand law and in accordance with New Zealand regulatory requirements for items intended for human consumption; and

b) The identification number of the processing establishment; and

c) That the product contains no discernible pieces of meat; and

d) That the meat based flavour has been packed in clean, new bags, wrappers or packing containers; and

e) That the meat based flavour has not been exposed to contamination before export; and.

f) The seal number of the container in which the meat based flavour is being shipped to Australia; and

g) The number of the government veterinary certificate for the meat based flavour ingredient

from the United States of America for each batch of the meat based flavour ingredient used in the final product; and

h) That the meat based flavour contains ingredients from the United States of America that were heat treated so that the core temperature of the meat based flavour ingredient exceeded 100° C for not less than 30 minutes; and

i) That the animals from which the meat was derived from were subjected to ante- and post-mortem veterinary inspection and passed in accordance with applicable laws and regulations of the country of origin; and

j) Species from which the meat was derived; and

k) Date(s) on which the meat was heat processed; and

l) That the meat based flavour does not contain ovine or caprine offal or proteins derived from ovine or caprine offal; and

m) That the meat based flavour was derived from bovine animals that have been born raised and slaughtered in Australia and or New Zealand only

3. Each consignment must be accompanied by a **Manufacturer's Declaration** stating:

That the manufacturer has official government veterinary certification for the meat based flavour ingredient from the United States of America for each batch of the ingredient used in the final product and can produce this on request.

The **Manufacturer's Declaration** must be:
.from

(Name of Company)

where the manufacturer is not specified above, the declaration must be issued by the individual manufacturing site or by the manufacturer's head office within the country of export.

Notes:
i) Point 2. c) can be confirmed by physical inspection of the product if required.

ii) Point 2 l) applies to product containing meat ingredients of ovine or caprine origin only.

iii) Point 2 m) applies to product containing meat ingredients of bovine origin only

Appendix 6. Conditions for the import of casings.

DAFF

AUSTRALIAN QUARANTINE AND INSPECTION SERVICE

Department of AGRICULTURE, FISHERIES AND FORESTRY - AUSTRALIA

3 March 2000

QUARANTINE REQUIREMENTS FOR THE IMPORTATION NATURAL SAUSAGE CASINGS FROM ANY COUNTRY.

These conditions apply to the importation of natural sausage casings derived from intestines of cattle, sheep, goats, deer and pigs.

1. DOCUMENTATION

1.1 Permission to import the product into Australia must be obtained in writing from the Australian Quarantine and Inspection Service (DAFF), prior to the product first being exported.

1.2 Each consignment must be accompanied by a Permit (or copy of a Permit) issued in Canberra and the prescribed certification in Section 3; and will require on arrival, a Quarantine Entry issued by DAFF at the port of entry.

1.3 Each application to the Director for permission to import must include the following details:

* country of export;

* name and identification/veterinary control number of producing establishment;

* species of origin;

* product type; and

* full details of any process of manufacture the casings have been subjected to.

Product type exported must correspond exactly to the product shown on the import permit issued in relation to the consignment.

1.4 Each application will be assessed on the above criteria as well as any other criterion that is considered relevant by the Director. This may include a country's health status with regard to diseases not listed in these guidelines and standards of meat inspection services and export establishments.

1.5 Each consignment must be accompanied by a Sanitary Certificate that conforms to the Office International des Epizooties (OIE) International Animal Health Code Article 5.10.4. The certificate must be signed by an *Official Veterinarian* of the country of export and each page of the certificate stamped with an official stamp.

Under ***II. Zoosanitary information*** the Sanitary Certificate must contain detail of the certifications listed in Section 2 of this document.

2. CERTIFICATION

Each consignment must be accompanied by a Sanitary Certificate signed by an *Official Veterinarian*. The Sanitary Certificate must conform to the Office International des Epizooties (OIE) International Animal Health Code Article 5.10.4. and must attest, under ***II. Zoosanitary information***, that:-

2.1 ***The casings were derived from animals originating in and slaughtered in the exporting country.***

2.2 The casings are of ovine, bovine, cervine, caprine or porcine origin*.

**[Note: Delete those not applicable.]*

2.3 The animals from which the casings were derived were slaughtered on the following dates.....

2.4 The animals from which the casings were derived were slaughtered at the following approved establishments:.....*

2.5 The casings for export were prepared and/or stored at the following approved establishments:.....*

*[*Note: Provide identification/veterinary control number(s) of the establishments.*]

2.6 The animals from which the casings were derived were subjected to ante and post-mortem veterinary inspection and were found to be free from contagious or infectious disease which could be transmitted in casings, or which could affect the quality of the casings.

2.7 The country/zone of origin of the meat is a ***BSE free country/zone.***

OR

The country/zone of origin of the meat is a ***BSE provisionally free country/zone,*** the meat and meat product is derived from cattle which have not been exposed to meat-and-bone meal imported from a *country* or *zone* with a high incidence of BSE, and

i) affected animals and the last progeny of affected females born within 2 years prior to or after the onset of clinical symptoms, have been slaughtered and completely destroyed, and

ii) the feeding of ruminant-derived meat-and-bone meal to ruminants is banned, and

iii) if BSE has been reported in the country/zone the consignment

either

does not include bovine brains, spinal cords or protein derived from them from cattle over 30 months of age and born before the ban on feeding ruminant derived meat-and-bone meal to ruminants

or

has been treated in accordance with *Code* (Appendix 4.3.3.1.) to inactivate BSE infective agents.

OR

The country/zone of origin of the meat is a ***country/zone with a low incidence of BSE***, and

i) affected animals and the last progeny of affected females born within 2 years prior to or after the onset of clinical symptoms, have been slaughtered and completely destroyed, and

ii) the feeding of ruminant-derived meat-and-bone meal to ruminants has been banned, and

iii) either

the consignment does not include bovine brains, eyes, spinal cord and distal ileum, or protein products derived from them, from cattle over 6 months of age and born before the ban on feeding ruminant derived meat-and-bone meal to ruminants

or

has been treated in accordance with *Code* (Appendix 4.3.3.1.) to inactivate BSE infective agents, and

OR

The country/zone of origin of the meat is a ***BSE high incidence country/zone***, and

i) affected animals and the last progeny of affected females born within 2 years prior to or after the onset of clinical symptoms, have been slaughtered and completely destroyed, and

ii) the feeding of ruminant-derived meat-and-bone meal to ruminants has been banned, and

iii) the cattle from which the meat destined for export originates:

- were permanently identified enabling them to be traced back to the dam and herd of origin;
- were not the offspring of BSE suspect or confirmed females; and

  either

  were born after the date of the ban on feeding ruminant-derived meat-and-bone meal to ruminants;

  or

  were born and remained in herds in which no case of BSE had been confirmed during the preceding seven years.

iv) a system is in operation enabling the fresh meat and meat products destined for export to be traced back to the establishment from which they are derived;

v) the *meat* and *meat products* did not contain brains, eyes, spinal cords, tonsils, thymus, spleen, intestine, dorsal root ganglia, trigeminal ganglia, bones nor nervous and lymphatic tissue exposed during the deboning process, nor products derived from them, from cattle over 6 months of age.

2.8 The consignment does not contain casings derived from sheep and goats over 12 months of age originating from *countries* or *zones* not considered free from scrapie.

2.9 Each establishment at which the animals from which the casings were derived were slaughtered ***had current DAFF approval*** and met

a a standard of construction equivalent to that set down in the "Australian Standard for Construction of Premises Processing Animals for Human Consumption" (1995)

b a standard of hygienic production equivalent to that set down in the "Australian Standard for Hygienic Production of Meat for Human Consumption" (2nd edition) (AS4461:1997)

2.10 Each establishment where the casings were prepared and stored *had current DAFF approval* and met

a a standard of construction equivalent to that set down in the "Australian Standard for Construction of Premises Processing Meat for Human Consumption" (1995)

b a standard of hygienic production equivalent to that set down in the "Australian Standard for Hygienic Production of Meat for Human Consumption" (2nd edition) (AS4461:1997).

2.11 The casings were packed:

a so that each packing container only contains casings derived from only a single species of animal;

b so that they were not exposed to contamination before export;

c in clean, new or disinfected packing containers; and

d so that the identification/veterinary control number* of the establishment where the casings were packed was readily visible on the outer wrapping or package.

[*Note: Numbers must not be able to be removed without damage.*]

3 IMPORTERS/AGENTS RESPONSIBILITIES

3.1 The casings must be transported to Australia in clean, sealed containers.

3.2 The casings shall be stored for no less than thirty days after the slaughter of the animals from which they were derived before release from quarantine in Australia.

3.3 Upon arrival in Australia, the casings shall be immediately removed to an approved post-arrival treatment facility, where they will be desalinated and soaked for 2 hours in chlorine solution maintained at a level of at least 80 ppm of free available chlorine.

Appendix 7. Dairy Minute (BIP to AB).

Australian Government

Department of Agriculture, Fisheries and Forestry

MINUTE

TO: **Dr. Andrew Cupit, Animal Biosecurity**

CC: **Dr. Carol Sheridan, Biological Imports Program**
Dr. Robert Heard, Dr. Peter Hewitt Animal Biosecurity

FROM: **Dr Jenny Cupit; Biological Import Operations & Marine Pests Branch**

DATE: **6 June 2012** **FILE:**

SUBJECT: **Request for a review of policies related to the importation of dairy products**

PURPOSE

To request a policy review covering the importation of dairy products

RECOMMENDATIONS

That Animal Biosecurity Branch (ABB) conducts a policy review for the importation of dairy products.

ISSUES

A number of issues in relation to dairy imports have been causing problems operationally and making it increasingly difficult to control the quarantine risk of these products. The issues relate to dairy sourced or processed in non FMD free countries and are outlined below.

1. Dairy products sourced from Australia and New Zealand but further processed and or dry blended in countries not considered free from FMD
2. Cheese aging and pH
3. Dairy, sourced from FMD approved countries, processed in non FMD approved countries
4. The ten percent dairy rule
5. Retorting dairy products.

There are also some issues in relation to the importation of dairy from FMD free countries. These are:

6. Current wording on import conditions
7. Third country certification of dairy products.

A brief description of each issue is provided below.

1. Dairy products sourced from Australia and New Zealand but further processed and or dry blended in countries not considered free from FMD

This request is incorporated into a previous minute (Appendix 1) seeking advice on this issue. Please refer to Appendix 1, which outlines operational and resourcing issues as a result of the current interim dairy policy for products that have been sourced from Australia and New Zealand but processed or dry blended in countries not considered free from FMD.

2. Cheese processing, aging and pH

Cheese is currently imported into Australia from non FMD free countries provided it meets processing, aging and pH requirements. Issues in regard to pH and aging have recently emerged. Applications have been granted for soft cheese type products, containing pasteurised dairy ingredients, where citric acid has been added to reduce the pH to below six. The transit to Australia results in the product being more than 30 days old. Technically this meets the policy as the product has a pH < 6 and the product is older than 30 days. BIP requires advice on whether this processing would appropriately mitigate the quarantine risks.

3. Dairy sourced from FMD approved countries and processed in non FMD approved countries

In addition to the specific issue raised in the previous minute (Appendix 1), a further issue may be associated with products processed in a non FMD country using ingredients sourced from other countries recognised by DAFF as being FMD free. Is this possible and under what conditions could the 'interim' dairy policy be expanded to include dairy ingredients from other FMD free countries into processing conducted in non FMD free countries.

4. The ten percent dairy rule

This policy is extremely hard to enforce as it is not possible to verify the percentage of dairy in a product through inspection and no reliable, recognised quantitative test for dairy content is available. This provides a loophole in our system as products containing greater than ten percent dairy may be mis-declared and imported. A possible solution would be to amend the wording in the Quarantine Proclamation, 1998 (or in the new regulations) e.g. to accept only highly processed dairy products containing less than ten percent dairy by dry weight. Further consideration of this issue is requested, including suggested amendments to the Proclamations to improve biosecurity controls on potentially high risk dairy commodities.

5. Retorting dairy products

Dairy sourced and or processed in a non FMD country must be retorted before importation to Australian. This requirement causes problems operationally. It is difficult to verify that products are actually retorted. BIP also queries whether many products, which are declared as retorted and, in some cases may contain in excess of 30% dairy, could be retorted without spoiling the product. BIP requests ABB look into the feasibility of retorting dairy and provide advice on additional risk mitigation measures that may be used in these cases.

6. Current wording on Import Conditions

The current wording on most dairy import conditions is dated and difficult to work with in an operational sense. The wording refers to lists that no longer exist and states countries can be FMD free with or without vaccination. In 2010 BIP requested advice from ABB and provided a number of revised permit conditions relating to Ovine, Caprine, and Bovine dairy and also pasteurised and unpasteurised products (please see Appendix 2). Advice from ABB on alternative words to adequately cover the variety of dairy cases would be appreciated.

7. Third country certification of dairy products

Competent authority certification of products containing dairy sourced from alternative markets is also becoming problematic. Current policy for dairy products from FMD free countries requires the exporting country certify to Australian's requirements. Issues arise when products are exported through, further processed or packaged in the final exporting country. Examples include cheese made in Europe and exported to the USA where it is cut and repackaged; or dairy powders sourced from Europe and blended and packaged in the UK. The products are imported to a second country, at times with little or no certification . When the product is further processed and ready for export to Australia, the final country cannot sign off to Australia's requirements. BIP would like ABB to confirm if and what type of documentation from the source country and exporting country would be acceptable for these types of products.

The priority for these issues would be:

- cheese
- interim dairy policy
- ten percent dairy rule
- wording on current permit conditions
- third country certification
- retorting of dairy products
- interim dairy policy using dairy from other FMD free countries

Yours Sincerely

Jenny Cupit
Assistant Secretary
Biological Import Operations and Marine Pests Branch
DAFF Biosecurity

Appendix 1:

TO: **Dr. Andrew Cupit, Animal Biosecurity**

CC: **Dr Jenny Cupit; Biological Quarantine Operations & Marine Pests Branch**

Dr. Robert Heard, Dr. Peter Hewitt Animal Biosecurity;

FROM: **Andrew Lieschke, Biological Imports Program**

DATE: **21 December 2011** **FILE:**

SUBJECT: **Advice on an alternative approach for the importation of dairy products sourced from FMD free countries but processed / dry blended in an FMD affected country**

PURPOSE

To request advice in regard to an alternative approach to import permit applications for dairy products sourced from FMD free countries but further processed and or dry blended in countries not considered free from FMD.

RECOMMENDATIONS

That Animal Biosecurity Branch provides advice to the Biological Imports Program (BIP) on an alternative approach to the interim dairy policy.

ISSUES

BIP has received a number queries and permit submissions for the importation of dairy products in to Australia that have been scoured from FMD free countries but processed or dry blended in countries not considered free from FMD. These requests have been from countries including Malaysia and the United Arab Emirates (UAE). If BIP were to approve these and future requests under the current interim dairy policy the program would not have the resources available to undertake audits of these facilities in line with the interim dairy policy.

In order to reduce audit workload and still ensure that quarantine risks are addressed BIP is proposing that the Competent Authority and a sample of facilities be audited every two years in place of the current interim dairy policy requirements. It would still be expected that any new facility would receive and initial audit, after which the Competent Authority would oversight the facility. The facility could also be selected as part of the sample of facilities for audit every two years.

Operationally then BIP would not grant any new permits for dairy products processed in non FMD free countries until a Competent Authority audit is undertaken. As Malaysia is the only country where facilities are currently approved to export this type of product BIP suggest that Malaysia undergo a Competent Authority audit to begin with.

BACKGROUND

The BIP currently has approximately six Malaysian facilities approved to export products containing products sourced from FMD free countries to Australia. These facilities require regular audits to ensure the associated quarantine risk is maintained at an appropriately low level. BIP is currently conducting audits on these facilities however if the number of facilities were to increase and particularly in other areas of the globe it would put a server strain on BIP resources to be able to audit all these facilities.

Appendix 2:

PC1730: Pasteurised Bovine Dairy from Approved FMD Free Countries

1. A valid Import Permit (or a method of identifying the Import Permit such as the Import Permit number) and all required documentation must accompany each consignment. Alternatively, necessary documentation will need to be presented to AQIS at the time of clearance. In order to facilitate clearance, airfreight or mail shipments should have all documentation securely attached to the outside of the package, and clearly marked 'Attention Quarantine'. Documentation may include Import Permit (or Import Permit number), manufacturer's declaration and invoice. The importer must meet all costs associated with the importation of this product.

CERTIFICATION/DECLARATION REQUIREMENTS

2. Each consignment must be accompanied by official government veterinary certification stating that:

a) The milk or the milk from which the dairy product was made is of bovine origin;

b) The milk or the milk from which the dairy product was made originated from «country/ies of origin» which is a country recognised by the World Organisation for Animal Health (OIE) as free from foot and mouth disease without vaccination;

c) The milk or the milk from which the dairy product was made originated from a country/zone recognised by the OIE as free from lumpy skin disease;

d) i) the country of origin has controls in place to ensure that only healthy animals are used for milk production;

OR

ii) The animals were clinically healthy at the time the milk was obtained;

e) The product was processed in a country recognised by the OIE as free from foot and mouth disease without vaccination;

Note: this statement is not necessary if the country of origin, manufacture and export is the same.

f) i) The packaging or immediate container is stamped with the date of manufacture;

OR

ii) a consignment specific manufacturer's declaration is provided with the date of manufacture for each batch or lot number;

g) The milk or the milk from which the dairy product was made was subjected to the following heat treatment:

«Pasteurisation at 72°C for a minimum of 15 seconds or an equivalent treatment, in terms of phosphatase destruction, OR UHT treatment of 135°C for a minimum of 1 second»;

Note: Point 2 g) will be accepted if on a consignment specific manufacturer's declaration endorsed by the Official Veterinarian of the exporting country.

Government veterinary certification must be:
.on official government letterhead.
. written in English.
. signed by a Government Veterinary Officer whose name, position and title also appear.
. identify the date of issue.
. issued and dated within the last 6 months (unless otherwise specified in this import permit).
. free from erasures and non certified alterations (all erasures and alterations must be endorsed by the issuer of the document. The only acceptable endorsement is a government stamp or seal and the signature of the Government Veterinary Officer responsible for signing the certificate applied adjacent to the alteration).
. sealed with the stamp/seal of the issuing National Competent Authority.
. contain the correct statement/s as required by the import conditions (all prescribed information on the certification must be legible and appear above the signature of the Government Veterinary Officer).
. specific to the relevant product(s) listed on this permit.
. have a unique identifiable link to the consignment such as one of the following: container number, bill number, commercial invoice number, preferential tariff certificate number, health certificate number, packing list number or letter of credit number, batch/serial number or date of manufacture.

The Government veterinarian endorsed manufacturer's declaration must be from «name of manufacturer»
. where the manufacturer is not specified above, the declaration must be issued by the individual manufacturing site or by the manufacturer's head office within the country of export.
. on manufacturer's letterhead including company address and country.
. signed by a designated representative of the manufacturer whose name, position and title also appear.
. written in English.
. identify the date of issue.
. issued by the manufacturer within the last 6 months (unless otherwise specified in this import permit).
. signed and dated by a Government Veterinary Officer within the last 6 months (unless otherwise specified in this import permit).
. include the Government Veterinary Officer's name, position and title.
. be sealed with the stamp/seal of the applicable Government Department.
. free from erasures and non certified alterations (all erasures and alterations must be endorsed by the issuer of the document. The only acceptable endorsement is a company/government stamp or seal and the signature of the officer responsible for signing the declaration applied adjacent to the alteration).
. contain the correct statement/s as required by the import conditions (all prescribed information on the certification must be legible and appear above the signature).
. specific to the product(s) listed on this permit.
. have a unique identifiable link to the consignment such as one of the following: container

number, bill number, commercial invoice number, preferential tariff certificate number, health certificate number, packing list number or letter of credit number, batch/serial number or date of manufacture.

All documentation must meet the requirements of the Minimum Documentary Requirements Policy. For full details of the AQIS minimum documentary requirements, please refer to http://www.daff.gov.au/aqis/import/general-info/documentary-requirements

PCXXXX: Unpasteurised Bovine Dairy from Approved FMD Free Countries

1. A valid Import Permit (or a method of identifying the Import Permit such as the Import Permit number) and all required documentation must accompany each consignment. Alternatively, necessary documentation will need to be presented to AQIS at the time of clearance. In order to facilitate clearance, airfreight or mail shipments should have all documentation securely attached to the outside of the package, and clearly marked 'Attention Quarantine'. Documentation may include Import Permit (or Import Permit number), manufacturer's declaration and invoice. The importer must meet all costs associated with the importation of this product.

CERTIFICATION/DECLARATION REQUIREMENTS

2. Each consignment must be accompanied by official government veterinary certification stating that:

a) The milk or the milk from which the dairy product was made is of bovine origin;

b) The milk or the milk from which the dairy product was made originated from «country/ies of origin» which is a country recognised by the World Organisation for Animal Health (OIE) as free from foot and mouth disease without vaccination

c) The milk or the milk from which the dairy product was made originated from a country/zone recognised by the OIE as free from lumpy skin disease;

d) i) the country of origin has controls in place to ensure that only healthy animals are used for milk production;

OR

ii) The animals were clinically healthy at the time the milk was obtained;

e) The product was processed in a country recognised by the OIE as free from foot and mouth disease without vaccination;

Note: this statement is not necessary if the country of origin, manufacture and export is the same.

f) i) The packaging or immediate container is stamped with the date of manufacture;

OR

ii) a consignment specific manufacturer's declaration is provided with the date of manufacture for each batch or lot number;

g) the milk or the milk from which the dairy product was made originated from a country which meets OIE requirements for freedom from:

- Rinderpest; and
- Bovine brucellosis; and
- Bovine tuberculosis; and
- Which is free from Jembrana.

Note: Milk and milk products that are imported under condition 2 g) will not be released from quarantine until the conclusion of a period of 30 days from the date of manufacture.

Government veterinary certification must be:
.on official government letterhead.
. written in English.
. signed by a Government Veterinary Officer whose name, position and title also appear.
. identify the date of issue.
. issued and dated within the last 6 months (unless otherwise specified in this import permit).
. free from erasures and non certified alterations (all erasures and alterations must be endorsed by the issuer of the document. The only acceptable endorsement is a government stamp or seal and the signature of the Government Veterinary Officer responsible for signing the certificate applied adjacent to the alteration).
. sealed with the stamp/seal of the issuing National Competent Authority.
. contain the correct statement/s as required by the import conditions (all prescribed information on the certification must be legible and appear above the signature of the Government Veterinary Officer).
. specific to the relevant product(s) listed on this permit.
. have a unique identifiable link to the consignment such as one of the following: container number, bill number, commercial invoice number, preferential tariff certificate number, health certificate number, packing list number or letter of credit number, batch/serial number or date of manufacture.

The Government veterinarian endorsed manufacturer's declaration must be from «name of manufacturer»
. where the manufacturer is not specified above, the declaration must be issued by the individual manufacturing site or by the manufacturer's head office within the country of export.
. on manufacturer's letterhead including company address and country.
. signed by a designated representative of the manufacturer whose name, position and title also appear.
. written in English.
. identify the date of issue.
. issued by the manufacturer within the last 6 months (unless otherwise specified in this

import permit).
. signed and dated by a Government Veterinary Officer within the last 6 months (unless otherwise specified in this import permit).
. include the Government Veterinary Officer's name, position and title.
. be sealed with the stamp/seal of the applicable Government Department.
. free from erasures and non certified alterations (all erasures and alterations must be endorsed by the issuer of the document. The only acceptable endorsement is a company/government stamp or seal and the signature of the officer responsible for signing the declaration applied adjacent to the alteration).
. contain the correct statement/s as required by the import conditions (all prescribed information on the certification must be legible and appear above the signature).
. specific to the product(s) listed on this permit.
. have a unique identifiable link to the consignment such as one of the following: container number, bill number, commercial invoice number, preferential tariff certificate number, health certificate number, packing list number or letter of credit number, batch/serial number or date of manufacture.

All documentation must meet the requirements of the Minimum Documentary Requirements Policy. For full details of the AQIS minimum documentary requirements, please refer to http://www.daff.gov.au/aqis/import/general-info/documentary-requirements

Ovine Caprine Dairy

1. A valid copy of this Import Permit (or a method of identifying the Import Permit such as the Import Permit number) and all required documentation must accompany each consignment. Alternatively, necessary documentation will need to be presented to AQIS at the time of clearance. In order to facilitate clearance, airfreight or mail shipments should have all documentation securely attached to the outside of the package, and clearly marked "Attention Quarantine". Documentation may include Import Permit (or Import Permit number), manufacturer's declaration and invoice. The importer must meet all costs associated with the importation of this product.

CERTIFICATION REQUIREMENTS:

2. Each consignment must be accompanied by official Government Certification, stating:

a) The milk or the milk from which the dairy product was made is of from «ovine and/or caprine» origin;

b) The milk or the milk from which the dairy product was made originated from «country/ies of origin» which is a country recognised by the World Organization for Animal Health (OIE) as free from foot and mouth disease without vaccination;

c) the milk or the milk from which the dairy product was made originated from a country/zone which meets OIE requirements for freedom from:

- sheep pox; and

- goat pox;

d) i) the country of origin has controls in place to ensure that only healthy animals are used for milk production;

OR

ii) The animals were clinically healthy at the time the milk was obtained;

e) The product was processed in a country recognised by the OIE as free from foot and mouth disease without vaccination, goat pox and sheep pox;

Note: this statement is not necessary if the country of origin, manufacture and export is the same.

f) i) The packaging or immediate container is stamped with the date of manufacture;

OR

ii) a consignment specific manufacturer's declaration is provided with the date of manufacture for each batch or lot number;

g) The milk or the milk from which the dairy product was made was subjected to the following heat treatment:

«Pasteurisation at 72°C for a minimum of 15 seconds or an equivalent treatment, in terms of phosphatase destruction, OR UHT treatment of 135°C for a minimum of 1 second»;

Note: Point 2 g) will be accepted if on a consignment specific manufacturer's declaration endorsed by the Official Veterinarian of the exporting country.

Government Veterinary Certification must be:
.on official government letterhead.
. signed by a Government Veterinary Officer whose name and title also appear (all alterations must be initialled or stamped by the government officer responsible for signing the certificate).
. dated and free from erasures and uncertified alterations.
. sealed with the stamp of the Government Department.
. written in English and containing the correct statement/s as required above.
. specific to the relevant commodity listed on this permit.
. specific to the consignment by referring to at least one of the following: container number, bill of lading number, commercial invoice number, preferential tariff certificate number, packing list number, letter of credit number, batch/serial number or date of manufacture.

The manufacturer's declaration must be:
.from

«Name and Address of the Manufacturer».

. on manufacturer's letterhead (including company address and country).
. signed by a senior company employee from the site of manufacture whose name, title and contact details also appear.
. dated and free from erasures and uncertified alterations (all alterations must be initialled by the senior company employee responsible for signing the declaration).
. written in English and containing the correct statement/s as required above.
. specific to the relevant commodity listed on this permit.
. specific to the consignment by referring to at least one of the following: container number, bill of lading number, commercial invoice number, preferential tariff certificate number, packing list number, letter of credit number, batch/serial number or date of manufacture.

Appendix 8. Conditions for import of feathers

Feathers - Manufactured articles containing feathers

Country:	All countries
End use:	All uses other than as animal foods, fertilisers or for growing purposes
Date printed:	Jul 27 2012

Condition C9884

Countries with Highly Pathogenic Avian Influenza (HPAI) for the importation of biological products (as at 29 June 2012)

Afghanistan, Azerbaijan, Bangladesh, Bhutan, Cambodia, China/Hong Kong, Egypt, India, Indonesia (including Bali), Iraq, Israel, Mexico, Myanmar, Nepal, North Korea (Democratic People's Republic Of Korea), Pakistan, South Africa, Sudan, Taiwan, Vietnam, Zimbabwe.

Please note that import conditions will vary according to the current HPAI status of the country of origin.

Condition C5065

This Condition is specific for consignments imported from countries listed in C9884.

Non-Commercial
For consignments that are commercially packaged or manufactured feather products

1. An Import Permit is not required.

2. A Quarantine Entry is not required.

3.Consignments of packaged feathers or manufactured feather products are subject to inspection on arrival to ensure the absence of animal tissue, soil, faeces, seeds and insect contamination.

4. If contamination or animal tissue is found, the feathers must be ordered for treatment prior to release from quarantine by one of the following methods:

a) gamma irradiation at 50 kGray (5 Mrad) (T9652), or
b)ethylene oxide treatment (T9020); or

c) formaldehyde fumigation (10% formalin) for 4 hours (T9263), or
d) exported; or destroyed by incineration or deep burial.

Non-Commercial

For consignments that are not commercially packaged or manufactured feather products

1. An Import Permit is not required.

2. A Quarantine Entry is not required.

3. Consignments of feathers or feather products that have not been commercially manufactured are subject to treatment prior to release from quarantine by one of the following methods:

a) gamma irradiation at 50 kGray (5 Mrad) (T9652), or
b)Ethylene oxide treatment (T9020); or
c) formaldehyde fumigation (10% formalin) for 4 hours (T9263), or
d) or re-exported; or destroyed by incineration or deep burial.

Commercial

1. An Import Permit is not required.

2. A Quarantine Entry must be lodged for each consignment.

3. Consignments must meet one of the following import requirements:

a) Consignments must be accompanied by a consignment specific Government Certificate, or a consignment specific manufacturer's declaration endorsed by a Government Officer, stating that the feathers in the product have received one of the following treatments:

i) gamma irradiation at 50 kGray (5 Mrad); or
ii) ethylene oxide treatment (T9020); or
iii) heated to a core temperature of at least 100°C for a minimum of 30 minutes; or
iv) heated to a temperature of at least 120°C for a minimum of 30 minutes; or
v) washed thoroughly in detergent followed by formaldehyde fumigation (10% formalin) for 4 hours.

* For ethylene oxide fumigation an AQIS Approved Offshore Pre-Shipment Treatment Provider can be used. In this case, each consignment must be accompanied by a valid consignment specific pre-shipment treatment certificate from an AQIS approved offshore treatment provider displaying an AQIS Identification Number with approval to treat the commodity. Consignments accompanied by a valid

pre-shipment treatment certificate do not require an additional manufacturer's or Government certificate. Further information on AQIS Approved Offshore Pre-Shipment Treatment Providers for Ethylene Oxide (ETO) Fumigation can be found on the AQIS website;

OR

b) For consignments of product where the country of product manufacture is different to the country of origin of the feathers:

Consignments must be accompanied by a manufacturer's declaration stating that 'the *<insert product name here>* was manufactured using feathers imported into the country of manufacture under Government Certificate number *<insert Government Certificate number here>*'.Consignments must also be accompanied by a copy of the Government Certificate which was used to import the feathers into the country of manufacture from the country of origin.

Please note: The country of origin of the feathers (i.e. the country that has provided the Government Certificate) must be a country not listed in C9884;

4. If the consignment is not accompanied by the necessary documentation verifying the treatment undertaken or sourcing as detailed in point 3 above, the goods must be ordered for treatment prior to release from quarantine by one of the following methods:

a) gamma irradiation at 50 kGray (5 Mrad) (T9652), or
b) ethylene oxide treatment (T9020); or
c) formaldehyde fumigation (10% formalin) for 4 hours (T9263), or
d) re-exported; or destroyed by incineration or deep burial.

5. Prior to importation, the importer may apply to have alternative treatment options assessed. Contact the AQIS Biologicals Program on phone 02 6272 4578 begin_of_the_skype_highlighting 02 6272 4578 end_of_the_skype_highlighting, fax 02 6249 1798, or email. The information required by the Biological Imports Program to assess an alternative treatment is as follows:

a) Contact details of importer and exporter including name, address, phone number (of the importer); and
b) Description of products and the country of origin (if not the same as the exporting country);and
c) A manufacturer's declaration providing details of the rinsing and washing process, including duration and temperature of process if applicable and details of any other disinfection, fumigation or steaming that takes place;and
d) Details of separation of treated from untreated feathers; and
e) Copies of any Government or Fumigation Certificates.

Condition C10526

This Condition is specific for consignments imported from countries not listed in C9884.

Non-Commercial

1. An Import Permit is not required.

2. A Quarantine Entry is not required.

3.Consignments of packaged feathers or manufactured feather products are subject to inspection on arrival to ensure the absence of animal tissue, soil, faeces, seeds and insect contamination.

4. If contamination or animal tissue is found, the feathers must be ordered for treatment prior to release from quarantine by one of the following methods:

a) gamma irradiation at 50 kGray (5 Mrad) (T9652), or
b) ethylene oxide treatment (T9020); or
c) formaldehyde fumigation (10% formalin) for 4 hours (T9263), or
d) exported; or destroyed by incineration or deep burial.

Commercial

1. An Import Permit is not required.

2. A Quarantine Entry must be lodged for each consignment.

3. Consignments must meet one of the following import requirements:

a) Consignments must be accompanied by a consignment specific manufacturer's declaration stating that the feathers within the manufactured article have been cleaned and are free of all animal tissue and other extraneous matter;

OR

b) Consignments must be accompanied by a consignment specific government certificate issued by the government in the country of export stating that the feathers within the manufactured article have been cleaned and are free of all animal tissue and other extraneous matter;

OR

c) Consignments must be accompanied by a pre-shipment ethylene oxide treatment certificate from an AQIS approved offshore treatment

provider. In this case each consignment must be accompanied by a valid consignment specific pre-shipment treatment certificate from an AQIS approved offshore treatment provider displaying an AQIS Identification Number with approval to treat the commodity. Further information on AQIS Approved Offshore Pre-Shipment Treatment Providers for Ethylene Oxide (ETO) Fumigation can be found on the AQIS website;

OR

d) Consignments of feathers must be inspected on arrival to verify the absence of animal tissue.

Please note: AQIS inspection will involve the removal of feathers from a sample of imported product. Importers wishing to avoid this potentially damaging process will need to meet the requirements of a) or b) above.

4. Consignments that cannot be inspected that arrive without the required declaration, or products inspected and found to be dirty or contaminated must be treated by:

a) gamma irradiation at 50 kGray (5 Mrad) (T9652), or
b) Ethylene oxide treatment (T9020); or
c) formaldehyde fumigation (10% formalin) for 4 hours (T9263), or
d) exported; or destroyed by incineration or deep burial.

Commodity:	Feathers - Animal tissue not present
Country:	All countries
End use:	All uses other than as animal foods, fertilisers or for growing purposes
Date printed:	Jul 27 2012

Condition C9884

Countries with Highly Pathogenic Avian Influenza (HPAI) for the importation of biological products (as at 29 June 2012)

Afghanistan, Azerbaijan, Bangladesh, Bhutan, Cambodia, China/Hong Kong, Egypt, India, Indonesia (including Bali), Iraq, Israel, Mexico, Myanmar, Nepal, North Korea (Democratic People's Republic Of Korea), Pakistan, South Africa, Sudan, Taiwan, Vietnam, Zimbabwe.

Please note that import conditions will vary according to the current HPAI status of the country of origin.

Condition C5066

Import conditions for ‘Manufactured articles containing feathers’ may be found here.

Non-Commercial

1. An Import Permit is not required.

2. A Quarantine Entry is not required.

3. Consignments of feathers are subject to inspection on arrival to ensure the absence of animal tissue, soil, faeces, seeds and insect contamination.

If contamination or animal tissue is found, the feathers must be ordered for treatment prior to release from quarantine by one of the following methods:

a) gamma irradiation at 50 kGray (5 Mrad) (T9652), or
b) ethylene oxide treatment (T9020); or
c) formaldehyde fumigation (10% formalin) for 4 hours (T9263), or
d) exported; or destroyed by incineration or deep burial.

Commercial

1. An Import Permit is not required.

2. A Quarantine Entry must be lodged for each consignment.

The following conditions are specific for consignments imported from countries listed in C9884.

3. Consignments must meet one of the following import requirements:

a) Consignments must be accompanied by consignment specific documentation indicating that the consignment has been treated by an acceptable treatment provider using one of the following treatments:

i) Ethylene oxide treatment (T9020); or
ii) Gamma irradiation (T9652)

For acceptable gamma irradiation and ethylene oxide treatment providers please refer to the AQIS Treatment Providers webpage.

OR

b) Consignments must be accompanied by a consignment specific Government Certificate, or a consignment specific manufacturer’s declaration endorsed by a Government Officer, stating that the feathers in the consignment have received one of the following treatments:

i) Moist heat sterilisation (T9990); or
ii) 10% formalin treatment (T9263); or
iii) Detergent wash followed by formaldehyde fumigation (T10005)

OR

c) The goods must be directed for treatment by one of the following methods, at the importer's expense, prior to release from quarantine:

i) Gamma irradiation (T9652); or
ii) Ethylene oxide treatment (T9020); or
iii) Moist heat sterilisation (T9990); or
iv) 10% formalin treatment (T9263); or
v) Detergent wash followed by formaldehyde fumigation (T10005); or
vi) Re-exported or destroyed by an AQIS approved method.

The following conditions are specific for consignments imported from countries not listed in C9884.

3. Consignments must meet one of the following import requirements:

a) Consignments must meet the requirements for C9884 countries above;

OR

b) Consignments of feathers must be directed for an inspection on arrival to ensure the absence of animal tissue, soil, faeces, seeds and insect contamination.

If contamination or animal tissue is found, the feathers must be ordered for treatment prior to release from quarantine by one of the following methods:

i) gamma irradiation at 50 kGray (5 Mrad) (T9652), or
ii)ethylene oxide treatment (T9020); or
iii) formaldehyde fumigation (10% formalin) for 4 hours (T9263), or
iv) exported; or destroyed by incineration or deep burial.

Commodity: Feathers - Animal tissue present

Country: All countries

End use: Processing

Date printed: Jul 27 2012

Condition C5064

Non-Commercial

1. An Import Permit is not required

2. A Quarantine Entry is required for all consignments except those that are imported as non-commercial consignments by mail or those that are imported as personal consignments with passenger's accompanied baggage.

3. All consignments must be accompanied by a manufacturer's declaration endorsed by a Government Veterinary Officer, stating that the feathers have been treated by one of the following methods:

a) moist heat treatment at a minimum of 100°C for not less than 30 minutes; or

b) autoclave sterilisation at 121°C for 15 minutes or 134°C for 4 minutes; or
c) soaked in 10% formalin for not less than 4 hours; or
d) cleaned of all extraneous matter and fumigated with formalin vapour for not less than 10 hours; or
e) gamma irradiated at a dosage of 50 kGray.

4. Consignments with the correct documentation may be released from quarantine without an inspection. However, they may be subject to periodic inspections to verify that the goods are feathers.

5 Consignments arriving without the required declaration shall be subject to gamma irradiation at 50 kGray, (T9652); or re-exported; or destroyed by incineration or deep burial.

Commercial

1. An Import Permit is required, permit applications must be sent to AQIS Canberra office for assessment.

2. Quarantine Entry must be lodged for each consignment.

3. All consignments must be accompanied by a manufacturer's declaration endorsed by a Government Veterinary Officer, stating that the feathers have been treated by one of the following methods:

a) moist heat treatment at a minimum of 100°C for not less than 30 minutes; or

b) autoclave sterilisation at 121°C for 15 minutes or 134°C for 4 minutes; or
c) soaked in 10% formalin for not less than 4 hours; or
d) cleaned of all extraneous matter and fumigated with formalin vapour for not less than 10 hours; or
e) gamma irradiated at a dosage of 50 kGray.

4. Consignments with the correct documentation may be released from quarantine without an inspection. However, they may be subject to periodic inspections to verify that the goods are feathers.

5. Consignments arriving without the required declaration shall be subject to gamma irradiation at 50 kGray, (T9652); or re-exported; or destroyed by incineration or deep burial.

Appendix 9. Import conditions for wool

Commodity:	Wool - Scoured	
	Country:	***All countries excluding:*** New Zealand
	End use:	All uses other than as animal foods, fertilisers or for growing purposes
	Date printed:	Jul 27 2012

Condition C9349

Non-Commercial

1. For samples less than 500 grams, refer to the ICON Commodity "Wool Samples – Scoured". For all other consignments the conditions under the Commercial section apply.

Commercial

1. An Import Permit is not required.

2. A Quarantine Entry must be lodged for each consignment.

3. The commodity must be packed in new and clean bags.

CERTIFICATION REQUIREMENTS

FMD Approved Countries (see C19394)

4. Each consignment must be accompanied by an official government veterinary certificate from the exporting country detailing the process of scouring used.

Note: *This applies only where the sourcing, processing and export to Australia of the wool occurs in a country (or countries) on the DAFF FMD Approved Countries list (see C19394). If sourcing, processing or export to Australia occurs in a country (or countries) not on this list then it must be treated as below for Countries NOT listed on the DAFF FMD Approved Country List.*

Countries NOT listed on the DAFF FMD Approved Country List (see C19394)

5. a) Consignments must be accompanied by official government veterinary certification, verifying date and place of origin of the wool and stating that the wool has been scoured at a minimum temperature of 60°C for at least 5 minutes at a minimum pH of 9. The storage and transit time between scouring and importation must be at least 4 weeks;

or

b) Consignment must be accompanied by official government veterinary certification, verifying date and place of origin of the wool and stating that the wool has undergone a heat treatment of approximately 95-100°C for at least 15 minutes (e.g. a typical dyeing process involving immersion in water);

or

c) Consignment must be accompanied by official government veterinary certification, verifying date and place of origin of the wool and stating that the wool has undergone an aqueous scouring process at 60-70°C and that after scouring the fibre was either:

i) dyed, or
ii) further washed in water for at least 1 minute at a temperature of not less than 75°C, or
iii) dried at a minimum temperature of 70°C for at least 10 minutes.

6. Documentation must comply with format requirements as detailed in AQIS's Minimum Documentary Requirements Policy.

7. Where consignments are not covered by valid documentation or are covered by documentation with an incorrect statement, amended documentation will be requested.

INSPECTION REQUIREMENTS

8. An inspection of at least 5% of the consignment is required. This will be drawn from the whole consignment following a full unpack at a quarantine approved premises.

9. If the wool is contaminated with seeds, the consignment must be held until the seeds are identified. If they are prohibited weed seeds then the consignment must be ordered for gamma irradiation (T9652), or re-exported or destroyed.

10. If insects are present, the consignment must be directed for methyl bromide fumigation (T9030) or phosphine fumigation (T9085).

11. If faecal pellets are present or if the scouring process or documentation is found to be inadequate, the consignment must be either:

a) re-scoured at a quarantine approved premise (or under the supervision of a quarantine officer), with a heat treatment involving immersion in water to a core temperature of the wool of at least 95°C for 25 minutes or 100°C for 15 minutes; or

b) put through a dyeing process or other treatment process at a quarantine approved premise (or under the supervision of a quarantine officer), with a heat treatment of at least 100°C for 15 minutes or 95°C for 25 minutes as approved by AQIS; or

c) gamma irradiated at 50 kGray (T9652); or

d) re-exported; or

e) destroyed.

f) In the case of product imported from countries on the **DAFF FMD Approved List** (see C19394), there is also the option of the wool being carded at a Quarantine Approved Premises (or under the supervision of a quarantine officer), with the carding waste being incinerated under AQIS supervision.

12. The above treatments, identifications or procedures for re-export or destruction are at the importer's expense.

Appendix 10. Import conditions for microorganisms

PC0691

1. Each consignment must be accompanied by a valid Import Permit (or a method of identifying the Import Permit such as the Import Permit number) and all required documentation. Alternatively, necessary documentation will need to be presented to AQIS at the time of clearance. In order to facilitate clearance, airfreight or mail shipments should have all documentation securely attached to the outside of the package, and clearly marked 'Attention Quarantine'. Documentation may include Import Permit (or Import Permit number), manufacturer's declaration and invoice. The importer must meet all costs associated with the importation of this product.

Documentation Requirements

2. Each consignment must be clearly identified and linked to the relevant item(s) on the Import Permit. Identifying documentation must be available to the quarantine officer at the time of clearance. This documentation may include:

a) an accompanying invoice or airway bill; or
b) the physical labelling of the goods; or
c) an overseas supplier's declaration describing the goods.

3. If the product description on the Import Permit varies from the identifying documentation provided for clearance, the importer is responsible for providing evidence to the quarantine officer that the Import Permit covers the products in the consignment.

Packaging Requirements

4. Cultures must be pure cultures (unless otherwise specified by this Import Permit) and labelled with the scientific name of the organism as it appears on this Import Permit including; genus, species and any other criteria e.g. subspecies, strain, biotype, serotype, pathovar, variety etc.

Post Entry Requirements

5. This Import Permit allows for the importation of goods for in vitro laboratory studies (or in vivo use in laboratory organisms only), unless approved by AQIS for specific in vivo use in non-laboratory organisms.

6. Laboratory organisms include those defined in the following list and must be contained under laboratory or animal house conditions (or equivalent): guinea pigs, hamsters, mice, rabbits, rats, rodents or micro-organisms. Work in all other animals and plants is not permitted.

7. For in vivo use in non-laboratory organisms (e.g. chickens, sheep, cattle, etc.) or plants a separate application for in vivo use must be lodged with, and approved by AQIS. This also

applies if the product is to be used in veterinary vaccine or veterinary therapeutic manufacture.

8. It is the end user's responsibility to ensure that all laboratory products are used in accordance with the current AS/NZS 2243 Safety in Laboratory standards Part 3: Microbiology. This includes handling and disposal procedures.

9. It is the importer's responsibility to ensure compliance with all international (e.g. IATA) and domestic requirements concerning the safe handling, transport and labelling of biological material.

10. It is the end user's responsibility to ensure that all laboratory products are used in accordance with the Office of the Gene Technology Regulator (OGTR) requirements

PC1248

This condition requires product to be directed to and held at a Quarantine Approved Premises.

1. A valid copy of this Import Permit (or a method of identifying the Import Permit such as the Import Permit number) and all required documentation must accompany each consignment. Alternatively, necessary documentation will need to be presented to AQIS at the time of clearance. In order to facilitate clearance, airfreight or mail shipments should have all documentation securely attached to the outside of the package, and clearly marked "Attention Quarantine". Documentation may include Import Permit (or Import Permit number), manufacturer's declaration and invoice. The importer must meet all costs associated with the importation of this product.

2. A Quarantine Entry that includes a reference to the Import Permit number must be lodged.

Documentation Requirements

3. Each consignment must be clearly identified and linked to the relevant item(s) on the Import Permit. Identifying documentation must be available to the quarantine officer at the time of clearance. This documentation may include:

a) an accompanying invoice or airway bill; or
b) the physical labelling of the goods; or
c) an overseas supplier's declaration describing the goods.

4. If the product description on the Import Permit varies from the identifying documentation provided for clearance, the importer is responsible for providing evidence to the quarantine officer that the Import Permit covers the products in the consignment.

Packaging Requirements

5. Cultures must be pure cultures (unless otherwise specified by this Import Permit) and labelled with the scientific name of the organism as it appears on this Import Permit including; genus, species and any other criteria e.g. subspecies, strain, biotype, serotype, pathovar, variety etc.

Post Entry Requirements

6. The micro-organisms are for use at:

«QAP»

7. The goods and their derivatives shall not be removed from these premises, except for disposal or re-export, without the prior approval of the Director of Quarantine. These premises must have current approval, at the time of importation, of the Australian Quarantine and Inspection Service, under Section 46A of the Quarantine Act 1908. The premises must be approved as a Class 5 Quarantine Approved Premises.

8. The level of containment must be QC (PC) «QC level» or the level stated in Australian Standards AS 2243.3, Safety in Laboratories, Part 3: Microbiology (2002), which ever is the greater level of containment.

9. Work must be limited to in vitro laboratory studies only (this does not include in vivo use in laboratory organisms or plants, or veterinary vaccine or veterinary therapeutic manufacture). Work in laboratory or other animals (including veterinary vaccine or veterinary therapeutic manufacture), or plants is not permitted without prior written approval from AQIS.

10. Where more than one Quarantine Approved Premises is listed in point 5 above, the samples may be transferred between the listed premises. All records of transfer must be maintained for audit purposes.

11. Direct or indirect exposure of native or domestic animals or plants to the materials or their derivatives is prohibited.

12. On completion of work all imported materials and the direct or indirect derivatives thereof shall be disposed of by incineration, autoclaving or other methods approved in writing by the Director of Quarantine.

13. It is the importer's responsibility to ensure compliance with all international (e.g. IATA) and domestic requirements concerning the safe handling, transport and labelling of biological material.

14. It is the end user's responsibility to ensure that all laboratory products are used in accordance with the current AS/NZS 2243 Safety in Laboratory standards and Office of the Gene Technology Regulator (OGTR) requirements.