

REVIEW OF SUBMISSIONS ON:

DRAFT IMPORT HEALTH STANDARD FOR THE IMPORTATION INTO NEW ZEALAND OF BIOLOGICAL PRODUCTS (INCLUDING SAMPLES)

Ministry of Agriculture and Forestry
Wellington
New Zealand

30 May 2011

Ministry of Agriculture and Forestry
Te Manatu Ahuwhenua, Ngaherehere
Pastoral House
25 The Terrace
P O Box 2526
Wellington
New Zealand

Telephone: 0800 00 83 33
Facsimile: +64 4 894 0733
Internet: <http://www.maf.govt.nz>

Standards Branch
MAF

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**DRAFT IMPORT HEALTH STANDARD FOR THE IMPORTATION INTO NEW
ZEALAND OF BIOLOGICAL PRODUCTS (INCLUDING SAMPLES)**

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Approved for general release

Matthew Stone
Animal Export/Import Group Manager
MAF New Zealand

INTRODUCTION

The draft import health standard for the importation into New Zealand of Biological Products (including samples) from all countries was notified for consultation on 30 March 2011.

MAF received submissions from the following:

| | |
|--|---------------|
| John Seccombe, Aquahort Ltd | 31 March 2011 |
| Graeme Fletcher, Plant and Food | 01 April 2011 |
| William Jones, Plant and Food | 06 April 2011 |
| Cathy Brehmer, Lab Plus, Auckland Hospital | 12 April 2011 |

This document summarises the issues raised in the submissions, and presents the MAF response to each.

MAFBNZ review of submissions

1. JOHN SECCOMBE, AQUAHORT LTD

1.1 Please identify exactly the modifications/amendments and additions to these drafts.

MAFBNZ response: For background on the development of the import health standard, please refer to the risk management proposal that was issued with the other consultation documents.

1.2 Why have non-pathological micro-organisms not been included on the “Negligible Risk Register”?

MAF response: Viable microorganisms are not covered in the scope of this import health standard. Under definitions, biological products have been defined as “Non-viable products derived from living organisms, including samples of animal origin.” For importation of viable microorganisms, please refer to the import health standard MICROIC.ALL: *Import Health Standard for Micro-organisms from All Countries*.

1.3 Also estimate the costs in administrating these new standards.

MAF response: The Ministry of Agriculture and Forestry recovers costs for a number of the services that it delivers. The costs recovered are managed through legislation (levies and regulations), and schedules of fees for the recovery of actual and reasonable expenses incurred. For more information regarding the costs associated with importing products into New Zealand, please see the Biosecurity (Costs) Regulations 2010.

1.4 What is a BSP format?

MAF response: The Border Systems Programme (BSP) is a MAF work stream in place to shape a new border system. The format of import health standards has changed as part of this programme and this is how the import health standard for biological products has been presented.

For more information on the objectives of the future import health standards, please refer to Issue 98 of the Biosecurity Magazine, webpage below.

<http://www.biosecurity.govt.nz/files/biosec/pubs-media/pubs/biosecurity-magazine/issue-98/biosecurity-98.pdf>

1.5 What is a “non-viable biological product”?

MAF response: Biological products have been defined in the import health standard as “Non-viable products derived from living organisms.” Non-viable is considered not capable of living, replicating, reproducing or developing.

2. ANGELENE HOLTON ON BEHALF OF GRAEME FLETCHER, PLANT AND FOOD

2.1 Are import samples of salmon fillet covered by this document? Are marine animals now meant to be included under the section on Animal Product Samples?

MAF response: Yes, the import of salmon fillet samples is covered by this document, and is eligible under the animal product samples for evaluation section, as will be any marine animal samples. The requirements and/or controls on the samples are that they are imported into a transitional facility approved to MAF standard 154.02.17 for Biological Products. The measures that are in the current import health standard for salmon offal include; records being kept relating to the movement, storage and testing of the samples within New Zealand, permission being required from a MAF inspector prior to transfer of the products to other facilities within New Zealand, and once evaluation is complete, the remaining samples, all residues and wrapping materials are to be destroyed. These requirements will remain the same, however they are specified in the transitional facility operator manual, rather than the import health standard itself, as they are more relevant to the requirements specific to the facility.

2.2 Food samples aren't covered, why not? These are for use in, or on, humans.

MAF response: Food samples are covered under both animal product samples for evaluation section, and the adequately processed risk goods for use in a transitional facility section. The scope of the import health standard is broad hence the descriptions of the products are generic and can not specifically mention every type of product the standard covers.

Any consignments of food imported for the purposes of human consumption should comply with the relevant import health standard for that commodity. The term "in, or on, humans" is more applicable to medications, antibiotics, vaccines, surgical implants etc.

2.3 Milk and milk products are specifically covered, other foods are not mentioned.

MAF response: The new import health standard seeks to incorporate a number of existing import health standards for animal product samples. As such, the requirements for these products must be incorporated if not already covered somewhere else (as is the case for salmon offal sample controls in a transitional facility manual). Milk and milk products are currently covered by the import health standard *DAISAMIC.ALL for the Importation into New Zealand of Dairy Product Samples for Evaluation*. This import health standard is the only one that allows the clearance of specific goods, rather than a biosecurity authority to move to a transitional facility for subsequent evaluation and destruction. These current measures have not been revoked; but rather incorporated into the biological products import health standard to allow the continued clearance of these specific products.

3. ANGELENE HOLTON ON BEHALF OF WILLIAM JONES, PLANT AND FOOD

3.1 Antibodies are listed on the Negligible Risk Register while Foetal calf serum, which is sold as a sterile product, is regarded as a risk biological product.

MAF response: MAF currently only allows the import of filtered, irradiated foetal calf serum from Australia under government certification (official assurance). This is because serum products such as foetal calf serum constitute a distinct risk of being contaminated with viruses. Historically, bovine viral diarrhoea virus type 2 (a type exotic to New Zealand) has been isolated from imported bovine foetal calf serum.

3.2 The exclusion of protein as antigens seems illogical to me for two reasons. Firstly when one imports a protein it would be unusual for the purchaser to specify the protein is an antigen and all proteins could potentially be used as

“antigens”. Secondly all use of proteins as antigens would require animal ethics approval to immunise animals and therefore the use of proteins as antigens is legally covered in New Zealand.

MAF response: The intention of excluding antigens from general import into New Zealand was to exclude the import of antigens to exotic diseases that have not been inactivated. MAF has noted the exclusion of antigens may be too generic given that any protein can be used as an antigen, therefore proteins that are eligible for clearance will now need to be individually named on the register. The description “enzymes” should cover a large majority. In addition, antigens from organisms that are exotic to New Zealand have the potential to interfere with surveillance of those exotic diseases in New Zealand due to the risk of the animals seroconverting after exposure.

Secondly, MAF agrees that the use of proteins as antigens (specifically to immunise animals) is covered by other controls such as ethics committees and Agricultural Compounds and Veterinary Medicines (ACVM) approvals, however these assessments are not specific to biosecurity concerns, that is, considerations of potential risk pathways of exotic organisms and surveillance of exotic diseases in New Zealand.

3.3 Bovine serum albumin. This is a highly purified component of serum. This product is excluded but the serum from which it is derived is not excluded. This makes no sense to me at all. Most bovine serum albumin is produced in the USA where Mad cow disease is absent.

MAF response: In the past, blood products have been known to be contaminated with viruses, a specific concern for example is that of bovine viral diarrhoea virus type 2. Although bovine serum albumin (BSA) is a purified product, both BSA and anti-sera have different end-uses. Some purified products (such as BSA), may be imported with the intention of using them in the manufacture or formulation of products that will be used directly in animals. An example of this is the case of products used in the storage of embryos to maintain their physiological integrity, that are to be transplanted into New Zealand animals, while anti-sera is imported specifically for the use of the antibodies that it contains.

In addition to considering the different end-uses of both anti-sera and BSA, MAF also made the assumption that commercially produced anti-sera would be sourced from specified pathogen free animals, and also requires ACVM approval for use in animals (whereas BSA has exemptions). As a result of this submission, both anti-sera and antibodies will be excluded from the Negligible Risk Register, and will remain items that require a permit to import.

4. CATHY BREHMER, LAB PLUS, AUCKLAND CITY HOSPITAL

4.1 Can you please provide a definition of “Non-viable” in the definitions section.

MAF response: Noted. MAF will include the description of non-viable as being considered not capable of living, replicating, reproducing or developing.

4.2 As the recipient of the product/shipment I have little control over how the product is shipped. This can only be the responsibility of the shipper and not the importer. IATA also states that compliance is the responsibility of the shipper and the courier company.

MAF response: Noted. MAF will amend the wording to imply that it is the importer's responsibility to *inform* the exporter of the packaging standards that are required.

- 4.3 It is pleasing to see the items listed in the Negligible risk register will not require an import permit. However to speed these items through customs clearance, it would be helpful to have specific wording that should be documented on the customs clearance form / shipping documentation. Can you please include in the standard MAF approved wording to include on documentation.**

MAF response: Noted. MAF will include the wording "Goods are included in the [insert item here] category on the negligible risk register in the guidance document of BIOPRODIC.ALL."

- 4.4 Biological products derived from humans are also eligible for biosecurity clearance without an import permit (Clause 8). Can you please include in the standard MAF approved wording to include on documentation when importing these items.**

MAF response: Noted. MAF will include the wording "If clearance of human derived products is sought, it is recommended that the accompanying documentation declares the products as being of human origin, and communicates that clearance is sought under clause 8 of BIOPRODIC.ALL" under the exclusions section.

APPENDIX ONE: COPIES OF SUBMISSIONS

1 John Seccombe

1.1 RE: DRAFT AMENDMENTS OR ADDITIONS TO THE FOLLOWING ARTICLES/ACTS FOR THE IMPORTATION OF BIOLOGICAL PRODUCTS.

Please identify exactly the modifications/amendments and additions to these drafts as to how they might effect the present RMPs to import biological products.

Re: MAF must ensure that these requirements are technically justified and provide an appropriate level of biosecurity protection.

May I add MAF requirements should be appropriate to the level of risk of any import might pose to the ecological/environmental, cultural, & financial structure of New Zealand.

For instance non-pathological bacteria as used in biological filters, or Bio-augmentation is a very low risk item, and I've demonstrated it would not phase me to eat a packet of my imported product.

Why has these products not been listed as "Negligible Risk Register"?

This is the first time I've heard of this registration.

Your department is acting for the New Zealand people, and so while it's much appreciated that your department offers out drafts for the New Zealand persons to comment on.

It is beyond most persons financially and education qualifications to evaluate these drafts, without spends thousands of dollars on lawyers or consultants.

I presume your depart would not use covert means to modify or add requirements that would affect present importers of biological products.

So please be open and say exactly what you have modified or added to the present act/standards?

Also estimates of costs in administrating these new standards?

Incidentally what is a BSP Format?

For instance Google/ Wikipedia describes .BSP is a map [file extension](#) used in games such as the [Quake series](#), and games that use Quake-derived engines,

I'd also like to know what a "non-viable biological product" ...is as that word is usually associated with financially sound or profitable?

Regards

John Seccombe

Aquahort Ltd

2 Angelene Holton On behalf of Graeme Fletcher

2.1 GREAT THAT PRODUCTS OF NEGLIGIBLE RISK ARE CLEARLY IDENTIFIED AND LISTED.

Comments:

We have previously imported samples of salmon fillet which should be covered by this document but I don't think it is. We didn't eat them but tested them for their suitability as food based on other quality measures. Is it? I see no special mention of marine organisms (salt water fish) suggesting no special requirements? I note that this standard replaces that on Frozen Salmon Offal Samples but there don't seem to be any specific controls for this. Is this intentional or are marine animals now meant to be included under the section on Animal Product Samples? If so it should be stated.

Section 19 of the "Import Health Standard for Biological Products (including samples)" and sections 1 and 11 of the "Guidance Document..." – these don't cover food samples. Why not? These are for use "in, or on, humans." Milk and milk products (one type of food) are specifically covered in section 20-24 of the first document and 12-13 of the latter but other foods are not mentioned. If this is because food is covered by other standards they should be referenced here. Otherwise food should specifically be discussed here.

Graham

3 Angelene Holton On behalf of William Jones

3.1 PART E: NEGLIGIBLE-RISK REGISTER

The following list contains biological products that have been assessed by MAF BNZ and considered as negligible risk. As such, they are eligible for clearance without a permit to import.

All items must be commercially manufactured and packaged, with the exception of DNA/RNA (including plasmids).

- 1 Amino acids
- 2 Antibodies (monoclonal and polyclonal)
- 3 Antimicrobials
- 4 Antisera
- 5 Chemical reagents and synthetic substances
- 6 DNA (naked, i.e. not contained within a vector)
- 7 Enzymes
- 8 Plasmids (naked, i.e. not contained within a vector)
- 9 Proteins (excluding antigens and bovine serum albumin)
- 10 RNA (naked, i.e. not contained within a vector)

Under the general group of antibodies items 2 and 4 antibodies can be purified or crude animal products (monoclonal mouse only; ascetic tumours) or polyclonal (sera) and from any animal source eg mouse, rabbit, donkey, goat, sheep or cattle. Yet **Foetal calf serum** for animal cell culture which is sold as a sterile product, is tested for virus and is also sera, is regarded as a risk biological product even though it is thoroughly screened to be free of risk contaminants.

Proteins. Items 7 and 9. Proteins including enzymes cover a huge range of amino acid polymers from all biological sources viz microbe, animal, plant some of which are toxins, or have biological activities which could be classified as “at risk biological products” as well as benign proteins where the risk is not inherent to the molecule but may be due to a contamination e.g. microbial.

The exclusion of protein as antigens seems illogical to me for two reasons. Firstly when one imports a protein it would be unusual for the purchaser to specify the protein is an antigen and all proteins could potentially be used as “antigens”. Secondly all use of proteins as antigens would require animal ethics approval to immunise animals and therefore the use of proteins as antigens is legally covered in New Zealand.

Bovine serum albumin. This is a highly purified component of serum. This product is excluded but the serum from which it is derived is not excluded. This makes no sense to me at all.

Most bovine serum albumin is produced in the USA where Mad cow disease is absent. Surely therefore when examining the risk potential of proteins any restrictions should be based on factors such as for example inherent toxicity, harmful biological activity whereas for benign proteins the country of origin of the product and exclusion should relate to whether or not certain diseases are present in the country of origin. For example, restriction should apply to bovine serum originating from Europe where ‘mad cow disease has been observed but not from USA, New Zealand or Australia which are free of this disease.

Regards,
Bill

4 Cathy Brehmer (ADHB)

4.1 Hi Charlotte

I am providing feedback/submission on the Draft Import Health Standard for Biological Products (March 2011).

I would like to raise several points:

A) Can you please provide a definition of "Non-viable" in the definitions section

B) In clause 18 the draft states that it is the Importers responsibility to ensure that biological products are transported according to the IATA regulations. As the recipient of the product/shipment I have little control over how the product is shipped. This can only be the responsibility of the shipper and not the importer. IATA also states that compliance is the responsibility of the shipper and the courier company. I therefore submit that this clause be removed from the document.

C) Negligible Risk Goods for Clearance: It is pleasing to see the items listed in the Negligible risk register will not require an import permit. However to speed these items through customs clearance, it would be helpful to have specific wording that should be documented on the customs clearance form/ shipping documentation. Can you please include in the standard MAFBNZ approved wording to include on documentation.

D) Biological products derived from humans are also eligible for biosecurity clearance without an import permit (Clause 8). Can you please include in the standard MAFBNZ approved wording to include on documentation when importing these items

Regards

Cathy Brehmer
Quality Officer
Lab Plus, Auckland City Hospital