Report Cover Page

ACERA Project
ACERA Project 1101F - Biologicals
Title
The Use of Manufacturer's Declarations as a Biosecurity Control for the Import of Biologicals
Author(s) / Address (es)
David Buckley, AGENV Pty Ltd, STIRLING ACT
Material Type and Status (Internal draft, Final Technical or Project report, Manuscript, Manual, Software)
Project report #2
Summary

In some cases, manufacturer's declarations (MDs) are used in place of official Government-to-Government certification for ensuring biosecurity control over the import of biological products into Australia. For some categories of products, this has led to reports of alleged falsification of these documents. For other products, no such problems have been reported.

Examination of the way that MDs are used led to the development of strategies to minimise the risk of misuse of the MDs. These strategies range from banning use completely, to various methods of increasing the reliability of the documents, such as requiring endorsement of the MD by an official of the competent authority in the exporting country, or implementing a program of audits, inspections or tests to verify the content of the documents.

Import conditions for a number of different types of biological products were then reviewed, and the use of MDs in relation to those products was considered. Where necessary, recommendations were made to improve the biosecurity of the imported products.

Finally, a framework for the future application of manufacturer's declarations was proposed.

ACERA Use only	Received By:	Date:
ACERA Use only	ACERA / AMSI SAC Approval:	Date:
ACERA Use only	ACERA / AMSI SAC Approval:	Date:

The Use of Manufacturer's Declarations as a Biosecurity Control for the Import of Biologicals

Contents

Glossary

ACERA	Australian Centre of Excellence for Risk Analysis
AIMS	AQIS Import Management System
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine & Inspection Service
Bioremediation	the use of micro-organism metabolism to remove pollutants
BIP	Biologicals Imports Program
BSG	Biosecurity Services Group
DAFF	Department of Agriculture Fisheries and Forestry
GMP	Good manufacturing practice
ICE	Import Clearance Effectiveness program
I & E	Investigations and Enforcement unit within DAFF
IP	Import Permit
IR	Incident Report
IIRs	Intelligence Information Reports
in vitro use	use other than in living animals
in vivo use	use in living animals
Manufacturer's Declaration	'a declaration signed by the manufacturer or authorised representative of the manufacturer of a product, specifically required under the terms of an import permit relating to that product, and providing information relevant to biosecurity decision making in relation to that product.'
MD	Manufacturer's Declaration
OIE	World Organisation for Animal Health
SIP	Supplier Import Profile
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures

UHT	ultra-high temperature treatment used for sterilisation of milk products
US CFR	United States Code of Federal Regulations
WTO	World Trade Organisation

Executive summary

This report addresses the second of three parts of ACERA Project No: 1001F (Biologicals), and is concerned with the use and reliability of manufacturer's declarations (MDs). The Problem Statement in the Project outline states:

" one measure that is used to manage the risk of importing biological products of animal origin is the requirement of manufacturer's declarations (MDs) to accompany such imports. MDs report the quality of the components or ingredients of the product under evaluation and detail the production systems. However, there is currently no system for monitoring the veracity of MDs and there is evidence that some are incorrect. Given that BSG relies on MDs to help manage the risk of biological contamination in a range of products, including some potentially high risk products such as cell and tissue cultures, there is a need to evaluate the reliability of MDs to determine whether or not they are appropriate and/or sufficient to manage the risk of some or all biological products of animal origin (or whether there is a need to have additional requirements such as formal veterinary certification by the appropriate country's Competent Authority)."

Throughout this report, a manufacturer's declaration is defined as 'a declaration signed by the manufacturer or authorised representative of the manufacturer of a product, specifically required under the terms of an import permit relating to that product, and providing information relevant to biosecurity decision making in relation to that product.'

During a review of imported goods documentation undertaken on behalf of the Australian Government Department of Agriculture Fisheries and Forestry (DAFF) in 2010, Tanner James Management Consultants (Tanner James Management Consultants., 21 October 2010) identified a number of concerns arising from the use of MDs. These concerns were described by the consultants as:

- Uncertainty as to the integrity of the document:
- Lack of proof as to who created the document;
- The difficulty of legal recourse in cases where documents were falsified;
- The difficulty of verifying that the document accurately reflects the processing of the goods; and
- Language difficulties (sometimes the documents are not in English).

Evidence is presented to confirm the concerns identified in the Tanner Janes Management Consultants report. This confirms that there is significant reason to doubt the accuracy of many MDs, compromising their effectiveness in reducing biosecurity risk. This impediment is likely to continue, without significant revision of the system.

Case studies were used to attempt to clarify what aspects of the use of MDs is contributing to the high level of incident reports relating to some types of product. This involved comparison of the way MDs are used to facilitate import of products containing dairy, which lead to a high number of incident reports, to the way they are used in relation to stock feeds of plant

origin, which do not. This comparison leads to recommendations on how to improve the reliability of documentary supporting evidence for products which currently rely on MDs.

Problems arise when the matters declared on the MD are unable to be independently verified by inspection on arrival, and when other independent methods of verification such as audits or official government endorsement of MDs are not practised. These problems are exacerbated when there is a financial incentive for importers to falsify these documents, and when there is little chance of adverse consequences arising from the detection of such falsification of documents.

There are a number of strategies which could be applied, either singly or in combination, to address these concerns. These strategies include:

1. Removing the ability to use MDs completely, and insisting on official Government certification for all biosecurity requirements.
2. Allowing the use of MDs but require endorsement of the MD by an official of the exporting country Government.
3. Allowing the use of MDs with a formal program of on-site audits of processing plants in the exporting country to demonstrate on-going compliance.
4. Formalising the requirement for inspections at the border with a routine level of inspections.
5. A combination strategy incorporating one or more of the above 4 strategies.
6. Removal of requirements for MDs where the matter being declared is of little importance to the biosecurity safety of the material imported.
7. Implementing a stricter system of end-use controls to further limit the likelihood of exposure to susceptible Australian animals.

The report then considers the import conditions applicable to a range of products where MDs are used, and considers the appropriateness of this use. While the range of products considered is not exhaustive, it does cover a variety of products which are regularly imported. In some of these cases the use of MDs is supported by other controls, and is considered appropriate. In other cases the use of MDs as currently practised is not appropriate. Recommendations are made based on the identified strategies to improve the level of biosecurity confidence in relation to the import of these products.

Finally, a framework is proposed by which DAFF can formalise the consideration of whether manufacturer’s declarations are an appropriate way of ensuring biosecurity confidence, and if so, which is the appropriate strategy for verification of the matters attested to in the declaration.

Background to the project

This report addresses the second of three parts of ACERA Project No: 1001F (Biologicals), and is concerned with the use and reliability of manufacturer's declarations (MDs). In so far as is relevant to MDs, the Problem Statement in the Project outline states:

" one measure that is used to manage the risk of importing biological products of animal origin is the requirement of manufacturer's declarations (MDs) to accompany such imports. MDs report the quality of the components or ingredients of the product under evaluation and detail the production systems. However, there is currently no system for monitoring the veracity of MDs and there is evidence that some are incorrect. Given that BSG relies on MDs to help manage the risk of biological contamination in a range of products, including some potentially high risk products such as cell and tissue cultures, there is a need to evaluate the reliability of MDs to determine whether or not they are appropriate and/or sufficient to manage the risk of some or all biological products of animal origin (or whether there is a need to have additional requirements such as formal veterinary certification by the appropriate country's Competent Authority)."

To this end, the report will consider the issues arising from the use of MDs and will estimate the reliability or otherwise of the declarations, and will recommend strategies for the future.

In preparation for the commencement of the review project, a preliminary exercise asked senior officers within the Biologicals Imports Program (BIP) to list the types of products that were considered to be 'biologicals' and therefore within the scope of the review; and to rate the overall level of risk associated with each of the groups of 'biologicals'. The outcome of that exercise is summarised at APPENDIX 1. This preliminary risk ranking will be referred to throughout the following discussions.

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 conditions on the import which are intended to manage the biosecurity risk. These conditions may include a requirement for the imported goods to be treated in some way to inactivate potential pathogens which may be present in or on the goods. 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;
- 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.

Within this legislative context, the Australian Government Department of Agriculture Fisheries and Forestry (DAFF) has responsibility for animal and plant quarantine. 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 gods 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.

In general, an import permit issued by BIP in accordance with the legislation is valid for a defined period (usually two years) from the date of issue. For some high risk products, permits may be issued for a single consignment. While it is the treatment that actually reduces the biosecurity risk, Australian biosecurity authorities do not (in most cases) actually perform the treatments, but rely on others to do so.

The role of DAFF staff at the border is 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 these conditions have been complied with. These include:

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

In many cases, 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. In such circumstances, we must rely on documentation to provide confidence that biosecurity conditions have been met. Forms of documentation used for this purpose include official government to government certification, and other forms of documentation such as MDs.

Government certification

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 is the OIE Terrestrial Animal Health Code (the Code), which provides, *inter alia*, guidelines for international veterinary certification. Similar arrangements also exist in relation to plant biosecurity.

The Code sets out matters which should be included in an international veterinary certificate, and in addition provides guidelines on how importing countries can assess the veterinary authorities in exporting countries to ensure that international veterinary certification can be relied upon. 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. DAFF performs competent authority assessments, whether by in-country audit in accordance with the guidelines in the Code, desk audit, or in accordance with a history of trade relations, prior to accepting government certification from exporting countries. This is therefore the most reliable means of ensuring that biosecurity conditions have been met.

Manufacturer's declarations

Throughout this report, a manufacturer's declaration is defined as 'a declaration signed by the manufacturer or authorised representative of the manufacturer of a product, specifically required under the terms of an import permit relating to that product, and providing information relevant to biosecurity decision making in relation to that product.'

For a variety of reasons, over time, international veterinary certification has not been available for some imported goods. In order to facilitate trade, DAFF has accepted alternative forms of documentation. These have included documents such as MDs, in which the manufacturer of the goods makes a declaration relating to such matters as the source of raw materials for the manufactured goods, that certain treatments have been applied, or that the goods are in compliance with other conditions. Such MDs may, in some cases, be countersigned by officials of the competent authority of the exporting country. For purposes of animal biosecurity, this is most often the veterinary authority, but this may not always be the case. For example, fisheries officers may provide certification in some cases.

Where government officers are required to endorse MDs, the government 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". This provides a greater level of confidence than similar MDs without the counter signature, but it has to be accepted that the level of checking varies between veterinary authorities.

In other cases the MD is not counter signed by the veterinary authority. These have a correspondingly lower level of confidence, since there may be commercial conflicts of interest arising where manufacturers are required to 'certify' their own products.

Where are manufacturer's declarations used?

Anecdotal evidence supplied by officers of BIP indicated that the greatest number of Import Permits requiring MDs were for:

- products for human consumption,
- *in-vitro* use products,
- human therapeutics,
- veterinary therapeutics,

- stock feeds, and
- fertilisers.

Products for human consumption should present a lower risk than other products due to the reduced likelihood of exposure to susceptible animals. However, this generalisation will need to be further examined, since some human consumption products may be more likely than others to be diverted to other uses. As an example, there have been a number of documented cases where fish products imported for human consumption (as per the import permit conditions) have been used as bait (S. Tognolini, *pers. comm*.), thus providing a greatly increased opportunity for exposure to susceptible animals in the Australian environment.

Products intended for *in vitro* use generally also present little risk, again due to the decreased likelihood of exposure to susceptible animals. However, the acknowledged difficulties with enforcing end – use conditions on individuals other than the importer mean that this cannot be entirely relied upon.

Of major concern is that the next two major categories of products requiring manufacturer's declarations are veterinary therapeutics and stock feeds. While there is a broad spectrum of biosecurity risk for these commodities based on ingredients used in manufacture, manufacturing processes and regulatory oversight in the country of manufacture, both of these categories include products that are considered to be high risk due to the extremely high likelihood of direct exposure to potentially susceptible animals.

Why are manufacturer's declarations used?

DAFF has a dual role in relation to the regulation of imports of goods into Australia, as evidenced by the following words, extracted from the DAFF mission statement;

"We help people and goods move in and out of Australia while managing the risks to the environment and animal, plant and human health".

The first is to help goods move in and out of Australia, implying a facilitative role which could be interpreted as requiring, *inter alia*, the minimisation of costs, and of unnecessary delay, to importers of goods. The second listed role, of course, is to manage risk.

One reason for the use of MDs as opposed to official government to government certification appears to arise from a desire to reduce costs to importers. Importers have complained that obtaining Veterinary Certificates for some products is not possible due to unavailability of government inspection services for some products in some countries. However, staff from the Biological Imports Program (BIP) advised that enquiries with exporting country authorities indicate that this is not generally the case and that government certification is available in almost all cases, albeit at a cost to exporters (R. Heard, *pers. comm.*).

Another reason for the use of MDs appears to be a desire by DAFF to allow clearance of consignments on documentation rather than having to rely on physical inspections at the border. This reduces the cost to importers, both in inspection charges and in delays to delivery.

While it is acknowledged that minimising cost to importers is a valid consideration, and consistent with the DAFF mission statement, the facilitation role must not at any time compromise biosecurity safety. At all times, the management of biosecurity risk is of primary importance and should never be compromised or made subservient to the facilitation role.

Recommendation 1. Whenever the use of manufacturer's declarations is being considered as a risk management measure for the import of biological products, care should be taken to ensure that the biosecurity confidence arising from the use of the MD is sufficient to ensure that risks are appropriately managed.

How are manufacturer's declarations used

The use of MDs varies from product to product. There are two major ways in which they are assessed. They may be used as part of the assessment process prior to granting of an import permit, or they may be used at the border for clearance purposes.

In the first case, the import permit application process requires that the importer provide full details of the manufacturing process for assessment, at the time of application for an import permit. The level of scrutiny applied to checking the veracity of MDs during the permit assessment process also varies. In some cases it is limited to a desk audit, while in other cases, such as for some types of plant based stock feeds, an extensive proof of process, including on-site auditing of the processes in use at the production facility, is required.

If the assessment is positive and the process is accepted as meeting biosecurity requirements, the import permit may require that each shipment of product to which the permit applies is accompanied by an MD certifying that the process, as assessed and accepted, has been applied to the product. For example, in relation to requirements for the import of culture media, PC0591 requires the Manufacturer to state:

the sourcing of raw ingredients and processing of materials for the products in this consignment have not changed since the information was provided to the Australian Quarantine and Inspection Service (AQIS) with the Import Permit application. The manufacturer will notify AQIS of any changes prior to shipment, if any of the sourcing or processing details alter from the original information supplied in the Import Permit application.

This is important because changes to sourcing or processing details may change the risk associated with the product, and may therefore affect the risk management measures required. Such changes may, or may not, affect the biosecurity status of the imported goods, and therefore may result in the permit being cancelled until the revised sourcing or processing has been assessed. After this reassessment, a new permit may be issued if the revised details provide adequate biosecurity. However, regardless of the level of scrutiny applied during the permit assessment process, it is clear that it is virtually impossible for a biosecurity officer at the border to independently verify the accuracy of this declaration by inspection alone.

Perceived problems with the use of manufacturer's declarations

During a review of imported goods documentation undertaken on behalf of DAFF, Tanner James Management Consultants (Tanner James Management Consultants., 21 October 2010) identified a number of concerns arising from the use of MDs. These concerns were described by the consultants as:

- Uncertainty as to the integrity of the document:
- Lack of proof as to who created the document;
- The difficulty of legal recourse in cases where documents were falsified;
- The difficulty of verifying that the document accurately reflects the processing of the goods; and
- Language difficulties (sometimes the documents are not in English).

Although this final point was included in the Tanner James report, it has been pointed out that MDs which were not written in English should not be accepted under the Minimum Document Requirements Policy (DAFF, 2012).

The integrity of manufacturer's declarations.

Discussion with staff from Animal and Border Compliance Divisions reveal numerous anecdotal references to misuse or alleged misuse of MDs. These anecdotal references indicate that the highest number of fraudulent MDs come from manufacturers of food products. Suggested reasons for this bias towards false declarations relating to food products include the fact that food producers generally are subject to a lower level of quality management systems than are manufacturers of other products such as laboratory materials, and that import conditions for food products allow the use of MDs from countries with less favourable animal health status than Australia.

Summary data provided by officers of Investigations & Enforcement (I & E) unit within DAFF back up the personal observation of other officers, and confirm that a large number of reported instances of fraudulent MDs are for food products. Since 1 January 2010, I & E has received 28 Incident Reports (IRs) in relation to false MDs. Of the 28 incident reports relating to MDs received, 20 (over 70%) were referred to investigation, which is 20% higher than the general referral rate of IR's. While the reason for this increased rate of referral for further investigation is not entirely clear, it can be surmised that it arises from:

- an increased level of genuine malpractice in this area, or
- an increase in active surveillance and investigation from border staff based on their knowledge of history of non-compliance with MDs).

Animal products were the most likely to be the subject of false MDs (16; 57%), half of which were for dairy products. The most common country of origin of goods which were the subject of false MDs was China (29%), followed by Korea (21%), and Taiwan (18%).

In addition, I & E has received 6 Intelligence Information Reports (IIRs) that specifically relate to false MDs. Of these, one was referred for further investigation.

The incidents referred to above relate directly to allegations of false MDs. Officers of I&E also suggested that there are other incidents with references to inconsistent documentation and labelling that may have implications as to the validity of the MDs, but these are not easily extracted from the database.

Some examples of the types of malpractice that is occurring are listed below:

- A common theme is reliance on foreign language issues. A suspected false MD was supplied for vanilla ice cream claiming that the product contained nil dairy, although the packaging stated, in English, "Made from Real Milk". The importer claimed the product only contains 'dairy flavour' and that the claim on the packaging was a translation mistake.

- Similarly, MDs have been found to match the English ingredient label, but when peeled off to reveal the non-English label, the product is found to contain meat products.

- A document satchel was inspected at Sydney Gateway Facility in early 2012. The documents related to the importation of a consignment of jig caught squid. Included in the documents was a packing declaration without any consignment details, as well as blank paper with the supplier's stamp imprinted on them that could have presumably been used for the falsification of an MD.

- Another broker submitted an MD that did not match the container number in AIMS or the bill of lading. He then provided new documents with exactly the same date as the previous documents. This included an MD for various seaweed species. At Imported Foods inspection, it was found that these species did not match. The importer advised that they had not provided species list to the broker, indicating that the MD had been falsified.

- Another example involved suspected dairy goods which were being held in quarantine, pending receipt of an MD. The biosecurity officer received an 'Authority to Treat' form for other lines, but the importer appeared to have changed their minds, as the line relating to dairy had been crossed out. About a week later, the broker supplied MDs suggesting the dairy product contained less than 10% dairy ingredients, although the inspecting officer considered them to contain 25-30%. In addition, the broker had falsely added the line as soft drink in AIMS, avoiding the use of the dairy tariff.

The above examples clearly indicate that there is a problem with the use of MD for clearance of goods at the border. There is opportunity for the MDs to be falsified, leading to an increased risk of introduction of exotic pests or diseases.

In addition, work undertaken within Cargo & Shipping Branch since January 2011 has shown that a significant number of supposedly official government veterinary certificates have been fraudulent. On 1 January 2011 the Chinese authorities implemented new security features in

the paper used for their certificates. Since 1 January 2011, Entry Management staff have been checking certificates and have identified possible fraudulent Chinese certificates i.e. Fumigation/treatment certificates, Phytosanitary certificates and Health/sanitary certificates. These certificates have been verified by China as being fraudulent. To date, DAFF has identified approximately 2400 fraudulent certificates from China. (J Weymouth, 2012, *pers. comm*.)

If exporters are prepared to forge official government certification in their own countries, there is little doubt that an MD that has no legal basis in the exporting country will also be a target for fraudulent activity.

Lack of proof as to who created the document

There is some concern that fraudulent MDs may be being produced by importers in Australia, and not by the exporter or manufacturer of the goods. This is based on anecdotal evidence of border staff being provided with MDs which were not consistent with requirements, and consequently rejecting these documents. A short time later, the documents were re-presented, with compliant MDs. It was the view of the border staff involved that, given the short time lapse between original presentation of the incorrect documents and re-presentation of the correct versions, it was likely that these declarations were not sourced from the overseas manufacturer but were prepared by the brokers or importers in Australia.

In such cases it would seem that there is adequate reason for a biosecurity officer to consider that the conditions had not been met, and to take some form of corrective action. Such action could range from rejection of the consignment, to requiring a verification inspection at the importers cost, or formal validation of the declaration with the manufacturer.

Difficulty of legal recourse

As stated above, the use of MDs was, at least in part, an attempt to minimise delays in clearance of goods, and to minimise costs to importers arising from such delays, and any tests or treatments which may be required. If all MDs were genuine, and accurate, this would not present a problem. However, this is not the case. Manufacturer's and/or importers, acting alone or in collusion, may provide false declarations in order to gain access to the Australian market for goods that would otherwise not be permitted, or would be permitted only if subjected to potentially expensive tests, or treatments.

This raises two problems. First and possibly most important, is that a false declaration, if accepted at face value, could lead to goods which pose an unacceptably high biosecurity risk being released from quarantine and distributed. If a biosecurity officer has reason to believe that an MD which relates to goods presented for import is false or incorrect, the goods should not be released. They can be ordered into quarantine for treatment, which may include verification of documents, or the undertaking of further enquiries, testing etc. This however, relies on the biosecurity officer realising that the MD is false. As will be demonstrated later, for many of the matters for which MDs are used, proving that the declaration is false is problematic at best. As a result of this difficulty, and in keeping with the initial purpose of the

move towards increased use of MDs, there is a tendency for these documents to be accepted, rather than questioned.

It is for this reason that it is important, where false MDs are detected, that effective legal enforcement action is taken to deter the future use of false MDs by manufactures/importers, in an attempt to avoid biosecurity compliance costs

There are a number of problems associated with the legal enforcement of MDs. Firstly, because the declarations are made by the manufacturer, usually in the country of origin, there is some doubt as to whether the declaration itself carries any legal weight. The legislation in the exporting country may not provide a system similar to the Australian 'Statutory Declaration' system, so that there may be no legal enforceability in the exporting country.

Even if there is a system equivalent to the Australian 'Statutory Declarations' system, there may be difficulties in enforcing these depending on how the MD is presented. For example, if the declaration is made by the manufacturer, and presented to the exporting country authorities as part of the export approval process, the exporting country authority is likely to have enforcement powers, while Australian officials are unlikely to have any direct jurisdiction, since the legislation, and the offence, both occur overseas.

Furthermore, in many cases MDs are signed by a representative of the manufacturer, and are then provided to the importer, or some other commercial party. As an example, Condition C10035, in relation to bulk mined or chemical fertiliser products, states in part:

2. Each consignment must be packed at the place of production, in new packaging, and in units of 100kg or less. The bulk mined or chemical product must not have been stockpiled outside in an open environment. NOTE: supporting evidence of this must be provided to your broker or shipping agent. Acceptable evidence includes a valid manufacturer's declaration stating that the consignment 'was not stockpiled outside and has been packed at the place of production in new packaging in units of 100kg or less'.

In this case, the permit condition requires that the 'supporting evidence' referred to must be provided to the 'broker or shipping agent', and not to a biosecurity officer.

The broker or shipping agent then presents the document to biosecurity staff at the border. In this case, the manufacturer may have made a false declaration, according to the legislation in force in the exporting country. However, the importer could argue that he has received the declaration, and passed it on to biosecurity staff, in good faith. In a legal sense, it would be difficult to prove that the importer had knowingly provided a false declaration to the biosecurity officer, under such circumstances.

DAFF has made a number of approaches to Government legal advisors requesting possible solutions to these legal difficulties. Advice received to date suggests that a legislative solution to the is unlikely to be available, although current proposals to replace the *Quarantine Act 1908* with a new set of biosecurity legislation may provide opportunities to address this problem. In the meantime, other operational solutions must be found. This project is part of that process.

The difficulty of verifying that the document accurately reflects the processing of the goods

The current system of import clearance relies largely on desktop assessment of documentation, with generally little or no routine physical inspection and verification. The reasons for this include the lack of resources, and on-going pressure from importers to minimise inspection costs and delays in clearance of goods, both of which will increase if testing or other verification activities are required.

DAFF does undertake random surveillance through the Import Clearance Effectiveness (ICE) program, and through the food program. The Supplier Import Profile (SIP) process identifies non-compliant importers who are then subject to further inspections. DAFF may also undertake targeted activities where specific entities with a history of non-compliance are subjected to increased levels of surveillance.

In many cases, even when resources are made available to perform inspections, whether as a result of routine procedures or targeted activities following history of non-compliance, suitable post arrival tests to confirm the application of particular processes during production are not available.

Referring to the extract from Condition C10035, in relation to bulk mined or chemical fertiliser products, reproduced above, we can see that the declaration contains four parts. These are:

1. The consignment was not stockpiled outside;
2. The consignment was packed at the place of production;
3. The consignment was packed in new packaging; and
4. The consignment was packed in units of 100kgs or less.

Of these four parts of the declaration, the first two, and arguably the third, cannot be verified by DAFF staff at the border. The fourth part of the declaration is verifiable by inspection, if physical inspection of the consignment is carried out.

Other examples include a requirement for manufacturers to state that a product has been frozen to a particular temperature for a minimum period of time. Once again, this is unverifiable on simple inspection. It is possible to demonstrate the temperature of the product at the time of the inspection, but without some alternative evidence it is not possible to say for how long the product has been frozen.

Similarly, it is not possible to verify that products have been cooked at particular temperatures for particular periods of time. Where the import condition states that the product must meet conditions of commercial sterility, laboratory tests exist to ensure compliance with that standard. However, if conditions relate to specified temperatures being maintained for specified times, such tests are not available. As an example of the difficulties associated with this, Animal Biosecurity Branch, in association with commercial partners, has attempted to develop tests to verify cooking times and temperatures for chicken meat products. It was possible to develop tests that showed that cooking had occurred, and that particular

temperatures had been reached. However, the particular temperatures that could be experimentally verified were a characteristic of the type of protein present in the particular product being tested. The tests were not able to be calibrated to the temperatures required by the biosecurity conditions, nor were the tests able to verify that the temperatures had been maintained for the required periods of time.

Language issues

On occasions, import clearance staff are presented with MDs in languages other than English, making verification difficult. As stated above, such MDs should not be accepted in accordance with the Minimum Document Requirements Policy (DAFF, 2012).

Furthermore, cases have been recorded where MDs presented in English were later found to be at variance with ingredients listed on the product label. In these cases, the MD appeared to have been falsified to comply with import requirements, while the original foreign language label was unmodified and indicated that prohibited ingredients were included.

Conclusions

The above brief discussions provide examples to confirm the concerns identified in the Tanner Janes Management Consultants report. There is significant reason to doubt the accuracy of many MDs, compromising their effectiveness in reducing biosecurity risk. This impediment is likely to continue, without significant revision of the system.

Officers of BIP advised that electronic certification initiatives are currently being trialled in cooperation with New Zealand MAF, with a view to wider introduction in the future. Implementation of such electronic certification systems, with appropriate levels of security, could assist in minimising the possibility of fraudulent certification.

The review will provide recommendations for addressing the problems raised above.

Method for the review

The review was undertaken in a number of stages.

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 **Error! Reference ource not found.**.

With this preliminary exercise providing guidance as to the scope of the project, discussions were held with officers from BIP and from I & E to ascertain:

- where MDs were being used successfully (if at all);
- where MDs were causing problems for biosecurity staff; and
- the range of problems which were being experienced with the use of MDs.

Having identified cases where MDs were being used successfully and cases where they were causing problems, a detailed case study was undertaken to determine the similarities and differences between the two cases. These were then used to provide the basis for some strategies to overcome the problems which were being experienced.

Subsequently, officers from BIP were asked to provide examples of permit conditions for a range of products where MDs were required, with emphasis on products which had caused problems in the past, whether through reports of deliberate misconduct, or through operational problems at the border. These were then reviewed individually, with reference to the level of risk presented by the particular product being imported, as determined by a preliminary review of risk categories and the level of confidence which could be placed on the declaration. The purpose of this individual review was twofold.

Firstly, the review was to lead to recommendation relating to individual products which had been causing concern for biosecurity staff. Secondly, it was to lead to recommendations for a generic process to be used in all case where manufacturer's declarations may be considered in future, to ensure that appropriate biosecurity is maintained whilemaking the most efficient use of available resources.

Case studies

Discussions with DAFF staff have revealed that, despite the difficulties discussed above, there are some situations where MDs are used that do not lead to problems. In an attempt to determine what makes the difference between a problematic use of MDs, and an appropriate one, we will consider a number of case studies. First we will look at the use of MDs in relation to products containing dairy, in order to attempt to clarify what aspects of the use of MDs is contributing to the high level of incident reports relating to this type of product. We will then consider cases where MDs are used which do not appear to be leading to a high level of allegations of misuse. This will lead to recommendations on how to improve the reliability of documentary supporting evidence for products which currently rely on MDs.

Products containing dairy

Referring to the assessment at APPENDIX 1, products containing dairy ingredients (milk or milk products) are considered to be of relatively high risk, with a score of 3.8 against a maximum possible score of 5. As stated previously in this report (See page 8), advice from I & E unit also suggests that dairy products represents the highest number of alleged fraudulent MDs.

It should be noted that this group of products covers an extremely wide range, and includes:

a) products that are almost 100% milk with little processing (e.g. fresh milk and some milk-based drinks) which would represent a higher risk;
b) relatively highly processed milk based products (baby formula) which would represent a lower risk than (a), but which may still be used for rearing young animals and thus represent a moderate level of risk;
c) cheeses (variable risk depending on processing); and
d) composite products containing some percentage of dairy product (eg lasagne) which would represent a variable risk depending on the composition and degree of processing of the product.

It may be that these products should be reassessed to ensure that the conditions are appropriate. This will be discussed further in a separate report as another part of this project. For the current report, we examine the current use of MDs in the assessment of biosecurity safety for this group of products. Extracts from conditions for the import of these products (obtained from the ICON database) are contained in APPENDIX 2.

Goods containing less than 10% dairy

The information provided by officers of I & E unit (see Page 8) indicated that the greatest number of allegations of fraudulent MDs comes from this group of products.

An examination of the conditions reveals the following:

"An Import Permit is not required for the following commercial consignments, from any country of origin:

Goods of which each individually packaged unit contains less than 10% by dry weight (other than any added water) of a dairy product, and are accompanied by a valid Manufacturers Declaration - stating that the goods "contain less than 10% dairy by dry weight for each individually packaged unit";

The examples of suspected false declaration incidents provided by I & E largely relate to falsely declaring that the percentage of dairy ingredients in a product is less than 10%, with the apparent intention of avoiding the need to obtain an import permit.

No documented scientific justification for the choice of 10% as an appropriate level for this exemption from the requirement for an import permit could be found. Logically, there is a point at which the dilution factor reduces the level of contamination of a product with pathogens derived from the raw ingredients to a level below that capable of producing infection in an exposed animal. This may be greater or less than 10%, or may, more likely, vary from product to product. There has also been some comment that the 10% rule may have been originally suggested to facilitate trade many years ago when Australia was considered too much of an 'isolationist' in its international trading perspective (major exporting country with limited need for imports). It should be noted that this trade related issue is unrelated to biosecurity and should not influence biosecurity decision making.

However, whether or not the '10% rule' is scientifically supportable, this provision in the import conditions allows a significant proportion of consignments of a product that is rated as relatively high risk to be imported without an import permit.

This has the effect of reducing the cost to the importer in two ways. Firstly the cost of applying for and obtaining a permit is avoided. Secondly, costs associated with conditions imposed by the permit are also avoided. This provides a financial incentive to fraudulently represent that a product contains less than 10% of dairy ingredients, and therefore qualifies to be imported without a permit.

The conditions do not explicitly require inspection or testing on arrival to confirm the accuracy of the declaration, nor do they specify any standardised means of objectively assessing the percentage of dairy product contained in the imported product. Due to the lack of a requirement to test, and the lack of a specified objective test method, there is little disincentive to the provision of falsified MDs. The previously mentioned legal difficulties associated with obtaining a successful prosecution in relation to a false MD (see Page 10) further reduce the disincentive.

It is therefore not surprising that the combination of a financial incentive to provide a false declaration, and a lack of obvious disincentive to do so, leads to the high level of reported malpractice relating to these products.

Goods containing greater than 10% dairy

An examination of the conditions for import of goods that contain greater than 10% of dairy products (APPENDIX 2) reveals that the majority of the conditions must be certified by an

official government veterinary officer. Options exist for the date of manufacture for each batch or lot number to be provided on an MD (on a consignment specific basis).

Additionally, in cases where the exporting country cannot be certified as meeting OIE requirements for freedom from specific diseases of international concern, an MD may be used to attest to pasteurisation or UHT treatments. If this is the case, the MD must be endorsed by the Official Veterinarian of the exporting country. The pasteurisation or UHT treatments provide a significant degree of biosecurity confidence that the import of dairy products will not pose a risk of introduction of diseases of concern. Therefore it is very important to biosecurity that this information is reliable.

The examples of potentially fraudulent MDs supplied by officers of I & E unit did not include instances where it was suggested that either the date of manufacture, or the processing requirements, had been falsified. There appear to be a number of possible reasons for this.

Firstly, products containing greater than 10% dairy still require an import permit, as opposed to those containing less than 10% dairy, which do not. The financial incentive to falsify this declaration relating to date of manufacture, and the processing conditions to which the product has been subjected, is therefore lower than was the case for a declaration that the product contained less than 10% dairy.

Secondly, the MD must be endorsed by an official veterinarian of the government of the exporting country. In order to falsify this declaration, the manufacturer of the product must therefore either:

- defraud an official of his own government into endorsing, in good faith, the false declaration;
- collude with the government official to knowingly provide a false endorsement; or
- forge the official endorsement on the MD.

Any of the above options is likely to represent a much greater disincentive than was the case in relation to the declaration that a product contains less than 10% of dairy ingredients. Clearly, there are manufacturers and exporters who are prepared to take this risk, as evidenced by the numbers of falsified government certificates that have been discovered, as discussed above (page 9). However, it can be concluded that the requirement for official government endorsement of MDs provides a higher level of biosecurity than is afforded without this requirement.

Stock feed

In contrast to the high level of Incident Reports referred to I & E unit in relation to dairy products, few Incident Reports are received in relation to import of stock feeds. MDs are also used for this group of products. The difference in reported levels of allegations of malpractice may be due to the different ways in which the MDs are used for this group of products.

Referring to the assessment at APPENDIX 1, stock feeds for terrestrial animals are considered to be high risk, with a score of 4.5 against a maximum possible score of 5. This high rating is derived as a result of their potential for contamination with infective material

during storage and transport in the exporting country, and their direct exposure pathway to the environment and to potentially susceptible animals.

Aquaculture feed is considered as being above average risk, scoring 3.8 out of a possible 5 when rated by senior biosecurity officers (see APPENDIX 1). The lower risk rating given to aquatic stock feeds reflects the more serious potential consequences involved in the introduction of a disease of terrestrial livestock, which represent a much greater percentage of Australia's agricultural product than do aquaculture stock.

Feeds may be based on plant material, or on animal material (including material derived from fish and/or birds). Logically, the risks differ between these two types of feeds, since plant based materials are less likely to be infected with animal pathogens, and so are unlikely to directly introduce such animal pathogens except by contamination during or after processing. These may, however, serve to introduce plant pathogens or weeds, and therefore represent a plant biosecurity risk. As was the case with Report 1 within this project, the present review was mainly directed to animal biosecurity issues as these are the responsibility of BIP, who have commissioned the project. Where the import of particular products raise concerns related to plant biosecurity, or human or environmental health problems, BIP consults with other appropriate agencies to ensure that these concerns are addressed.

Plant based stock feeds

Officers from Plant Biosecurity provided details on the processes used in assessing and granting permits to import plant based stock feed. The process is set out below.

All plant based stock feed import permit applications are subject to a desk audit. A questionnaire and details of DAFF requirements for the desk audit will be forwarded to the applicant by officers from Plant Biosecurity, upon receipt of an import permit application. Detailed information regarding the approval and inspection of the processing plant by the relevant government authority in the exporting country, the stock feed manufacturing process, provision of Quality Assurance manuals and operating procedures are required to perform the desk audit. Depending on the desk audit outcome, the manufacturing facility and export pathway may be subject to an on-site audit and inspection, prior to granting of an import permit. The importer is responsible for all costs associated with any site inspection (including airfares, accommodation, meals, business related incidentals and auditing fee for service). If the desk audit (and site audit if required) findings are satisfactory, permit conditions are developed that require, *inter alia*, that the manufacturer declares that the processing, packaging and post processing treatment of the product are in accordance with requirements.

APPENDIX 3 contains copies of generic "Quarantine requirements for the importation into Australia of processed stockfeeds and stockfeed ingredients of plant origin." An examination of the conditions contained in APPENDIX 3 shows that the manufacturer of the product is required to confirm, by way of an MD, matters relating to:

- *"the nature and quality of the raw materials contained in the stock feed;*

- *the processing involved in the manufacture of the product, including heating times and temperatures;*
- *the packaging of the product;*
- *prevention of post-processing contamination; and"*
- that "*the processing plant, its products and records are available, upon request, to the certifying authority and/or AQIS for the purposes of confirming compliance with import conditions*".

The first four of these directly impact on the biosecurity safety of the product, and in keeping with other arguments contained in this report, are too important to be left solely to an MD. However, in this case, "*an authorised official of the certifying authority of the country of origin and export*" is required to provide further confirmation of these matters. In particular, the authorised official is required to certify that:

- *"the processing plant is in compliance with relevant government requirements;*
- *the processing plant has been inspected by the certifying authority within the previous 12 months;*
- *there is no opportunity for cross contamination of the product by livestock or birds; and*
- *that the product has not been reported to have been involved with the transmission of animal disease within the previous 12 months."*

The authorised official is further required to certify that:

> *"after due enquiry, he/she is satisfied that all product of the class being exported to Australia is heat treated according to the requirements specified in the Permit to Import, and that he/she has no reason to doubt all other statements made in the manufacturer's declaration".*

This provides an example of where an MD is backed up by a well-defined formal audit process, prior to permit approval, and is further supported by a requirement for official government certification on an on-going, consignment by consignment basis. There is also provision for on-going on-plant audits by DAFF or by authorised officials of the certifying authority. These conditions appear to be working well and providing a good level of biosecurity.

It could be argued that the matters which are subject to an MD in the stock feed conditions could just as easily be incorporated into the official government certificate. While this is true, there may be reasons why this is not convenient or desirable. For example, government authorities do not regulate the production of stockfeeds in all countries, so in some cases, government certification may not be possible. In this case, the existing system of desk audits, followed by on-site audits prior to permit issue, and endorsement of the MD by an official of the exporting country government, leads to a system which is providing appropriate biosecurity. This is further strengthened by the requirement for the manufacturing plant to be made available on request for follow up audits.

Options for addressing problems arising from the use of manufacturer's declarations

The case studies discussed above provide strong pointers to the ways in which MDs can be relied upon, and what leaves them open to abuse. Problems arise when the matters declared on the MD are unable to be independently verified by inspection on arrival in Australia, and when other independent methods of verification such as audits or official government endorsement of MDs are not practised. These problems are exacerbated when there is a financial incentive for importers to falsify these documents, and when there is little chance of adverse consequences arising from such falsification of documents.

At first glance, the problems associated with the use of MDs can be eliminated by simply removing the ability to use MDs completely, and insisting on official government certification for all biosecurity requirements. However, the desire to minimise costs to importers which has resulted in the increased use of MDs to allow the clearance of import consignments on the basis of documentation is in keeping with the overall mission of DAFF to help the movement of people and goods into and out of Australia.

For some categories of products, there may be opportunities to continue to use MDs, which would lead to overall savings in time and resources for importers, without putting biosecurity at risk. There are a number of strategies which could be applied, either singly or in combination, to address these concerns. These strategies are set out below.

Strategy 1 – Require government certification in all cases

Requiring official government certification in place of MDs for all biosecurity requirements will address the uncertain legal status of the declarations, which is one of the major disadvantages of the MDs. There would appear to be a much greater likelihood of effective follow up in cases of detected false declarations, since the responsibility for corrective action would fall upon the competent authority in the exporting country. However, it has previously been mentioned that there are cases on record of falsification of official government health certificates, so it is obvious that this will not completely remove the problems associated with ensuring compliance with biosecurity conditions. This problem could, at least in part, be addressed by ensuring that competent authority audits are undertaken prior to granting import permits. The audit process would help to ensure that exporting country competent authorities have the legislative power, and administrative system in place to minimise the risk of fraudulent certification being produced.

The use of this strategy would mean that costs to importers may increase if the competent authority charges for the provision of inspection and certification services. Some opposition from importers to this proposal should be expected. In general, official government certification, especially if linked with other risk management measures or biosecurity conditions, offers a high level of assurance as to statements made about the products or processes.

Strategy 2 – Require government endorsed MDs on a consignment by consignment basis

This strategy is similar to Strategy 1 in so far as it shifts some of the onus for follow up action in cases where false declarations are discovered back to the competent authority in the country of export. In doing so, it removes some of the legal jurisdictional difficulties associated with enforcement action, and therefore decreases the incentive to falsify the documents. In general, government endorsed MDs offer a reasonably high level of assurance as to the biosecurity safety of the products to be imported into Australia.

Strategy 3 – Allow use of MDs with formal program of on-site audits to demonstrate on-going compliance

Short of requiring government certification in all cases, a formal program of desk and/or on-site audits of manufacturing plants in the exporting country is the best option in terms of the increased biosecurity confidence provided. However, it has the greatest resource implications for both DAFF and for importers. Costs will be incurred for audits and there may be some concerns raised over the frequency of audits, and the total costs involved in complying with audit requirements. Audits may be carried out by DAFF staff or by independent third party auditors. The biosecurity confidence provided by a program of audits is similar to that provided by government certification. Although auditors are not present in the processing plants at all times, but only during audits, they do have the ability to independently review the operations and inspect records to ensure that import permit conditions are met. In many cases where government certification is required, the exporting country competent authority provides its certification on the basis of their own audits, rather than as a result of full-time supervision of operations.

Strategy 4 – Formalise requirements for inspections at the border

Formalising the requirement for inspections at the border with a routine level of inspections would be of value if the matters that are required to be addressed in the MD are things that can be effectively and efficiently verified at routine inspection, but not otherwise. In order to progress this strategy, it may be necessary to commission the development of inspection methods or tests for verification of satisfactory compliance with some requirements. Whether such tests can be developed in all cases is unlikely, but may be worthy of consideration for some. If suitable tests are not available to assist in verification of information contained in MDs, alternative documentary evidence may be required (e.g. thermograph records for freezing or heating treatments, or treatment certificates from independent organisations).

Mandatory testing would be likely to increase costs to importers, due to costs associated with inspection and sampling, and the costs of any laboratory procedures that may be required. This increase could be minimised by the use of a sliding scale, with lower inspection rates following a number of acceptable inspection results, as is currently used for some food imports. It may also be possible to build into the scheme a provision for cancellation of an import permit following an unacceptable record of inspection findings, whether this be a single major deficiency or a number of on-going smaller faults.

Advantages of this strategy largely arise from the increased deterrent effect on importers knowing that their consignments will be randomly inspected, and therefore detection of falsified MDs is more likely. The legal difficulties with enforcement of the MD remain. However, administrative action such as the withdrawal of import permits would be a further deterrent, as would the costs of increased inspections following 'failure' of a consignment to pass inspection.

Strategy 5 - Combination of one or more of the strategies listed above

As an example of the way these strategies can be combined in order to improve the overall level of biosecurity confidence without unduly impacting on DAFF or industry, it may be possible to combine Strategies 2, 3 and 5, as follows.

At the time of permit application, exporters could be required to submit an MD including details of, for example, the processes used in the manufacture of a product. This declaration should be endorsed by an official of the competent authority in the exporting country, who could be required to state that the process has been audited and found to be in compliance with the requirements. Alternatively, this could be endorsed by an independent certifying body.

This endorsed MD could then be subject to desk audit to ensure that all Australian biosecurity requirements were covered, prior to issuing an import permit. This would lead to increased costs to importers if the endorsed MD was required for every import. However, this cost impost could be reduced by not requiring the MD for every consignment. Once the endorsed MD had been desk audited and an import permit issued, the requirement for the MD to be presented with every consignment could be withdrawn, and individual consignment could be passed based simply on the import permit. The endorsed MD would be required to be re-submitted at the time of application for permit renewal which would provide for a regular desk audit of the manufacturing process. This regular desk audit at the time of permit renewal provides a higher level of confidence than an unaudited MD with every consignment.

The implementation of such a combination approach has a number of advantages. These include:

1. The endorsed MD would describe the actual process carried out in the plant, as audited by the competent authority of the exporting country government, rather than declaring that the product met some minimum standard which may not be related to the actual process used.
2. The assessing officer considering the permit application can see exactly how the biosecurity conditions are being met by the process being used, rather than simply relying on the declaration that the conditions have been met.
3. The legal jurisdictional difficulties associated with MDs are largely overcome by transferring the onus back to the competent authority of the exporting country.
4. The audit requirements will likely increase costs for importers. However, it provides a significant improvement in biosecurity confidence, over that provided by an MD alone without the audit requirement. In addition, requiring the MD to be provided

only once (at the time of permit application) and not for each consignment reduces the resource implications for both importers and DAFF staff, which will assist in offsetting the increased cost arising from the audit.

A possible down side of such a combination strategy is that, if a manufacturer changes a process during the period of validity of an import permit, DAFF may not be made aware of the change until such time as the permit comes up for renewal. However, under the present system, where no audits are conducted, there is no guarantee that the MD was accurate at the time of submission; nor is there any guarantee that changes to the process will be notified at all. Changes to the processes may, or may not, affect the biosecurity of the imported goods.

Strategy 6 – Removal of requirement for MDs where the matter being declared is of little importance to the biosecurity safety of the material imported

Removal of unnecessary and/or unhelpful declaration requirements will save time at the border by reducing the need for assessment of documentation that does not contribute to improved biosecurity outcomes.

Strategy 7 - Implementing a stricter system of end-use controls to further limit the likelihood of exposure to susceptible Australian animals

A stricter system of end-use controls on imported goods could assist in limiting risk by reducing the likelihood of exposure of imported infective material to susceptible Australian animals. However, this solution raises problems of its own, including the difficulties associated with enforcement of end-use controls on persons other than the importer. While not insurmountable, this solution would likely impose greater costs on importers, and on DAFF. There would be a need for greater levels of record keeping to ensure that all imported goods subject to these conditions were appropriately accounted for, and there may be a need for legislative changes as well to ensure the enforceability of the conditions. However, for some high risk goods the costs may be considered reasonable.

Review of Current use of MDs for various products

Problems identified during the case study of products containing dairy were discussed above . After consideration of the case studies and development of strategies to address issues raised, the following recommendations are made in relation to dairy products.

Recommendation 2. It is recommended that consideration be given to whether the '10% rule' remains appropriate, and if so, to formalising the basis on which the percentage of dairy ingredients is measured.

Recommendation 3. It is recommended that consideration be given to

a) requiring government certification as to the percentage of dairy ingredients in a product (Strategy 1); or

b) requiring further supporting evidence in addition to the MD of the percentage of dairy ingredients (Strategy 2 or 3).

Recommendation 4. It is recommended that consideration be given to

a) requiring government certification of the processing of dairy products containing less than 10% dairy (Strategy 1); or

b) requiring further supporting evidence of compliance with processing requirements, in addition to the MD (Strategy 2 or 3).

In order to continue with the second phase of this review, Officers of BIP were asked to provide examples of permit conditions for biological products in which MDs were used as part of the documentary evidence supporting the biosecurity safety of the goods. The list of examples provided was not necessarily complete, but included conditions for products which were regularly involved in incident reports to I & E staff (such as products containing dairy), and other products which were not involved in such reports. The list is reproduced below.

Food products for human consumption

- Kopi Luwak (Civet coffee)
- Birds' nest products
- Fish for human consumption
    - Crustaceans
    - Fin fish
- Egg noodles/pasta

Human therapeutics

- Herbal tea containing Ganoderma
- Salmon oil
- Green lipped mussel powder

Meat based flavours

Laboratory material

- Diagnostic kits
- Cell culture supernatant

- Genetic material
- Culture media

Products containing dairy

Animal feed

- Pet food
- Stock feed

Bioremediation products

Fertilisers

- Veterinary therapeutics.

Food products for human consumption

Kopi luwak/Civet coffee

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).

This coffee is widely noted as the most expensive coffee in the world with prices reaching $160 per pound [(Wikipedia)]. As a result of its cost and rarity, it is highly unlikely that this product will be exposed to susceptible Australian animals, and is therefore considered to pose a low risk to animals and the environment. However, some concern has been raised over possible human health risks associated with civets. Little is known about possible disease agents associated with civets, which were the source of severe acute respiratory syndrome (SARS), a viral respiratory disease of humans caused by the SARS coronavirus which produced a pandemic in 2002-2003. Kopi luwak was not considered in the preliminary exercise summarised at (APPENDIX 1), but is nevertheless considered to be a relatively low risk product. The Quarantine Proclamation states that the import of Luwak coffee in any form (including whole beans, ground beans or for instant use) for personal use is permitted under the following conditions:

> (a) the beans, or the beans from which the product is made, have been roasted; and
> (b) the product is commercially prepared and packaged; and
> (c) the product is imported in an amount not more than 1 kilogram or not more than 1 litre; and
> (d) the product is for the personal consumption of the person wishing to import the product.

However, for commercial shipments of kopi luwak, and insofar as is relevant to MDs, the import conditions for kopi luwak are reproduced below.

*2. Each consignment must be accompanied by a **manufacturer's declaration,** stating:*

1. The product is manufactured using coffee beans collected from the scats of Indonesian palm civet cats; and
2. The beans are thoroughly washed and dried before roasting; and

3. The beans are roasted in a chamber for approximately 15 minutes as the temperature rises from 90°C to 223°C; and
4. The product is in individually packaged in 100g units.

The main risk mitigation measure is the roasting treatment, which will inactivate all pathogens likely to be present in the product. This treatment is 'certified' by the MD, which, as currently required, is largely unverifiable by any form of inspection or testing, except for the statement regarding individual packaging units. The MD must therefore be considered to be of questionable reliability.

In this case, a combination strategy such as that which was described above seems to be an appropriate solution. An MD describing the processing of the product, endorsed by an appropriate, independent body (whether the competent authority of the exporting country government, or third party quality assurance auditing organisation) would provide improved confidence that the processing plant was capable of processing the product adequately. The gourmet nature of this product, and the desire to maintain consistent quality, would mitigate against unauthorised alteration of the process after the permit had been issued. These facts, combined with the low risk nature of the product, indicate that the provision of an MD with each consignment is probably unnecessary.

Recommendation 5. It is recommended that consideration be given to a combination strategy requiring independent verification (by the competent authority of the exporting country government, or a third party quality assurance auditing organisation) of the manufacturing process for kopi luwak at the time of permit application (Strategy 5) , and removal of the requirement for provision of an MD on a consignment by consignment basis.

Bird's nests products

Bird's nest products are considered to be low risk (APPENDIX 1), with a score of 1 against a maximum possible score of 5. While the nature of bird's nest is such that contamination with avian pathogens is possible, the fact that bird's nest is considered a delicacy in Chinese cuisine, and that edible bird's nests are among the most expensive animal products consumed by humans (Wikepedia), mean that the product imported for human consumption is highly unlikely to be exposed to susceptible Australian birds.

Relevant extracts from import permit conditions for bird's nest products are attached at APPENDIX 4. These conditions include a requirement for official government certification or a government endorsed MD stating that the heat treatment and packaging conditions have been met. The severity of the heat treatment process, and the low likelihood of exposure to susceptible animals, virtually guarantee that the risk associated with commercial imports in compliance with the import conditions pose no risk to Australia's biosecurity.

There is a financial incentive to attempt to 'shortcut' the biosecurity requirements due to the stated preference of customers for dried product, and a consequent decrease in value for product which has been retorted. Anecdotally, there have been reports of bird's nest products being imported which have been sealed in cans, but which were likely not 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.

The ICON entry for this product also requires mandatory inspection on arrival (APPENDIX 4) 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, although the inspection will not by itself confirm the details of time and temperature used during the retort process.

Recommendation 6. It is recommended that consideration be given to the risk posed by bird's nest products and, if risk mitigation continues to be considered necessary, a combination strategy requiring independent verification of the manufacturing process for bird's nest products at the time of permit application, and removal of the requirement for provision of an MD on a consignment by consignment basis ((Strategy 5).

Fish for human consumption

Fish for human consumption, in consumer ready form, is considered to be low risk, with a score of 1 against a maximum possible score of 5 (APPENDIX 1). This is due to the relatively low likelihood of fish imported for this purpose being exposed to susceptible Australian animals. A search of the Import Conditions database (ICON) for conditions for fish for human consumption reveals a large number of examples. Only some of these make reference to manufacturer's (or supplier's) declarations. Examples of conditions that make reference to declarations include the following.

Crustaceans (other than brine shrimp eggs, raw prawns, raw freshwater crayfish and crustacean meal)

Crustacean meat products for human consumption are considered to be low risk, with a score of 1 against a maximum possible score of 5 (APPENDIX 1). There is a small probability that they could be diverted for use as bait. The conditions for this class of fish for human consumption require the following declarations:

> *Consignments of frozen product must be accompanied by a declaration stating that the product has been held at –18°C for at least 7 days. Consignments with this type of documentation are to be subject to random inspections only to verify freezing.*

The random inspection requirement will not fully address the need to verify this process, since the inspection can only verify that the product is frozen, and to what temperature. It cannot determine for how long the product has been frozen to this temperature. This is an example of conditions which are subject to MDs which are unverifiable by post arrival testing. If the freezing treatment is a vital part of the treatment, then other methods of verification are required, such as requiring that the thermograph records are presented to show that the product has been frozen to -18 degrees for the required time. However, if the freezing treatment does not contribute significantly to reducing the risk then the extra resources required to check the thermograph records may not be justified, especially for what is recognised as a very low risk product.

Recommendation 7. It is recommended that consideration be given to requiring thermograph records to verify the freezing treatment for crustaceans (other than brine shrimp eggs, raw prawns, raw freshwater crayfish and crustacean meal) to be available for inspection if requested.

Consignments of fresh chilled crustacean meat (product without shell) must be accompanied by a supplier's declaration stating that the consignment contains non-viable crustacean meat only (no shells). Consignments with this type of documentation are to be subject to random inspections only to verify freedom from contamination.

In this case the random inspection requirement can verify that the declarations provided are correct, by confirming the absence of shell fragments in the consignment.

Discussions with officers of Animal Biosecurity Branch suggest that this requirement was introduced by the operational area for 'shellfish' (as in molluscs). The requirement was that molluscs had to be inspected to make sure they were dead and clean. Post-arrival inspection procedures involved placing a sample of product into a glass of water and checking with a dissecting microscope for attached parasites or other extraneous organisms. There was inconsistency in inspection procedures between states and operations introduced freezing to ensure the mollusc, and any associated organisms, were dead. The MD was introduced to replace inspection to ensure the product was frozen (R Heard, *pers.comm.* 2012).

It appears that this requirement has been expanded to cover crustacean meat as well as molluscs.

Recommendation 8. It is recommended that the requirement for crustacean meat product to be declared free of shell fragments be reviewed to confirm its applicability to this product. If not applicable, the requirement ofr an MD to tis effect should be removed.

Finfish - Consumer-ready form

Import permits for this type of product define consumer ready as follows:

"Consumer ready product is defined as product that is ready for the householder to cook/consume and includes the following examples:
a) cutlets, including the central bone and external skin but excluding fins, each cutlet weighing no more than 450 grams; or
b) skinless fillets, excluding the belly flap and all bone except the pin bones, of any weight; or
c) skin-on fillets, excluding the belly flap and all bone except the pin bones, each fillet weighing no more than 450 grams; or
d) eviscerated, headless 'pan-size' fish, each fish weighing no more than 450 grams; or
e) fish that is headless and eviscerated which has been salted, dried or smoked, of any weight; or
f) product that is processed further than stage's described in points 2 a) to e), including commercially canned product. Consumer ready product is defined as product that is ready for the householder to cook/consume and includes the following examples:

a) cutlets, including the central bone and external skin but excluding fins, each cutlet weighing no more than 450 grams; or
b) skinless fillets, excluding the belly flap and all bone except the pin bones, of any weight; or
c) skin-on fillets, excluding the belly flap and all bone except the pin bones, each fillet weighing no more than 450 grams; or
d) eviscerated, headless 'pan-size' fish, each fish weighing no more than 450 grams; or
e) fish that is headless and eviscerated which has been salted, dried or smoked, of any weight; or
f) product that is processed further than stage's described in points 2 a) to e), including commercially canned product."

The conditions for this class of fish for human consumption require that:

> *All consignments must be accompanied by documentation to verify that the product is in a consumer ready form as outlined above. Documentation may be in the form of an invoice, manufacturer's declaration or government health certificate. Where consignments are not covered by valid documentation or are covered by documentation with an incorrect statement, consignments will be subject to inspection to ensure that the goods are in consumer ready form. An inspection fee will apply.*

The declaration that the product is in consumer ready form is easily verifiable by inspection. However, the inspection is only required in cases where there is no documentation, or the statement in the documentation is incorrect. There is apparently no provision for random sampling of consignments with correct documentation, in order to confirm the accuracy of the statements relating to the consumer ready form of the product. A separate report as part of the Biologicals Project (ACERA, 2012) concluded that finfish for human consumption is a low risk commodity. In such cases, government certification may not be necessary. However, some form of verification of the consumer ready status of the imported product would be valuable.

Recommendation 9. It is recommended that consideration be given to either
a) requiring a government endorsed MD attesting to the consumer ready form of consignments of fish for human consumption (Strategy 2); or
b) implementing a program of random checks to validate the accuracy of the statement contained in the alternative documentation (invoice or MD) (Strategy 4).

Egg noodles/pasta

These products come under the broad heading of foodstuffs, and therefore carry a relatively low risk (1.2 out of 5) according to estimate shown at APPENDIX 1. Plain pasta products in general are unlikely to be diverted to use as feed for livestock and so are relatively unlikely to be exposed to susceptible Australian animals except by accidental feeding of wastes to backyard poultry. In addition, the ingredients in most plain pasta products are unlikely to contain serious pathogens. However, some pasta products may contain significant quantities of egg or dairy products, which may represent a risk.

Condition PC0608 (See APPENDIX 5) for import of these products requires either a government certificate, or a government endorsed MD stating that the product does not contain more than 20% egg content, and that the product has been heated to at least a specified temperature for a specified time. For details of the times and temperatures see APPENDIX 5.

The times and temperatures specified will address biosecurity concerns with these products, provided we have confidence that these have been correctly applied. However, the matters that are required to be declared under this permit condition are not able to be easily verified by inspection or any other form of post arrival testing, although it may be possible to develop tests to determine the proportion of egg in the product. This however presents further problems, since the basis on which the proportion is calculated is not stated. Is the egg measured as fresh egg weight, or on the basis of egg powders such as are used in some manufacturing processes? Also, is the proportion calculated by weight of wet ingredients in the pasta, or as finished dry pasta? The requirement for government endorsement of the MD provides a slightly increased level of biosecurity confidence, but this will depend on the level of oversight involved. In some cases this may not be great.

A separate permit condition (PC 0640 see APPENDIX 5) requires that an MD be provided attesting that the product contains less than 10% of dairy ingredients. This condition does not appear to require government endorsement. It seems inconsistent to require endorsement of one MD (relating to the egg content), while not requiring endorsement for a very similar declaration for the same product (relating to the dairy content).

Recommendation 10. It is recommended that consideration be given to specifying more accurately the basis on which the 20% egg content in egg pasta is calculated, in order to remove confusion.

Recommendation 11. It is recommended that consideration be given to a combination strategy requiring independent verification of the manufacturing process for egg pasta / noodle products at the time of permit application, and removal of the requirement for provision of an MD on a consignment by consignment basis (Strategy 5).

Meat based flavours

Meat and meat based flavours (*e.g. stock cubes/powder*) for human consumption are considered to be low to moderate risk (APPENDIX 1), with a score of 1.8 against a maximum possible score of 5. The increase in perceived risk for this group of products derives from the fact that some of the major animal diseases of biosecurity concern are diseases of ruminants and/or pigs, so the likelihood of meat products derived from these common animals being infected or contaminated with pathogens is higher than for some other products for human consumption. Although intended for human consumption, some of these products may be diverted to use in animal feeds, with a resulting increase in the likelihood of exposure. However, flavours are more likely to be diverted to use in pet food (for dogs and cats) than stockfeed, so 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 diseases of livestock species.

A search of ICON records shows that there are two Permit Conditions (PC0672 and PC0673 — see APPENDIX 6), which have very similar statements included, relating to the ingredients and the processing of meat based flavours. One of these conditions requires an MD, while the other requires a government certificate. The requirement for an MD applies only to meat based flavours that contain less than 5% meat. If the flavour contains greater than 5% meat then a government certificate is required.

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. While it is true that a lower proportion of meat in the raw materials is less likely to contain an infectious dose of a disease agent, the 5% level is largely arbitrary and unrelated to any known scientific analysis. For a product with less than 5% meat, an MD attesting to the heat treatment is considered sufficient, while for the 'riskier' product with greater than 5% meat, a government certificate is required.

However, the logic of this reasoning is doubtful. As stated above, the 5% level is arbitrary and it is difficult to accept that at product containing 4.9% meat is safe, while a similar product containing 5.1% meat is not. This distinction is even harder to accept once we consider that the difference between these two products hinges upon the statement of the manufacturer, who stands to save the cost of official government certification if he declares his product to have the smaller percentage of meat in its raw materials. This is further complicated by the difficulty of verifying the percentage of meat in the raw material of what is a highly processed product, especially where the basis for the percentage calculations is not clearly set out.

Recommendation 12. It is recommended that, in all cases where an arbitrary percentage figure is used to justify different biosecurity treatments, (such as the 10% rule for dairy products and the 5% rule for meat based flavours), the conditions be reviewed to ensure that they remain appropriate.

Recommendation 13. It is recommended that consideration be given to requiring official government certification or other independent verification, of the percentage of meat in all meat based flavours, including those with less than 5% meat ingredients. This should apply equally to other products (such as dairy and egg products) where percentage composition limits are used to apply different biosecurity requirements (Strategy 1).

Therapeutic goods

Human therapeutics

Human therapeutics are considered to be low risk, with a ranking of 1.6 out of 5 (see APPENDIX 1). This will be due to the relatively low likelihood of exposure to susceptible Australian animals. Some people may treat domestic animals with supplements or other therapeutics however, resulting in these products being slightly more risky than food products

imported for human consumption. A number of extracts of conditions for products falling into this broad category have been provided below.

Herbal tea containing Ganoderma

An extract from the import requirements for this product follows:

2. Each consignment must be accompanied by a manufacturer's declaration, stating:

The Ganoderma extract was obtained by extraction in 75% ethanol, at 18°C at 1MPa for 30 minutes, then dried at 50°C for 45 minutes.

The alcohol extraction process as described is likely to inactivate the range of possible organisms of quarantine concern that may be present in this product. However, the statements in relation to this processing cannot be verified easily at the border, so the biosecurity safety of this product is, so far as it is affected by the processing, solely dependent on the accuracy of the declaration. False declarations may reduce the level of safety of the products. In the absence of structured audit protocols, it is impossible to estimate the rate of false declaration that may result in elevated risk.

Other products

Import conditions for salmon oil and green lipped mussel powder in bulk (extracts below) include requirements for an MD attesting to the origin of the materials involved in the manufacture of the product.

Salmon oil

Each consignment must be accompanied by a manufacturer's declaration, stating:

- the only ingredient of animal origin is fish oil derived from «Common Name/Species».

Green lipped mussel powder – bulk

2. Each consignment must be accompanied by a manufacturer's declaration, stating:

a) The only ingredient of animal, microbial or plant origin contained in this product is green lipped mussel from New Zealand.

Both of these sets of conditions require the manufacturer to make a declaration relating to the origins of the ingredients contained in the product. Obviously, this can have a bearing on the level of biosecurity risk associated with the product. Also, in both cases, it is difficult for any test to verify the contents of the declaration, so the declaration is likely to be accepted at face value.

Recommendation 14. It is recommended that import conditions all human therapeutic products be reviewed to ensure that they remain relevant. For some such products, which present very low risk, current requirements for MDs may be removed (Strategy 5) Where requirements remain necessary to ensure biosecurity safety, consideration should be given to requiring further supporting evidence in addition to the MD (Strategy 1, 2 or 3). However, due to the relatively low biosecurity risk associated with these products, this is not considered to be a high priority.

Veterinary therapeutics

Referring to the assessment at APPENDIX 1, veterinary therapeutics as a group are considered to be the highest risk biological products imported into Australia, with a score of 4.9. This high rating is derived as a result of their potential for contamination with infective material during production, storage and transport in the exporting country, and their direct exposure pathway to potentially susceptible animals. However, there is a broad spectrum of biosecurity risk for these commodities based on ingredients used in manufacture, manufacturing processes and regulatory oversight in the country of manufacture.

This broad group contains highly purified, fermentation derived, semi-synthetic compounds with no animal based inputs, such as antibiotics or mectins, which are considered to be relatively safe.

Advice received from BIP is that current work instructions divide the conditions applied to veterinary therapeutics into one of two categories:

- Products containing highly processed or low risk animal material, into a low risk target species which are imported accompanied by a manufacturer's declaration; and
- Products containing higher risk animal material which are accompanied by official government certification.

An example of the type of MDs required for a veterinary therapeutic product is reproduced at APPENDIX 7. As with a number of other groups of biological products, statements included in the MD are critical to the biosecurity safety of these products. The manufacturer is required to state that there are no ingredients of animal or microbial origin involved in the manufacture of the product, (or in some other similar cases to describe the nature of all ingredients of animal or microbial origin), and that the final product is highly purified and does not contain any residual fermentation product other than the highly purified end product.

These statements, if true, will provide a high level of confidence that the product is safe from a biosecurity perspective. Like many of the other examples of MDs quoted earlier, these statements are difficult, if not impossible, to verify at the border, and there is no formal requirement for testing to verify the statements contained in MDs for these products.

However, in the case of veterinary therapeutics there are a large number of other conditions that must be satisfied before the permit is granted. All veterinary therapeutics used in Australia are subject to registration requirements imposed by the Australian Pesticides and Veterinary Medicines Authority (APVMA). APVMA requires that manufacturers of these products comply with a code of Good Manufacturing Practice (GMP), and many are directly audited by APVMA auditors. Manufacture in a facility compliant with APVMA GMP standards provides some additional assurances to DAFF that there are quality systems supporting production processes i.e. there are controls in place to ensure that what is being documented as being manufactured, is actually being manufactured. In addition, these products must meet various other requirements such as those in the European Pharmacopeia, or in the US CFR.

These other requirements mean that this group of products, which contains some intrinsically high risk products, is generally well managed. However, there appears to be scope to improve biosecurity requiring some further evidence of the veracity of statements made in MDs. This could be by requiring audits of production facilities, or by requiring government endorsed MDs at the time of permit assessment. There would also appear to be scope to further sub-divide the group to allow for reduced resource expenditure on highly purified, semi-synthetic products that are considered to be low risk.

Recommendation 15. It is recommended that consideration be given to further sub-dividing the broad category of veterinary therapeutics to allow for reduced scrutiny of products considered to be low risk.

Recommendation 16. It is recommended that consideration be given to requiring further confirmatory evidence of the statements made in MDS for products that are rated as medium risk. This could take the form of a requirement for government endorsed MDs at the time of permit assessment, or third party audit of manufacturing facilities prior to granting of import permits (Strategy 2 or 3).

Laboratory material (excluding microorganisms)

This group of biological materials was rated as being of low to moderate biosecurity risk (rated 2 out of a possible 5; APPENDIX 1). Although these products do not normally contain microorganisms, this rating arises from the fact that they may be contaminated with microorganisms, and may be used (deliberately or inadvertently) in laboratory experiments involving live animals, so there is a low probability of exposure to susceptible Australian animals. Conditions placed on the import of these materials are designed to minimise the likelihood of contamination with microorganisms, and also to minimise the likelihood of exposure to susceptible animals by limiting the end-use of the material to *in vitro* uses only. The incorrect and unauthorised use of these materials for *in vivo* purposes is not considered further here, but is being addressed in Part 3 of this project

Manufacturer's declaration requirements for a number of types of laboratory materials (diagnostic kits, cell culture supernatant, and genetic material) are shown below. These conditions all contain similar requirements. Essentially the manufacturer is required to state that the products do not contain viable biological material capable of replicating.

Diagnostic kits

2. Each consignment must be accompanied by a manufacturer's declaration, stating:

The product does not contain any live or whole inactivated viruses, bacteria or any other microorganisms.

Cell culture supernatant

2. Each consignment must be accompanied by a manufacturer's declaration, stating:

The cell culture supernatant fluid does not contain viruses, bacteria or any other microorganisms

Genetic material

(Purified DNA/cDNA or RNA from microorganisms excluding those listed in PCt0965)

2. Each consignment must be accompanied by a manufacturer's declaration, stating:

a) The genetic material has been highly purified and is unable to replicate.

As was the case with many of the products reviewed, the accuracy of these declarations is critical to the biosecurity safety of these products, but is difficult if not impossible to verify on inspection. Appropriate sampling and laboratory testing could be used as a check procedure, but it is unlikely that this would be routinely undertaken for reasons of high cost and insufficient laboratory capacity. Since these products are considered to be relatively low risk, it may be appropriate to employ a combination strategy as outlined on page 22, to provide increased confidence in the veracity of statements made in relation to the manufacture of the products, while reducing the administrative burden on a consignment by consignment basis.

Recommendation 17. It is recommended that consideration be given to requiring further supporting evidence in addition to the MD in relation to all laboratory materials. This could be achieved by implementing a combination strategy (Strategy 5).

Microorganisms

Microorganisms as a group are considered as moderate, scoring 3 out of a possible 5 (see APPENDIX 1). Clearly, the risk level varies from species to species, with some organisms presenting little if any risk and others far more risk. In addition, the risk varies with intended end use, with *in vivo* uses representing far greater risk than *in vitro* uses.

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.

At the other extreme, a pathogen such as Influenza A virus represents a very high risk as it is a potentially serious pathogen of poultry as well as a potential cause of pandemic influenza in humans. When being imported as a potential vaccine strain, as is the case in the example conditions set out below, with the added risk factor of an end use involving direct injection into potentially susceptible hosts, this clearly represents a very high risk.

Import conditions for influenza A virus for vaccine production are attached at APPENDIX 8. The conditions include a requirement for an MD relating to:

- the suitability of the virus for use in vaccine production;
- the methods used to attenuate the virus; and
- subsequent testing to confirm the attenuation.

It can be seen that the matters which are addressed in the MD are critical to the biosecurity safety of this virus. In this case, however, the MD is not the only guarantee that biosecurity conditions have been met. The DAFF "Policy for the importation of microorganisms for *in vitro* use" (Department of Agriculture Fisheries and Forestry) 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. Where necessary, DAFF will consult with other agencies to ensure that human health concerns are addressed. Permits are issued only to restricted laboratories or laboratories with appropriate containment facilities such as the Australian Animal Health Laboratory (AAHL) and only from selected known and respected sources. End use conditions are in place and strictly enforced, so that these organism are only able to be used for *in vitro* studies in secure laboratories.

In this case, the MD is an extra layer of biosecurity added to the already strict controls placed on the import of potentially pathogenic organisms, and this use is acceptable.

Culture media

Culture media are considered as being above average risk, scoring 4.2 out of a possible 5 when rated by senior biosecurity officers (see APPENDIX 1). This high risk rating derives from the fact that culture media are often made from animal or plant materials, are used in the manufacture of vaccines and other therapeutic goods for administration direct to animals, and are also used in laboratory settings where they, or products produced from them, may be exposed to live animals. However, the range of materials that are included under this broad grouping is very wide, with a resulting wide range in risk when considered on a case by case basis.

Examination of conditions for import of various culture media (for example, PC0586, PC0591, PC0588, and PC0587. See APPENDIX 9) reveals that a consistent requirement is for an MD detailing the animal derived materials used in the production of the product. Information required includes the nature of the ingredient, the species of animal from which it is derived, and the country of origin. These matters are obviously highly relevant to the level of risk posed by the product. The conditions then require further animal health information relevant to the raw materials to be provided by the competent authority of the exporting country, via a government veterinary certificate. This procedure will provide appropriate biosecurity confidence provided that all relevant raw materials are identified in the MD. However, if the MD is not accurate, significant animal health information may be over looked.

Other conditions for this type of product contain similar requirements for an MD, with additional statements required. For example, PC0591 contains very similar requirements, but in addition the Manufacturer is required to state that there have been no changes to the sourcing and processing of raw materials since the information was supplied to DAFF at the time of permit application. This statement is impossible to verify at the time of inspection, and some further evidence should be required. government certification of the processing, or auditing of manufacturing plants, would assist.

Recommendation 18. It is recommended that consideration be given to

a) requiring government certification of the sourcing and processing of raw materials used in the production of culture media (Strategy 1); or

b) requiring further supporting evidence of compliance with permit conditions, in addition to the MD (Strategy 2 or 3).

Further, PC0588 requires the Manufacturer to state that the manufacturer continues to adhere to Good Manufacturing Practices (GMP) and/or continues to be certified under ISO9000 standards relating to quality systems. Once again, these statements are very difficult to verify at import inspection. However, it should not be difficult for a manufacturer which meets these conditions to provide further documentary evidence of its status. This could be done by government certification or by provision of copies of GMP certificates at the point of the assessment of the import application.

Recommendation 19. It is recommended that consideration be given to requiring further evidence of continued compliance with GMP or ISO9000 standards.

PC0587 (APPENDIX 9) requires that the MD must confirm that the culture media does not contain bovine material from countries which have recorded cases of bovine spongiform encephalopathy, and that the any ovine or caprine materials included in the product are from Australia or New Zealand only. If the sourcing of raw materials was to be included in a government certificate as suggested at Recommendation 18, this requirement could also be covered in that certificate and the need for the Manufacturer to declare this aspect would be removed.

Finally, in relation to culture media, there is a requirement in some cases (e.g. PC0591**)** for an MD to state that:

1. Each consignment must be accompanied by a manufacturer's declaration, stating that the product contains less than 20g or 20mL of animal derived material.

From discussion with senior officers from Animal Biosecurity, it appears that the rationale behind requirements limiting the amount of material that can be imported is that it makes it less likely that the product will be used for *in vivo* purposes, and also that it limits the likelihood of bulk quantities of product being imported, and subsequently repackaged and on-sold to other end users who may then not comply with end use requirements. This type of requirement is one which is easily confirmed at border inspection. It seems that the requirement for an MD attesting to this packaging requirement may be an attempt to enable clearance of shipments on documentation only, without resorting to resource intensive (and therefore costly) inspections. While this is an appropriate path to take, it should be backed up by an on-going, random inspection and verification program.

Recommendation 20. It is recommended that consideration be given to formalising a program of random inspection and verification of packaging requirements which are currently covered by an MD (Strategy 4).

Animal feeds

Pet food

Pet food is considered to be high risk, with a score of 4 against a maximum possible score of 5 (APPENDIX 1). This high risk is associated with the fact that raw materials used in the manufacture of pet foods are often derived from ruminant sources, and therefore can potentially contain major livestock pathogens. There is also a direct exposure pathway to Australian animals after importation. Pet foods are considered to represent a somewhat lower level of biosecurity risk than are stock feeds due to the fact that these products are designed to be fed (largely) to dogs and cats (carnivores) and are therefore less likely to be diverted to stock feed use. This reduces the likelihood of exposure to susceptible Australian animals, and therefore decreases the likelihood of an outbreak of disease as a result of importation of such pet foods. However, due to the ingredients often contained in pet foods, a significant biosecurity risk remains. In addition to the direct feeding of pet food to animals there is also potential for accidental exposure to wild animals (mainly birds) which can access food left out for pets.

The primary reference to MDs in relation to pet food occurs in the *Quarantine Proclamation 1998* (Australian Government, 2012) itself. It is also of interest that this is the ONLY reference to MDs in the *Quarantine Proclamation.* Paragraph 38 of the Proclamation allows the importation of rawhide chews without a permit, if accompanied by an MD stating that the product has been soaked in a lime solution of pH 14 for not less than 8 hours. There is no checking of validity of the MD required except for assessment of the product on arrival. This border assessment is not applicable to 'composite' chews which are unable to be assessed by the method approved for other types of product. If correctly applied, the treatment by soaking in lime solution will adequately manage risks associated with this product, but there is little ability to accurately determine whether the declaration is accurate. This situation is exacerbated by the fact that the majority of dog chews are imported from countries which have, in the past, been implicated in terms of false MDs.

Recommendation 21. It is recommended that consideration be given to removing the reference to MDs from the Quarantine Proclamation 1998.

Recommendation 22. It is further recommended that subsequent to Recommendation 20, that the requirement for soaking in lime solutions for raw hide chews be certified by government certificate or government endorsed MD (Strategy 1 or 2)

Moving beyond this reference to MDs in the Proclamation, there are a number of different sets of import conditions which have been used for import of different types of pet foods from different countries. Some are outlined below (APPENDIX 10).

In each case, important aspects of the risk management measures applied to these products, such as the processing times and temperatures, are the subject of an MD. Also in each case, the government veterinary certificate that accompanies the shipments must state '*that the veterinarian has examined the manufacturer's declaration and has no reason to doubt the truth of any particular in that declaration*.' The level of biosecurity confidence that can be

placed on this combination of MD and government certification depends on the level of scrutiny undertaken by the official veterinarian prior to signing this statement.

As part of the assessment of import permit applications for pet food products from countries other than the USA, Canada and New Zealand, all new import permit applications for pet food require desk audits to be undertaken, for which the manufacturer supplies information about their QA system. Manufacturers are required to provide information about training, heat treatment, traceability, sanitation and hygiene, document control etc.

Once the information provided for the desk audit has been assessed and found to be satisfactory, then site audits of the manufacturing facilities are performed to verify the information. In cases where the final manufacturing facility does not apply the required 100°C for 30 minutes heat treatment, but this is done by suppliers, audits of the supplier's facilities are conducted as well. For the USA and Canada, DAFF relies on competent authorities in the exporting country to do the audits on its behalf.

Once desk and site audits are done and found to be satisfactory, an import permit is issued. After this, there is a program of site audits every 4 years and desk audits every 2 years. Under the current system, import permits are valid for two years so this desk audit would occur at the time of application for a new permit. As a last resort, gamma irradiation at 50 kGrays, carried out by an approved operator in Australia, has been used as an alternative to the audits. However, there have been potential toxicity issues arising from the irradiation of pet food, and strict labelling requirements are applied where irradiation is used.

Overall, this system appears to be managing risk appropriately.

Aquaculture feed

The import conditions for plant based stock feeds, and the processes for assessing permit applications for these products, were discussed earlier in the case studies section of this report (see page 17). These products provide an example of an appropriate use of MDs, appropriately backed up by desk- and/or on-site audits, and other procedures. However, conditions for a particular plant based aquaculture feed (so far as they are relevant to the discussion of MDs) are detailed at APPENDIX 11. This set of conditions raises some questions.

The conditions require an MD addressing such matters as:

- the nature of the raw materials, including the highly processed nature of any plant based materials, and the lack of seeds or other viable plant materials;
- the absence of animal based materials, either in the formulation, or in the production plant;
- clean and new packaging; and
- protection from post processing contamination.

These statements address both animal and plant biosecurity concerns. As stated above, these plant based stock feeds are appropriately addressed under the current system, where MDs are backed up by auditing procedures prior to permit approval.

However, this particular set of conditions requires that, if inspection reveals that the packaging requirements have not been met, there is a requirement to test for ruminant DNA. This raises the question, why is this investigation not done, when the packaging requirements are met? There does not seem to be a causal relationship between packaging and the presence or absence of ruminant DNA in the product. While not directly relevant to the subject of MDs, this question should be clarified. It has been suggested that this requirement relates to the possibility of cross contamination from second hand packaging.

Recommendation 23. It is recommended that the requirement to test to establish the presence or absence of ruminant DNA only when packaging requirements are not met be reviewed.

Stock and pet food supplements, synthetic and mineral

Synthetic or mineral based stock feed supplements should be of much lower risk than animal or plant based stock feeds. However, the ICON entry for this class of products raises some interesting points. A copy of the ICON requirements for this class of products is also included at APPENDIX 12. ICON states that no import permit or quarantine entry is required for these products, but goes on to say that the importer must

"supply sufficient documentation to satisfy the quarantine officer that the product does not contain components of biological origin. Documentation may need to include a manufacturer's declaration, stating that:

a) The product is 100% synthetic or mineral in nature; or

b) The product is not derived from animals, plants or microorganisms."

If no permit or quarantine entry is required, there will be no routine inspection of these products or their accompanying documents. It appears that the requirement for an MD is a 'just in case' requirement which, in practice, will be rarely used. This leads to a situation where a product which is to be included as food for livestock, and as a result has a direct pathway of exposure to susceptible Australian animals, can be allowed entry with very little scrutiny, based solely on a declaration from the manufacturer. While product which fully complied with the statements required would be safe, there is scope for significant adverse consequences if the statements in the MD were false. If such products represent a real risk, then the use of an MD in the absence of a permit or quarantine entry is insufficient to provide appropriate biosecurity confidence. If not, then requirement for an MD is superfluous and should be deleted.

Recommendation 24. It is recommended that the risks associated with synthetic stock feed supplements be reviewed and if considered warranted, consideration be given to requiring further supporting evidence in addition to the MD for all synthetic and /or mineral stock feed supplements (Strategy 1, 2 or 3).

Bioremediation products

Bioremediation products are considered as being high risk, scoring 3.9 out of a possible 5 when rated by senior biosecurity officers (see APPENDIX 1). This high rating arises from the fact that these products are, by their nature, viable organisms, and that they are intended to be released directly into the environment, and therefore there is a relatively high likelihood of exposure to susceptible animals. Often the mode of operation of these agents is not fully understood and there is a possibility of unexpected adverse outcomes.

An extract from the import conditions for a bioremediation product is attached at APPENDIX 13.

As with many of the MDs discussed previously, the contents of this declaration are very difficult to verify at inspection. If it is false, there is no way to easily determine that this is the case, by inspection. This is another example where the easiest way to verify information provided in the MD is to implement a program of audits of the manufacturing process.

Recommendation 25. It is recommended that consideration be given to

a) requiring government certification of the matters currently required in the MD for bioremediation agents (Strategy 1); or

b) requiring further supporting evidence of compliance with permit conditions, in addition to the MD (Strategy 2 or 3).

Fertilisers

Referring to the assessment at APPENDIX 1, fertilisers are considered to be high risk, with a score of 4.1 against a maximum possible score of 5. This high risk arises from the nature of the materials which can be used for fertiliser, including but not limited to animal waste products (manures) and rendered materials such as blood and bone meal, both of which are likely to be contaminated with animal pathogens, either through the use of material from diseased animals, or as a result of post processing contamination. In addition, fertilisers have a direct pathway to the environment, and thus potentially to susceptible Australian animals. However, there is a broad range of other material which are far less risky. For example, artificial, chemically manufactured fertilisers, and some mined raw materials, should be much less likely to contain animal pathogens.

The ICON database contains 2 sets of conditions for such mined or artificial fertilisers are set out below. The first (Condition C10035) is for "Fertilisers - Mined & chemical including rock phosphate - Bags less than or equal to 100kg" while the second relates to "Fertilisers - Mined & chemical including rock phosphate - Bags greater than 100kg/loose in container". Extracts from these two sets of conditions (so far as is relevant to the discussion) are set out at APPENDIX 14.

Examination of these two sets of conditions reveals that the difference in biosecurity treatment arises only from the nature of the packaging. The description of the raw material in both cases is the same. However, where the material is packed into bags of less than 100 kg

in weight, no import permit is required. An MD stating that the product '*was not stockpiled outside and has been packed at the place of production in new packaging in units of 100kg or less*' is required. Where both of these statements are made '*AQIS will refer a percentage of consignments meeting the above conditions for inspection at a quarantine approved premises to verify the consignment is free of quarantine risk material. This inspection will be charged at standard AQIS fee for service rates.'*

However, if the product is in units greater than 100kgs, or is containerised in bulk, an import permit is required, and all consignments are inspected. These conditions seem to be inconsistent, in that the inherent risk posed by the product is unlikely to be reduced by packaging in smaller bags. Indeed this could provide unscrupulous importers an opportunity to reduce inspections costs simply by packing the material in smaller packages. This in itself incurs a cost, but the relative cost difference will depend largely on the percentage of consignments which are subject to random inspection.

A further complication arises from the fact that one of the statements in the MD (that the product '*was not stockpiled outside and has been packed at the place of production'*) is unverifiable by inspection at the point of unloading.

These conditions appear to provide further examples of inconsistent treatment of essentially similar risks, and of relying on MDs where there is little if any opportunity to independently verify the accuracy of the declaration. There is also some doubt as to what percentage of consignments is actually inspected, and how the random samples are obtained.

Conditions for 'Fertilisers - Mined & chemical – Liquid' are similar in that there is a requirement for an MD as shown below.

'Each consignment must be accompanied by a manufacturer's declaration, stating: 'the liquid fertiliser contains no ingredients of animal, plant or microbial origin'.'

However, in this case there appears to be no requirement for random inspections of even a percentage of the consignments, provided that the documentation appears to be correct. No import permit is required, and if the documentation appears correct, the consignments will be cleared on presentation of documents. For a commodity which is accepted as being high risk material, and which has recently been found to be non-compliant with the existing conditions, this seems a very lax approach.

Recommendation 26. It is recommended that consideration be given to

a) requiring government certification of the matters currently required in the MD for fertilisers (Strategy 1); or

b) requiring further supporting evidence of compliance with permit conditions, in addition to the MD (Strategy 2 or 3).

Recommended framework for the future application of manufacturer's declarations.

The above discussions have highlighted some instances where manufacturer's declarations have been used inappropriately, and made recommendations to correct the situation in the particular cases studied. From these discussions, it has been possible to formulate a generic approach to the use of manufacturer's declarations which should ensure that problems such as those highlighted in this report do not arise again in future. In developing this framework, the primary importance of managing biosecurity risk is acknowledged, while recognising the secondary objective of facilitating trade.

When considering the use of manufacturer's declarations, DAFF staff should first consider the level of risk presented by the product being considered for importation. This consideration should take into account the nature of any raw materials included in the product, the source of those raw materials, any processing which is involved in the manufacture of the product, the intended end use of the product, the packaging (whether in bulk or in consumer ready form), and the likelihood of alternative end uses which could result in direct exposure to animals.

Once the level of risk has been assessed, appropriate risk management measures should be considered. Risk management measures may include such requirements as restrictions on the nature of raw materials, or on the sourcing of such raw materials, requirements for particular processing during the manufacture of the product, particular storage and transport requirements, specific packaging requirements, post arrival quarantine treatments such as irradiation or disinfection, or other options. In many cases, appropriate biosecurity confidence will only be achieved by the application of a combination of two or more of the above options. In cases where a combination of risk management measures is required to effectively manage risk, it is likely (although not in every case) that one of the risk management measures will make a major contribution to the risk management, while the other measures will provide additional confidence. In each case, the contribution of the individual measure to the total of biosecurity confidence should be assessed.

Once this assessment has been made the appropriate strategy from those listed above (see page 20) should be applied. The greater the contribution of an individual risk management measure to the overall risk management relating to a product, the stricter should be the burden of evidence to support that measure.

Assuming that DAFF has applied the internationally accepted guidelines for assessment of the competent authorities in exporting countries, and has accepted that appropriate standards have been met, the greatest confidence is likely to be provided by official government to government certification. In cases where a particular risk management measures is being relied upon to provide significant risk reduction, government certification provided by an approved competent authority in accordance with Strategy 1 outlined above (Page 20) should be the default requirement.

If it is determined that government certification is not required, but that a manufacturer's declaration can be accepted, methods of ensuring that the matters attested to in the declaration are correct will be required.

Strategy 2 (page 21) which involves government endorsement of manufacturer's declaration would provide a high level of confidence, provided that the basis on which the endorsement was provided had been determined to be sound.

Similarly, Strategy 3 (page 21) involving auditing of production facilities provides good confidence that the matters contained in a manufacturers' declaration can be accepted as correct.

The application of some of the necessary risk management measures will be able to be readily verified by inspection, while others will not be so readily obvious. Where inspection can be used to verify the accuracy of manufacturer's declarations, and this is considered to be an appropriate risk management approach, formal inspection regimes should be implemented. These may involve a sliding scale of inspections where good performance over a number of shipments results in a lowered rate of inspections (see Strategy 4, page 21).

Of course, the option to implement a combined strategy (Strategy 5, page 22) is always open and should be considered where extra security is considered necessary.

Where none of the above strategies is considered to be necessary, removal of the requirement for manufacturer's to provide declarations which are ultimately unhelpful will free up resources to concentrate on more important matters (Strategy 6, page 23)

Finally, while not directly relating to the use of manufacturer's declarations *per se*, the implementation of improved end use restrictions on some products would decrease the likelihood of inappropriate exposure of imported products to susceptible Australian animals and would therefore improve biosecurity confidence (Strategy 7, page 23).

The legal difficulties of enforcing end use controls have been a source of concern for BIP and its predecessors for many years. Significant resources have been expended trying to find a solution to this difficulty. Current proposals to revise the Biosecurity legislation may provide opportunities to overcome this difficulty.

Recommendation 27. It is recommended that DAFF investigate the opportunities provided by the review of the Biosecurity legislation to improve end use controls on biological products.

Recommendation 28. It is recommended that BIP formalise the above framework for determining whether manufacturer's declarations should be applied in a particular case, and if so with what level of supporting evidence should be required.

Appendices

APPENDIX 1. Risk estimate by Senior BIP officers of commodities in the program (Range from 1 to 5: 1 is lowest risk, 5 is highest likely risk)

Commodity	Rating	Comments
Bird's 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. Extracts from various conditions for the import of products containing dairy

Commercial

1. An Import Permit is required for dairy products that do not fit any of the descriptions below, and must be applied for prior to importation. Permit applications must be sent to AQIS Canberra office for assessment.

Please note: An Import Permit may only be issued for un-canned/un-retorted dairy products that are sourced and manufactured in a country specified on the DAFF FMD Approved Country List and intended for human consumption. Approved country information can be found under the following ICON case Dairy products (excluding cheese) from Foot and Mouth Disease (FMD) Approved Country List. Canned/retorted dairy products may be imported from all countries subject to compliance with relevant biosecurity requirements which will be determined during the permit application process.

2. An Import Permit is not required for the following commercial consignments, from any country of origin:

a) Goods of which each individually packaged unit contains less than 10% by dry weight (other than any added water) of a dairy product, and are accompanied by a valid Manufacturers Declaration - stating that the goods "contain less than 10% dairy by dry weight for each individually packaged unit";

PC1730

CERTIFICATION/DECLARATION REQUIREMENTS

2. Each consignment must be accompanied by official government veterinary certification from the country of export 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 a country recognised by the World Organization for Animal Health (OIE) as free from foot and mouth disease, with or 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 foot and mouth disease-free country, with or 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) i) the milk or the milk from which the dairy product was made originated from a country/zone which meets OIE requirements for freedom from:

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

OR

ii) The milk or the milk from which the dairy product was made was subjected to one of the following heat treatments:

- 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) ii) will be accepted if on a consignment specific manufacturer's declaration endorsed by the Official Veterinarian of the exporting country.

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

The Government veterinarian endorsed manufacturer's declaration must be from «name of manufacturer»

PC0613

DECLARATION REQUIREMENTS

2. Each consignment must be accompanied by a manufacturer's declaration, stating either:

a) The product contains less than 10% egg ingredient by dry weight and the product contains no discernible pieces of egg;

OR

b) The product does not contain egg or egg derived ingredients.

The Manufacturer's Declaration must be:
.from «name of manufacturer»

PC5676

1. Consignments of product sourced from the United Kingdom may be imported provided the date of manufacture is either:

a) prior to 1 July 2007; or

b) on or after 19 February 2008.

2. Product produced on or after 1 July 2007 and prior to 19 February 2008 will not be permitted entry using this Import Permit.

Documentation Requirements

3. In order to facilitate clearance, consignments should be accompanied by a consignment specific **Manufacturer's Declaration** indicating:

a) the date of manufacture of the product; and

b) referring to each batch or lot number of the product in the consignment.

Note: For cheese, the date of manufacture is the date the curd was set.

Inspection Requirements

4. Consignments not accompanied by documentation, or covered by invalid documentation, may be inspected to verify the date of manufacture as stamped on the packaging or immediate container.

5. Consignments with valid documentation, or those which have been verified upon inspection, may be released provided that:

a) the date of manufacture for the product is confirmed as either:

i) prior to 1 July 2007; or

ii) on or after 19 February 2008.

b) all other conditions for the product as specified on this Import Permit have been met.

APPENDIX 3. Conditions for the import of plant based stock feeds

QUARANTINE REQUIREMENTS FOR THE IMPORTATION INTO AUSTRALIA OF PROCESSED STOCKFEEDS AND STOCKFEED INGREDIENTS OF PLANT ORIGIN

MANUFACTURER'S DECLARATION

3.1 Each consignment must be accompanied by a declaration signed by the manager of the plant which processed the stockfeed or stockfeed ingredient specifying the date(s) on which each ingredient was processed to meet the Australian requirements, and declaring that:

3.1.1 the raw material was inspected prior to processing and was free from obvious faecal contamination and from feathers, dead birds or rodents,

3.1.2 all product was processed by heating to at least .... (temperature in °C) for at least ..... (time in minutes) as specified in the Permit to Import No. .....,

3.1.3 where product is stored and/or transported in bags, such bags are previously clean and new,

3.1.4 the product contains no meat meal or meat and bone meal, or other material derived from animals or birds,

3.1.5 the product has been protected from post-processing contamination by animals or birds,

3.1.6 the processing plant, its products and records are available, upon request, to the certifying authority and/or AQIS for the purposes of confirming compliance with import conditions,

3.1.7 the product contains no whole seeds.

4 OFFICIAL CERTIFICATION

4.1 Each consignment must be accompanied by a certificate signed by an authorised official of the certifying authority of the country of origin and export, certifying that:

4.1.1 the processing plant in which the material was processed complies with all relevant government requirements,

4.1.2 after due enquiry, he/she is satisfied that all product of the class being exported to Australia is heat treated according to the requirements specified in the Permit to Import, and that he/she has no reason to doubt all other statements made in the manufacturer's declaration (clauses 3.1.1 to 3.1.7),

4.1.3 the processing plant was inspected by an official of the certifying authority during processing of product destined for Australia on ..... (date, which must not be

more than 12 months prior to the date of export), and on the basis of that inspection, he/she is satisfied that there is no opportunity for livestock and birds to contaminate the product during or after processing, and,

4.1.4 transmission of animal disease has not been reported to be associated with product of the processing plant in the previous 12 months.

QUARANTINE REQUIREMENTS FOR THE IMPORTATION INTO AUSTRALIA OF TAPIOCA PELLETS FROM THAILAND

2 MANUFACTURER'S DECLARATION

2.1 Each consignment must be accompanied by a declaration signed by the manager of the plant which manufactured the tapioca pellets stating:

2.1.1 the date(s) on which the pellets were processed and heat treated to meet the Australian requirements.

2.1.2 that the manufacturing plant maintains a permanent record of the heat treatment used to process tapioca pellets.

2.1.3 that the heat treatment records accompanying the consignment relate to the processing of the pellets in the consignment.

3 HEALTH CERTIFICATION

3.1 Each consignment must be accompanied by a certificate signed by a full-time employee of the Office of Commodity Standards, Thai Department of Foreign Trade, or the Sociétie Générale de Surveillance (SGS) Thailand, stating that:

3.1.1 the tapioca pellets originate from a plant approved by AQIS.

3.1.2 the plant in which the tapioca pellets were processed and stored is registered with the Thai Industrial Standard Institute and meets its quality control specifications.

3.1.3 livestock have not had access to the pellets.

3.1.4 any surfaces with which the pellets have come in contact during processing and loading have been cleaned prior to use for the consignment of pellets destined for Australia.

3.1.5 the conveyances used to transport the pellets have been inspected and found to be clean and there is no evidence that they might have been used for the carriage of livestock.

3.1.6 after due enquiry, I have no reason to doubt the statements made in the manufacturer's declaration (clause 2).

3.1.7 a valid Permit to Import has been sighted.

3.2 Each consignment must be accompanied by a phytosanitary certificate signed by an officer of the agricultural regulatory division of the Ministry of Agriculture and Cooperatives certifying that the tapioca pellets had been fumigated in accordance with the requirements in Appendix 1.

3.3 Each consignment must be accompanied by a certificate signed by the ship's master stating that the ship used to transport the pellets to Australia has not carried livestock within the preceding 12 months.

APPENDIX 4. Relevant extracts from import conditions for bird's nest products

CERTIFICATION REQUIREMENTS

2. Each consignment must be accompanied by official Government certification or a Government endorsed manufacturer's declaration, stating that:

a) The final product has been retorted, and during the retorting process the product was heated to a minimum core temperature of 100^{o}C, obtaining an F_0 value of at least 2.8; and

b) The final product is in a hermetically sealed (airtight) container and has been retorted (treated under heat and pressure) within this container so that the final product is shelf stable and does not require refrigeration.

The Government 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.

The conditions also require inspection to verify compliance with import requirements, as follows:

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.

APPENDIX 5. Extracts from conditions for import of Egg noodles/pasta

PC0608

2. Each consignment must be accompanied by official Government certification or a Government endorsed manufacturer's declaration, stating:

a) the product contains not more than 20% egg content; and

b) the product is cooked by a process sufficient to raise the core temperature of the noodles to at least one of the following temperatures:

. 87°C for 2 minutes 30 seconds; or
. 75°C for 15 minutes; or
. 60°C for 5 hours; or
. 60°C for 30 minutes followed by 54°C for 5 hours; and

c) the product was packed in clean new containers, and not exposed to contamination before export.

PC0640

CERTIFICATION/DECLARATION REQUIREMENTS

2. Each consignment must be accompanied by a manufacturer's declaration which states:

a) the product contains less than 10% dairy ingredients by dry weight;

OR

b) the product does not contain dairy or dairy derived ingredients.

APPENDIX 6. Extracts from conditions for the import of meat based flavours

PC0672

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

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.

APPENDIX 7. Extract from Conditions for import of a veterinary therapeutic product

2. Each consignment must be accompanied by a manufacturer's declaration, stating:

a) Manufacture of (this product) includes a fermentation process; and
b) There are no ingredients of animal origin used at any stage of manufacture including the culture media used in fermentation; and
c) The final product has been highly purified so that it does not contain any residual fermentation material other than the highly purified end product.

APPENDIX 8. Extract from Conditions for import of influenza A virus for vaccine production

2. Each consignment must be accompanied by a manufacturer's declaration, stating:

a) The strains have been recommended and approved by the World Health Organisation (WHO) as attenuated influenza A (subtypes H2, H5, H7 and H9) candidate vaccine strains from human or avian origin; and
b) The candidate vaccine strains have been attenuated through genetic reassortment with the attenuated human PR8 strain or mouse adapted WSN strain; and
c) If present the polybasic cleavage site from the haemagglutinin gene has been removed and haemagglutinin genes sequenced verifying removal; and
d) Attenuation has been verified by tests recommended by WHO for attenuated candidate vaccine strains and performed by a WHO reference laboratory.'
AQIS does not permit the importation of strains of influenza virus which have not been attenuated in accordance with the procedures outlined above i.e. reverse genetics or conventional reassortment with PR8 or mouse adapted WSN and removal of the polybasic cleavage site from the haemagglutinin gene.

APPENDIX 9. Extract from conditions for import of culture media

PC0586

CERTIFICATION / DECLARATION REQUIREMENTS

2. Each shipment must be accompanied by a declaration from the manufacturer stating the culture media contains only the following animal derived ingredients sourced and processed as follows:

«media component, species and country of origin»

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.

3. Each consignment must be accompanied by official Government veterinary certification stating:

a) The species and country of origin for all animal derived ingredients; and

b) For abattoir sourced material, the product was derived from animals which received ante and post-mortem inspection and were found to be free of infectious or contagious diseases, or for donor herd sourced material, the material was derived from donor herds under veterinary supervision and clinically free from infectious or contagious diseases; and

c) That the country of origin (and the country of export if the country of origin of the raw materials is different from the country of export) of the animal derived materials contained in, or used in the manufacture of the product was free of the relevant diseases listed below:

For materials of bovine origin:
- foot and mouth disease
- rinderpest
- bovine spongiform encephalopathy (country of origin of raw materials only)

Note: Milk and milk products; protein free tallow; Di-Calicum Phosphate (DCP); hides and skins; and gelatin and collagen prepared from skins are not considered to be a BSE risk. Therefore, the BSE statement does not need to be made for these products.

For materials of porcine origin:
- foot and mouth disease
- swine vesicular disease
- African swine fever
- classical swine fever (hog cholera)

For materials of equine origin:
- African horse sickness

For materials of ovine and/or caprine origin:
- foot and mouth disease
- rinderpest
- peste des petits ruminants
- sheep pox/goat pox
- scrapie (country of origin of raw materials only).

4. Where consignments are not covered by valid documentation as detailed above, the consignment must be re-exported or destroyed at the importer's expense.

PC0591

The sourcing of raw ingredients and processing of materials for the products in this consignment have not changed since the information was provided to the Australian Quarantine and Inspection Service (AQIS) with the Import Permit application. The manufacturer will notify AQIS of any changes prior to shipment, if any of the sourcing or processing details alter from the original information supplied in the Import Permit application.

PC0588

b) the manufacturer continues to adhere to Good Manufacturing Practices (GMP) and/or continues to be certified under ISO9000 standards relating to quality systems.

PC0587

(a) The products containing material of animal origin have been subject to gamma irradiation at 50 kGy (5 Mrad); and

(b) The product contains no bovine material from countries that have recorded cases of bovine spongiform encephalopathy; and

(c) The product contains no ovine or caprine material from countries other than Australia or New Zealand.

3. If satisfactory documentation is not provided to address point 2(a) above, prior to release from quarantine the material must be subjected to gamma irradiation at 50 kGy (5 Mrad).

4. If satisfactory documentation is not provided to address points 2(b) or 2(c) above, the product must be re-exported or destroyed.

APPENDIX 10. Extracts from various Conditions for import of pet foods

CONDITIONS FOR THE IMPORTATION OF DRY PET FOOD FROM FRANCE

3 CERTIFICATION

Certificate(s) issued by an official veterinarian and a declaration by the manufacturer must accompany each consignment of product.

3.1 The declaration by the manufacturer must include the following information:

3.1.1 that the veterinary control number of the processing establishment and batch number(s) of the product to which the declaration applies are indelibly printed on each container;

3.1.2 the processing which the product has undergone;

3.1.3 that the processing in 3.1.2 and the packaging are approved by the Director of Quarantine (Australia);

3.1.4 that the product does not require refrigeration.

3.2 The veterinary certificate must include the following information:

3.2.1 Species of animal in each batch / product type;

3.2.2 that the animals from which the meat was derived were subjected to antemortem and post-mortem veterinary inspection and were found to be free from contagious or infectious disease;

3.2.3 that the raw materials from which the pet food was manufactured were low-risk materials in accordance with Articles 2, 5 and 17 of EU Directive 90/667/EEC;

3.2.4 that the veterinarian has examined the manufacturer's declaration and has no reason to doubt the truth of any particular in that declaration.

CONDITIONS FOR THE IMPORTATION OF DRY PET FOOD FROM THE USA

3. CERTIFICATION

a. A certificate(s), issued by a USDA veterinarian, and a declaration by the manufacturer, must accompany each consignment of meat.

b. The declaration by the manufacturer must include the following information:

i) that identification number / veterinary control number of the processing establishment and batch number(s) of the product to which the declaration applies are printed in indelible ink on each container;

ii) the processing which the product has undergone;

iii) that the processing in ii) and the packaging are approved by the Director of Anima1 and Plant Quarantine (Australia);

iv) that the product does not require refrigeration.

c. The veterinary certificate must include the following information:

i) species of animal in each batch / product type;

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

iii) that the veterinarian has examined the manufacturer's declaration and has no reason to doubt the truth of any particular in that declaration.

CONDITIONS FOR THE IMPORTATION OF CANNED PET MEAT FROM THE USA

3. CERTIFICATION

(a) A certificate(s), issued by a USDA veterinarian, and declaration by the manufacturer, must accompany each consignment of meat.

(b) The declaration by the manufacturer must include the following information:

(i) that identification number/veterinary control number of the processing establishment and batch number(s) of the product to which the declaration applies are embossed or stamped in indelible ink on each can or container.

(ii) in the course of manufacture, every portion of the contents of the batch of cans or containers to which this declaration applies has been heated to a temperature of 100 degrees Celsius

(iii) the temperature of the heat used for that purpose and the length of time for which it is maintained

(iv) that the meat does not require refrigeration while it remains canned.

(c) the veterinary certificate must include the following information:

(i) species of animal in each batch/product type

(ii) that the animals from which the canned meat was derived were subjected to ante-mortem and post-mortem veterinary inspection and were found to be free from contagious and infectious disease.

(iii) that the veterinarian has examined the manufacturer's declaration and has no reason to doubt the truth of any particular in that declaration.

APPENDIX 11. Extract from conditions for import of plant based aquaculture feed

These conditions allow for the importation of the following aquaculture additive packaged in clean, new packaging

Skretting mix XY6-18

NOTE : This product is not permitted for use as a feed for livestock or poultry.

4. The consignment must be accompanied by a signed Manufacturer's Declaration from:

Pancosma France SAS
ZI d'Arlod -, rue des Freres Lumiere 01200 Bllegarde sur Valserine
France

stating:

- The only ingredients of plant origin contained in this product are highly refined plant extracts and plant oils.
-That this product contains no whole seeds, or viable plant material.
-That this product contains no meat meal or meat and bone meal, or other material derived from animals or birds.
-The manufacturing facility does not store or use any animal proteins, fats or any substances of animal origin on site.
-That this product has been protected from post-processing contamination.
-That the product has been packaged in clean, new packaging on site at the production facility.

Quarantine Procedures

10. All consignments meeting the above conditions must be directed to a metropolitan Quarantine Approved Premises (QAP) or a storage facility within the wharf area for a partial unpack and inspection (or full unpack if required). The quantity to be unpacked is at the discretion of the Quarantine officer and should be sufficient to ascertain that the conditions of import have been met.

11. Each consignment must be inspected by the Quarantine officer to confirm:

a) product is packaged in clean and new packaging;
b) the product's packaging is in sound condition; and
c) freedom from live insects, soil, disease symptoms, prohibited seeds, other plant material (e.g. leaf, stem material, fruit pulp, pod material, etc.), animal material (e.g. animal faeces, feathers, etc.) and any other extraneous contamination of quarantine concern.

12. Consignments meeting the above conditions may be released from quarantine by the Quarantine officer.

13. If the product is not packaged in clean new packaging or the integrity of the packaging is found to be deficient, the consignment will require testing for ruminant DNA, in accordance with the following procedure:

APPENDIX 12. Conditions for the import of stock and pet feed supplements

QUARANTINE REQUIREMENTS FOR THE IMPORTATION INTO AUSTRALIA OF STOCK AND PET FOOD SUPPLEMENTS, SYNTHETIC AND MINERAL.

An Import Permit is not required.

A Quarantine Entry is not required.

The product must be clearly identified as synthetic. It is the importer's responsibility to provide sufficient documentation to satisfy the quarantine officer that the product does not contain components of biological origin. Documentation may need to include a manufacturer's declaration, stating that:

a) The product is 100% synthetic or mineral in nature; or
b) The product is not derived from animals, plants or microorganisms.

The manufacturer's declaration must comply with format requirements.

Where consignments are not covered by valid documentation or are covered by documentation with an incorrect statement, consignments will be subject to inspection to ensure that the product is 100% synthetic or mineral in nature. An inspection fee will apply. If an inspection does not aid in identifying the nature of the product, the Biologicals Program, AQIS Canberra office may be contacted by email, phone (02 6272 4578) or fax (02 6249 1798) to discuss further options.

APPENDIX 13. Extract from conditions for import of bioremediation agents

*2. Each consignment must be accompanied by a **manufacturer's declaration,** stating:*

a) The sourcing of raw materials, method of manufacture and any testing during processing has not altered since information was supplied to AQIS with the application; and
b) No new microorganisms, or new strains of the same microorganisms, have been added to the product since information was supplied to AQIS in support of the application; and
c) The final product does not contain ingredients derived from animals, nor were any animal derived ingredients used during the manufacture; and
d) The only material(s) of plant origin contained in the product are highly processed extracts, meals, powders and/or acids; and
e) The product contains no whole seeds or viable plant material; and
f) The product has been protected from post-processing contamination; and
g) The final product has been packaged in new and clean containers only.

APPENDIX 14. Extracts from the conditions for the import of fertiliser

Condition C10035

These conditions relate to manufactured chemical fertilisers and mined raw materials used in the making of fertilisers. For example, rock phosphate, sulphur and potash, soil conditioners, growth promotants, growth regulators, and any other growth enhancers that aid plant growth which do not contain organic, plant, animal or microbial materials.

If the fertiliser contains organic material refer to the ICON commodity, 'Fertilisers, soil conditioners and potting mixes of plant and microbial origin'.

If the fertiliser contains non-mineralised guano refer to the ICON commodity, 'Fertilisers, soil conditioners and potting mixes of terrestrial animal and avian origin,.

If the fertiliser is in greater than 100kg bags refer to the ICON commodity Fertilisers - Mined & chemical including rock phosphate-Bags greater than 100kg/loose in container.

Commercial

1. An Import Permit is not required.

2. Each consignment must be packed at the place of production, in new packaging, and in units of 100kg or less. The bulk mined or chemical product must not have been stockpiled outside in an open environment. NOTE: supporting evidence of this must be provided to your broker or shipping agent. Acceptable evidence includes a valid **manufacturer's declaration** stating that the consignment 'was not stockpiled outside and has been packed at the place of production in new packaging in units of 100kg or less'.

3. Each consignment must be free of live insects, seeds, soil, animal material, plant material and other quarantine risk material prior to arrival in Australia.

4. Containers, timber packing, pallets or dunnage will be subject to inspection and treatment on arrival, unless certified as having been treated by an AQIS approved method. (Refer to the AQIS publication 'Cargo Containers: Quarantine aspects and procedures').

5. AQIS will refer a percentage of consignments meeting the above conditions for inspection at a quarantine approved premises to verify the consignment is free of quarantine risk material. This inspection will be charged at standard AQIS fee for service rates.

6. All other consignments meeting the above conditions will be released.

7. Consignments that are found to contain bags greater than 100kg will be held pending the presentation of an Import Permit.

8. Consignments that are contaminated will be ordered into quarantine pending the determination of treatment options. If there are no treatment options available the consignment will be exported or destroyed.

9. All costs associated with inspection, treatment, export and/or destruction of the consignment are to be borne by the importer.

Condition C8823

Commercial

1. An Import Permit is required and must be valid at the time the goods are imported into Australia. Permit applications must be sent to AQIS Newcastle office for assessment:

AQIS Bulk Commodity National Coordination Centre (NCC), Newcastle
Quarantine Import Clearance
PO Box 69
Carrington, NSW 2294

Phone: (02) 4962 4450
Fax: (02) 4962 4460
Email: fertiliser.chemical@aqis.gov.au

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

3. Each consignment must be free of live insects, seeds, soil, animal material, plant material and other quarantine risk material prior to arrival in Australia.

4. Any packaging used with the consignment must be clean and new.

5. For containerised fertiliser, each Full Container Load (FCL) will be directed to a metropolitan Quarantine Approved Premises for a full unpack and inspection. All containers must be held securely and intact until the inspection. If the consignment is bagged, all bags within the consignment will undergo a visual inspection for contamination with quarantine risk material. Random sampling of the fertiliser using a sieve will be carried out on 5 bags per container. If the consignment is loose within the container, the consignment will be inspected visually and sieved for quarantine risk material once the container has been emptied.

6. Non-containerised, bagged fertiliser will be directed to a metropolitan Quarantine Approved Premises or a storage facility within the wharf area. Any transport from the wharf must be carried out using an AQIS approved method. The consignment must be held securely and intact until the inspection. All bags within the consignment will undergo a visual inspection for external contamination with quarantine risk material. Random sampling of the fertiliser using a sieve will be carried out on 5% of the bags.

7. In areas where there are no metropolitan Quarantine Approved Premises, the goods may be inspected at a non-metropolitan Quarantine Approved Premises subject to approval from the AQIS office in that region. Land-bridging of the goods between ports is not permitted.

8. Timber packaging, pallets or dunnage in FCL containers will also be subject to inspection and treatment on arrival, unless certified as having been treated by an AQIS approved method (refer to the AQIS publication ‘Cargo Containers: Quarantine aspects and procedures’).

9. After inspection, all consignments that meet the above import conditions will be released from quarantine.

10. Consignments that are contaminated will be ordered into Quarantine pending the determination of treatment options. If there are no treatment options available the consignment will be re-exported or destroyed.

1. Bibliography

ACERA. (2012). *Relative Risk of Different Categories of Imported Biological Products of Animal Origin.* Melbourne: ACERA.

Australian Government. (2012, June 20). *Quarantine Proclamation 1988*. Retrieved August 10, 2012, from ComLaw: http://www.comlaw.gov.au/Details/F2012C00492

DAFF. (2012, November 06). *Minimum Document Requirements Policy*. Retrieved November 22, 2012, from Australian Government Department of Agriculture Forestry and Fisheries: http://www.daff.gov.au/aqis/import/general-info/documentary-requirements/minimum-document-requirements-policy

Department of Agriculture Fisheries and Forestry. (2001). *POLICY FOR THE IMPORTATION OF MICROORGANISMS FOR IN VITRO USE.* Canberra: Department of Agriculture Fisheries and Forestry.

Tanner James Management Consultants. (21 October 2010). *Documentation Review Workshop Consultancy Report.* Tanner James Management Consultants.

Wikepedia. (n.d.). *Bird's nest soup*. Retrieved February 17, 2012, from Wikipedia: http://en.wikepedia.org/wiki/Bird%27s_nest_soup

Wikipedia. (n.d.). *Kopi_Luwak*. Retrieved March 1, 2012, from http://en.wikipedia.org/wiki/Kopi_Luwak