Ministry for Primary Industries
Manatū Ahu Matua

Risk Management Proposal

Specified Animal Products

SPECPROD.ALL

29 November 2019

Growing and Protecting New Zealand

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Contact for further information:

Ministry for Primary Industries (MPI)
Agriculture & Investment Services
Animal Trade (Imports)
PO Box 2526
Wellington 6140
Email: animal.imports@mpi.govt.nz
Telephone: 04 890 0134

Contents

1 Purpose

The purpose of this document is to:

(1) Show the risk management decisions for the Import Health Standard (IHS) for Specified Animal Products.

2 Background

(1) The following IHSs have some long-standing import requirements:

a) *IHS: Emu Oil from Australia*, *EMUOILIC.AUS.AUS*, 17 June 2004
b) *IHS: Pre-cooked Heat-and-Eat Meals Containing Animal Products for Human Consumption from Australia*, *HEAMEAIC.AUS*, 1 November 2001
c) *IHS: Pre-cooked Heat-and-Eat Meals Containing Animal Products for Human Consumption from Canada and the United States of America*, *HAEMEAIC.SPE*, 10 April 2014
d) *IHS: Specified Animal Products and Biologicals*, *INEPROIC.ALL*, 8 June 2011
e) *IHS: Specified Foods for Human Consumption Containing Animal Products,* EDIPROIC.ALL, 15 January 2019
f) *IHS: Specified Porcine Enzymes from Canada and the United States of America*, *PORENZIC.NAM,* 16 January 1998

(2) These animal products share at least one of the following characteristics:

a) Being shelf-stable;
b) Have undergone intensive industrial processes;
c) Having specific commodity descriptions that restrict their end uses and the country from which they originate.

(3) The risk decisions supporting the above IHSs will be reviewed in this RMP, and where they are in line with MPI risk advice the commodities will be included in the *IHS for Specified Animal Products (SPECPROD.ALL)*, which has been drafted as one single IHS to manage risk associated with the importation of these animal products.

(4) MPI proposes shifting provisions, contained in the following specific clauses and IHSs, to the *IHS SPECPROD.ALL*, without making any changes to import requirements. As a minor amendment, they will not be publically consulted.

a) Clauses 6.4, 6.8, 6.16, 6.23 in the *IHS: Specified Animal Products and Biologicals*, *INEPROIC.ALL, 08 June 2011*
b) Clauses 2.4, 2.14, 2.16, 2.17, 2.18, 2.20, 2.23 in the *IHS: Specified Foods for Human Consumption Containing Animal Products*, *EDIPROIC.ALL*, 20 September 2019
c) *IHS: Emu Oil from Australia*, *EMUOILIC.AUS.AUS*, 17 June 2004

(5) MPI proposes revoking provisions, contained in the following specific clauses and IHSs, for commodities that have not been imported for a prolonged time (e.g. 10 years).

a) Clauses 6.6, 6.7, 6.9, 6.10, 6.11, 6.12, 6.13, 6.14, 6.15, 6.17, 6.18, 6.19, 6.20, 6.21, 6.22, 6.26, 6.27, 6.28 in the *IHS: Specified Animal Products and Biologicals*, INEPROIC.ALL, 08 June 2011
b) *IHS: Heinz Watties Frozen or Chilled Meat Extracts from Japan*, *MEASHWIC.JPN*, 9 October 2001
c) *IHS: Processed Animal Products for use by Airlines and the Military for Flights Leaving New Zealand,* *AIRPROIC.ALL*, 19 November 1999
d) *IHS: Specified Meat Products from Australia for use on Flights Leaving New Zealand,* *AIRMEAIC.AUS*, 25 February 2000
e) *IHS: Specified Meat Products from France for Use on Flights Leaving New Zealand*, *AIRMEAIC.FRA*, 25 February 2000
f) *IHS: Specified Protein Digested Animal Products from France*, *PRODIGIC.FRA*, 8 May 2001
g) *IHS: Tacos containing Cooked Beef from Mexico*, *MEATACIC.MEX*, 12 March 2001e

3 Objective

(1) The objective of the *IHS SPECPROD* is to effectively manage biosecurity risks associated with the import of specified animal products, consistent with New Zealand's domestic legislation and international obligations.

4 General considerations

(1) Considering the characteristics mentioned in clause 2 (2), MPI's assessment of the exporting countries' export and certification systems, and bilateral country-to-country negotiation, will not be required.

(2) Risk will be effectively managed by at least one of the following general measures:

a) An import permit assessment process;
b) Documentation (e.g. official certification, government-endorsed manufacturer's declaration or manufacturer's declaration) attesting to specific treatments or processes;
c) Demonstration of disease freedom as officially recognised by the OIE;
d) Evidence (e.g. commercial documents, product labelling) demonstrating the nature of the animal product and thus correct determination of the commodity (e.g. products containing less than 5% each of aquatic animal, dairy or egg products).

5 Recommendations for Goods Containing Animal Products for Human Consumption

5.1 Canned or retorted animal products

(1) Clause 2.1 (2) of the *IHS EDIPROIC.ALL* has the requirements for commercial consignments of canned or retorted animal products, which may be imported from any country provided all of the following requirements are met:

a) The product is shelf-stable.
b) The consignment is accompanied by:

i) A manufacturer's declaration stating that the product has been subjected to a retort process of Fo3 or greater (refer to Schedule 1 of this RMP for times and temperatures to achieve Fo3); or
ii) A government-endorsed manufacturer's declaration stating that the product (may or may not be retorted) has been subjected to a heating process equivalent to Fo3 or greater.

(2) The *IHS EDIPROIC.ALL* has the following definition for shelf-stable:

a) The product has been commercially manufactured.
b) The product has been packaged by the manufacturer.
c) The product is in that package.
d) The package has not been opened or broken.
e) The product:

i) Is able to be stored in the package at room or ambient temperature.
ii) Does not require refrigeration or freezing before the package is opened.

(3) The definition has not been apparent for some importers and MPI biosecurity inspectors. It will be amended in the *IHS SPECPROD.ALL* to add clarity.

(4) Canned or retorted products that are hermetically sealed are air tight, completely sealed and impermeable to gas. It is a distinctive product feature that indicates the retort process has been effectively carried out. 'Hermetically sealed' will thus be set as a requirement.

(5) The *IHS EDIPROIC.ALL* requires products to be accompanied by documentation, that is, a manufacturer's declaration or government-endorsed manufacturer's declaration. To enhance the veracity of

documentation presented to MPI, official certification issued by the exporting country will be required to attest to the retort process, and if applicable, the BSE risk status of the exporting country, zone or compartment (see below).

(6) To manage the risk of BSE (applicable to products derived from *Bos taurus* and *B. indicus*), MPI will adopt the OIE *Terrestrial Animal Health Code* (the *Code*) recommendations for the importation of bovine meat and meat products from:

a) a country, zone or compartment posing a **negligible BSE risk**; or
b) a country, zone or compartment posing a **controlled BSE risk**.

Recommendation

(7) The RMP proposes that canned or retorted animal products may be imported from any country provided the following requirements are met:

a) The product does not require refrigeration before the package is opened.
b) The product is commercially manufactured and packaged.
c) The package has not been opened or broken.
d) The product is accompanied by an official certificate stating that the product has been heat-treated in a hermetically sealed container to an F0 value of 3 or more (see Schedule 3 of the IHS for equivalent time/temperatures combinations to achieve an F0 value of 3).
e) In addition to the above requirements, products containing bovine products is accompanied by an official certificate that meets the specified *Code* recommendations for:

i) a country, zone or compartment posing a **negligible BSE risk**; or
ii) a country, zone or compartment posing a **controlled BSE risk**.

5.2 Collagen (edible)

(1) Clause 2.8 of the *IHS EDIPROIC.ALL* has the requirement for commercial consignments of edible collagen products such as manufactured sausage casings and hydrolysed collagen used as a dietary supplement, which may be imported from any country provided the product is shelf-stable.

(2) Currently, BSE is managed by the MPI *Food Notice: Importing Food*, under which, bovine products can only be imported into New Zealand from countries that have been assessed as posing minimal BSE risk and that have a pre-clearance agreement with New Zealand. On the other hand, the *Code* contains recommended BSE control measure for the importation of collagen. MPI proposes to align collagen import requirements with the OIE's *Code* recommendations, specifically, that prepared from bones intended for food, and that prepared from hides and skins for food.

(3) Collagen may be produced from a range of different animal tissues, including bovine tendons, calves skins, sheepskins, pigskins, sheep gut and bovine bones.

(4) The followings does not pose a BSE risk:

a) Collagen produced from species other than *Bos taurus* and *B. indicus*; and
b) Collagen prepared exclusively from hides and skins, in accordance with the OIE *Code*.

(5) Although the OIE *Code* has no recommendation relating to BSE for collagen produced from species other than *B. taurus* and *B. indicus*, and does not recommend official certification for collagen prepared exclusively from hides and skins, requiring an official certificate to respectively state the species and that the collagen is prepared exclusively from hides and skins provides assurance to MPI.

(6) Commercial manufacturing in collagen production further ensures that non-BSE risk is minimised.

Recommendation

(7) The RMP proposes that edible collagen derived from *B. taurus* and *B. indicus* and prepared from hides and skins may be imported from any country provided that the product is accompanied by an official certificate stating that the collagen has been prepared exclusively from hides and skins.

(8) The RMP proposes adopting the *Code* recommendations for collagen that is derived from *Bos taurus* and *B. indicus,* and prepared from bones. Accordingly, the product must be accompanied by an official certificate stating that:

a) The product originates from a country, zone or compartment having a **negligible BSE risk**; or
b) The product originates from a country, zone or compartment having a **controlled BSE risk** and is derived from cattle which have passed ante- and post-mortem inspections; and that

i) Vertebral columns from cattle over 30 months of age at the time of slaughter and skulls have been excluded; and
ii) The bones have been subjected to a process which includes all of the following steps:
1. degreasing;
2. acid demineralisation;
3. acid or alkaline treatment;
4. filtration;
5. sterilisation at >138 degrees Celsius for a minimum of 4 seconds.

(9) The RMP proposes that edible collagen derived from species other than *Bos taurus* and *B. indicus* may be imported from any country provided the product is accompanied by an official certificate that states the animal species, showing that the animal species is not *B. taurus* nor *B. indicus*.

(10) In addition to the above requirements, the RMP proposes that all edible collagen, regardless of species and which animal part the collagen is derived from, is commercially manufactured.

5.3 Composite foods

5.3.1 Pre-cooked heat-and-eat meal

(1) The *IHS HEAMEAIC.AUS* and *IHS HEAMEAIC.SPE* have long-standing import requirements for pre-cooked heat-and-eat meals containing animal products for human consumption from Australia, and Canada and the USA, respectively. The requirements are as follows.

(2) Pre-cooked heat-and-eat meals containing animal products for human consumption may be imported from Australia provided all the following requirements are met:

a) The product is commercially packaged and sealed in foil or plastic;
b) The product does not contain poultry meat.

(3) Pre-cooked heat-and-eat meals containing animal products for human consumption may be imported from Canada and the USA provided all the following requirements are met:

a) The product is commercially packaged and sealed in foil or plastic;
b) The product does not contain poultry meat.
c) The product is accompanied by a government-endorsed manufacturer's declaration that certify:

For mammalian meat:

i) The product contains only meat derived from animals slaughtered in Canada or the United States of America.
ii) The product contains meat that is free of bone.
iii) During manufacture of the product, the meat products have been heated to the following minimum core temperatures/times, prior to freeze-drying, dehydrating or any other process:

1) 70ºC for at least 25 minutes; or
2) 80ºC for at least 3 minutes.

For egg products:

i) The egg products have been heated to the following minimum core temperatures/times, prior to freeze-drying, dehydrating or any other process:

1) 60ºC for at least 30 minutes;
2) 100ºC for at least 1 minute.

For dairy products:

i) The milk used to manufacture the dairy ingredients used during manufacture of the product has been heat treated:

1) a sterilisation process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]); or
2) if the milk has a pH less than 7.0, a sterilisation process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]); or
3) if the milk has a pH of 7.0 or over, the HTST process applied twice.

(4) These are historic import health agreements with Australia, Canada and the USA, and are consistent with the risk assessment that supports other IHSs for unprocessed animal products.

Recommendation

(5) The RMP proposes the requirements remain unchanged in the *IHS SPECPROD.ALL*.

5.3.2 Products containing less than 5% each of aquatic animal, dairy or egg products

(1) Clause 2.22 of the *IHS EDIPROIC.ALL* has the requirements for products containing less than 5% fish, dairy or egg ingredients, which may be imported from any country provided all of the following requirements are met:

a) The product is commercially prepared and packaged.
b) The product is in its original sealed packaging on arrival.
c) The product must be:

i) Accompanied by a manufacturer's declaration which certifies that the product contains no meat ingredients and less than 5% each of fish, dairy, or egg ingredients; or
ii) In commercial packaging that states the product contains no meat ingredients and less than 5% each of fish, dairy, or egg ingredients.

(2) This is a long-standing provision. Products imported under this provision are commercially prepared and packaged for human consumption. This reduces the possibility of waste production, and the amount of waste if it does occur. The low percentage (i.e. 5%) requirement further reduces the amount of fish, dairy or egg ingredients being exposed to animal populations if waste is produced. Considering the above, MPI determines that the commodity poses a negligible biosecurity risk to New Zealand.

(3) Following the reasoning in clause 5.3.2 (2) of this RMP, MPI also considers that products containing less than 5% aquatic animal products (e.g. finfish, crustaceans, mollusca) pose negligible risk to New Zealand.

(4) Manufacturer's declaration attesting to the absence of meat ingredient and the percentage of aquatic animal, dairy or egg products, or labelling to demonstrate the same, is considered sufficient in providing MPI the confidence required to ascertain the composition of the product.

Recommendation

(5) The RMP proposes the requirements remain unchanged in the *IHS SPECPROD.ALL*, except the wording 'fish' is replaced by 'aquatic animal'.

5.4 Gelatine (edible)

(1) Clause 2.20 of the *IHS EDIPROIC.ALL* has the requirement for edible gelatine and gelatine products, which may be imported from any country provided they are shelf-stable.

(2) Gelatine may be prepared from hides and skins, or bones. The OIE recommends that gelatine prepared from hides and skins is a safe commodity as it does not carry BSE infectivity; whereas gelatine prepared

from bones should be accompanied by an official certificate with specific attestations as recommended by the OIE.

(3) Considering the following scientific evidence, MPI will not adopt the OIE's recommendation for gelatine prepared from bones.

(4) *Appendix 4: Does gelatine pose a BSE risk to consumers* of the MPI document *Officials' Review of New Zealand's BSE Country-Categorisation Measure* states that BSE infectivity has not been found in skin, even in advanced clinical cases. This supports the OIE's recommendation for gelatine prepared from hides and skins.

(5) The paper described the following chemical processes used in the manufacture of gelatine:

a) Bone degreasing. This has the ability to remove 98-99% of nervous tissue proteins.
b) Acid treatment. This drops the pH value to less than 1.5 for a period of at least 2 days and brings about changes to the internal structure of the BSE prion protein.
c) Alkaline treatment. This increases the pH value to greater than 12.5 for a period of between 20 and 50 days. This again brings about changes to the internal structure of the BSE prion protein.
d) Extraction of gelatine. This involves filtration and sterilisation processes that further remove suspended particles and remove remaining, if any, BSE infectivity.

(6) The paper concluded that the series of chemical processes used in the manufacture of gelatine, regardless of whether it is derived from hides and skins, or bones, is sufficient to inactivate any BSE infectivity which might have been present in the raw material from which the gelatine is made.

Recommendation

(7) The RMP proposes that commercially manufactured edible gelatine, regardless of whether it is prepared from hides and skins, or bones, may be imported from any country.

(8) Intermediate gelatine products (e.g. gel bone) produced during the manufacture of gelatine have not undergone all the industrial processes described in clause 5.4 (5). The proposed requirements therefore do not apply to intermediate products. Imports of intermediate products would need to meet other IHSs.

5.5 Insect and arachnid based products

(1) Insect and arachnid based food products, such as insect-containing hard candy and cricket flour, are becoming a more commonly traded commodity.

(2) MPI risk analysts completed *Technical Advice (TA): the Biosecurity Risk of Insect-based Products Intended for Consumption by Humans and Animals*, September 2015.

(3) According to the TA, insect products intended for human or animal consumption pose a very low biosecurity risk to New Zealand if:

a) The commodity contains insects that were reared in a commercial environment using a formulated insect diet and standard hygienic insect rearing techniques; and
b) The commodity is not produced from insects that are wild caught.

(4) The TA states that most commercial insect food manufacturers are registered with the US Food and Drug Administration (FDA), apply the processing principles set out in the Codex Alimentarius, including Hazard Analysis Critical Control Point (HACCP), or follow Good Manufacturing Practices (GMP). Some manufacturers may comply with all or a combination of the above systems. Out of the above systems, HACCP is an internationally recognised system commonly applied by food industries.

(5) Commercial manufacturing of insect-based food products commonly involves cooking, freeze-drying or dehydration, which leads to insects to become non-viable. The TA also states that transmission of plant pathogens can only occur when the insect is alive.

(6) While the scope of the risk advice includes only insect based food products, it would also apply to arachnid based food products that follow the same harvesting and processing.

Recommendation

(7) The RMP proposes that insect and arachnid based products may be imported from any country provided the product is accompanied by a government-endorsed manufacturer's declaration stating that:

a) The insect or arachnid is raised in farms specifically for human consumption; and
b) The product is processed in facilities operating a current Hazard Analysis and Critical Control Point (HACCP) programme; and
c) The product does not contain viable insects or arachnids.

5.6 Meat and meat products

5.6.1 Processed foods containing less than 5% meat

(1) Clause 2.21 of the *IHS EDIPROIC.ALL* has the requirements for products containing less than 5% meat ingredients, which may be imported from any country provided all of the following requirements are met:

a) The product is shelf-stable.
b) The product must be:

i) Accompanied by a manufacturer's declaration, which certifies that the product contains less than 5% meat ingredients; or
ii) In commercial packaging that states the product contains less than 5% meat ingredients.

(2) This is a long-standing import provision, and is intended to mitigate risk from products that contain discernible meat or meat pieces. The wording 'ingredient' should therefore be removed from the commodity title to add clarity. For products containing meat based ingredients (including broth, concentrate, meat extract, fat, flavours, floss, stock or tallow), the provision for 'processed foods containing meat-based ingredients' applies (see clause 5.6.2 of this RMP).

(3) Products imported under this provision are commercially prepared and packaged for human consumption. This reduces the possibility of waste production, and the amount of waste if it does occur. The low percentage (i.e. 5%) requirement further reduces the amount of meat being exposed to animal populations if waste is produced. Considering the above, MPI determines that products containing less than 5% of meat poses a negligible biosecurity risk to New Zealand.

(4) Based on the rationale in clause 5.6.3 (3), whether the product requires refrigeration before the package is opened is not considered to be a risk mitigation measure. Also refer to clause 5.1 (2) and (3) of the RMP on the discussion about the shelf-stable requirement.

(5) The *IHS EDIPROIC.ALL* requires a manufacturer's declaration to state that the product contains less than 5% meat. It is important that this statement is authentic. Government-endorsed manufacturer's declaration should provide New Zealand an acceptable level of confidence. The labelling provision will thus be removed.

Recommendation

(6) The RMP proposes that processed foods containing less than 5% meat may be imported from any country provided all of the following requirements are met:

a) The product is commercially prepared and packaged.
b) The package has not been opened or broken.
c) The product must be accompanied by a government-endorsed manufacturer's declaration which certifies that the product contains less than 5% meat.

5.6.2 Processed foods containing meat-based ingredients

(1) Clause 2.2 of the *IHS EDIPROIC.ALL* has the requirements for commercial imports of animal product-based floss, flavouring or stock, which may be imported from any country provided all of the following requirements are met:

a) The product is shelf-stable.

b) The product does not require further cooking before consumption, but may require rehydration or reheating prior to consumption.

(2) See clause 5.1 (2) and (3) of the RMP for a discussion on the shelf-stable requirement.

(3) The commodity title in the *IHS EDIPROIC.ALL* 'animal product-based flavouring or stock' does not clearly convey the intent of the provision, nor does it sufficiently defines the commodity. This provision is intended for processed foods that are ready for direct human consumption or for direct use as an ingredient in the preparation of food for human consumption, limiting the risk of any product waste getting exposed to animals. This has only been implied in the clause 'not requiring further cooking before consumption'. By requiring products to be in shelf-ready packaging (see definition in Schedule 2 of the IHS) that is ready for direct human consumption, or for direct use as an ingredient in the preparation of food for human consumption, the intent of the provision should be clarified.

(4) Flavouring and stock are derived from meat, and meat is defined as all edible parts of an animal according to the OIE *Code*. The wording 'animal-based ingredients' is thus replaced with 'meat-based ingredients' to add clarity. Flavouring and stock are not specific nor informative. They should therefore be replaced by specific examples: broth, concentrate, extract, fat, flavours, floss, stock or tallow.

(5) Considering the clarifications described in 5.6.2 (3), the provision therefore will not apply to commercial, bulk (e.g. in drums) imports of meat-based ingredients.

Recommendation

(6) The RMP proposes that processed foods containing meat-based ingredients (ingredients include broth, concentrate, extract, flavours, floss, stock or tallow), may be imported from any country provided the following requirements are met:

a) The product does not require refrigeration before the package is opened.
b) The product is commercially manufactured and is in shelf-ready packaging.
c) The package has not been opened or broken.
d) The product is in a form ready for:
   i) direct human consumption; or
   ii) the preparation of food for human consumption.

5.6.3 Pork crackling

(1) Clause 2.4 of the *IHS EDIPROIC.ALL* has the requirement for commercial consignments of pork crackling, which may be imported from any country provided they are accompanied by a manufacturer's declaration stating that the product has been subjected to a heating process of F03 or greater (see Schedule 3 of the IHS for equivalent time/temperatures combinations to achieve an F0 value of 3).

Recommendation

(2) The RMP proposes the requirements remain unchanged in the *IHS SPECPROD.ALL.*

5.7 Enzymes, microorganisms and other products used in food

(1) The *IHS INEPROIC.ALL* has the following requirements:

a) Clause 6.4: commercially manufactured food cultures, enzymes or starters derived from or consisting of micro-organisms (e.g. yoghurt, cheese and sausage starters, enzymes or cultures) from any country may be given clearance.
b) Clause 6.5 of the *IHS INEPROIC.ALL* has the requirements for commercially manufactured rennet, which may be imported from Australia.
c) Clause 6.8: brewer's yeast, baker's yeast or any other yeast products used in the food industry from any country may be given clearance.
d) Clause 6.16: commercially packaged isinglass air bladder of fish (clarifying agent for alcoholic beverages) from any country.

(2) These are long-standing requirements that represent a very low risk to New Zealand and thus are eligible for biosecurity clearance.

(3) Rennet is a complex of enzymes used in food, and is eligible for importation from any country under the provision 'commercially manufactured food cultures, enzymes or starters derived from or consisting of micro-organisms (e.g. yoghurt, cheese and sausage starters, enzymes or cultures)'.

(4) Products containing probiotic microorganisms are commodities commonly traded. A probiotic microorganism is eligible for importation when it is:

a) Deemed by the New Zealand Environmental Protection Authority (EPA) as present in New Zealand under the Hazardous Substances and New Organisms (HSNO) Act 1996.
b) Not an unwanted organism under the Biosecurity Act 1993.
c) Not contaminated by any other organisms that may not meet 5.7(4) a) and b).
d) Not for use in or on animals or plants.

Recommendation

(5) The RMP proposes that the provision in clause 6.5 of the *IHS INEPROIC.ALL* be revoked; and clause 6.4, 6.8 and clause 6.16 remain unchanged.

(6) The RMP proposes that products containing probiotic microorganisms may be imported from any country provided the following requirements are met:

a) The product is accompanied by a manufacturer's declaration stating:

i) The scientific name (genus and species) of the microorganisms; and
ii) The product is for human consumption; and
iii) The probiotic microorganism, or each respective microorganism if the product contains more than one, is in the form of a pure culture that consists of a single species and that has no contaminating organisms.

b) The product is accompanied by a confirmation from the New Zealand Environmental Protection Authority (EPA) stating that the microorganisms are deemed to be present in New Zealand under the Hazardous Substances and New Organisms (HSNO) Act 1996.
c) The microorganisms are not unwanted organism under the Biosecurity Act 1993.

6 Recommendations for Non-Food Goods Containing Animal Products

6.1 Bile and bile derivatives (bovine and ovine)

(1) Clause 6.3 of the *IHS INEPROIC.ALL* has requirements for concentrated ox gall/ox bile and derivatives from any country, which may be imported when the following requirements are met:

a) The product shall be commercially packaged
b) The packaging shall be clean and free from visible signs of contamination
c) The product shall be shelf-stable (i.e. does not require refrigeration.).

(2) MPI has revised import requirements of bovine and ovine bile and their derivatives, and the *MPI Technical Advice on Processed Bovine and Ovine Bile* (TA dated 2 Oct 2019) identified the following hazards for which further assessment was undertaken around the efficacy of industrial processes in inactivating each identified hazard:

a) Viruses

i) Bluetongue virus
ii) Bovine herpes virus - 1
iii) Bovine viral diarrhoea virus
iv) Foot and mouth disease virus
v) Lumpy skin disease virus
vi) Peste des petitis ruminants virus
vii) Rift valley fever virus
viii) Sheep pox virus

b) Bacteria

i) Mycoplasma mycoides subsp. mycoides SC

c) Prions

i) Bovine spongiform encephalopathy (BSE)
ii) Scrapie

(3) The industrial processes considered in the TA were:

a) Heat treatment at a minimum of 100 degrees Celsius for a minimum of 8 hours; and
b) Hydrolysis with sodium hydroxide.

(4) The TA concluded that in order to mitigate all the identified hazards, bile must be treated with the industrial processes described in 6.1(3) of this RMP.

(5) The TA also states that the collection of bile from animals that passed ante- and post- mortem inspections at premises with competent authority oversight ensures bile is collected only from healthy animals.

(6) Processed bile and bile derivatives may be contaminated with unprocessed bile. Precautions to prevent contamination prior to dispatch from the processing premises in the exporting country is able to mitigate risk of post-processing contamination.

(7) Considering the New Zealand industry may import bile that has been subjected to heat treatment as described in 6.1 (3) a) of this RMP, bile may be directed to an MPI-approved transitional facility for further processing to meet 6.1 (3) b).

Recommendation

(8) The RMP proposes that bovine and ovine bile, and their derivatives, may be imported from any country provided it is accompanied by an official certificate that states the bile, or the bile that produces the bile derivatives:

a) Has been collected from animals that have passed ante- and post-mortem inspection at premises with competent authority oversight.
b) Has undergone a heat treatment of 100 degrees Celsius for a minimum of 8 hours.
c) Has been treated with sodium hydroxide.
d) Has been subjected to precautions to prevent contamination prior to dispatch from the processing premises.
e) Is in packaging that is clean and free from visible signs of contamination.

(9) The RMP proposes that bovine and ovine bile that has not undergone the treatment as described in 6.1 (3) b) of this RMP may be imported from any country provided it is accompanied by:

a) An official certificate that states the bile:

i) Has been collected from animals that have passed ante- and post-mortem inspection at premises with competent authority oversight.
ii) Has undergone a heat treatment of 100 degrees Celsius for a minimum of 8 hours
iii) Has been subjected to precautions to prevent contamination prior to dispatch from the processing premises.
iv) Is in packaging that is clean and free from visible signs of contamination.

b) An import permit that nominates an MPI-approved transitional facility where the bile will be treated with sodium hydroxide.

6.2 Emu oil from Australia

(1) The *IHS EMUOILIC.AUS* has the requirements for emu oil from Australia, which may be imported when it is presented with

a) a manufacturer's declaration stating that the emu oil has been heat treated to a core temperature of the product to a minimum of 100 degree C for at least 1 minute during manufacturing; and
b) a veterinary certificate to state that records of the manufacturer has been examined and the signing government veterinary official has no reason to doubt the veracity of the manufacturer's declaration.

Recommendation

(2) The RMP proposes that the requirements remain unchanged.

6.3 Gelatine (inedible)

(1) Clause 6.23 of the *IHS INEPROIC.ALL* has the requirements for inedible gelatine and products containing gelatine, which may be imported from any country provided the product is commercially packaged.

(2) The scientific article in *Appendix 4: Does gelatine pose a BSE risk to consumers* of the document *Officials' Review of New Zealand's BSE Country-Categorisation Measure* presented and discussed in clause 5.4 of the RMP can be applied to both edible and inedible gelatine. Recommendation for inedible gelatine will therefore be the same as that for edible gelatine.

Recommendation

(3) The RMP proposes that commercially manufactured inedible gelatine, regardless of whether it is prepared from hides and skins, or bones, may be imported from any country.

(4) Intermediate products (e.g. gel bone) during the manufacture of gelatine have not undergone all the chemical processes described in clause 5.4 (5). The proposed requirement therefore do not apply to these intermediate products. Imports of intermediate products would need to meet other IHSs.

6.4 Highly processed inedible collagen/protein products

(1) Clause 6.25 of the *IHS INEPROIC.ALL* has the requirement for highly processed inedible collagen/protein products, which may be imported from any country provided the products are commercially packaged. Examples of such products are keratin setting retarder (product used for making plaster), hydrolysed collagen, other products containing animal proteins for use in the building trade (e.g. Durafoam protein).

(2) These products should be prohibited for use as animal feed to minimise the risk exposure of the products to animals.

(3) When commercially manufactured, these products do not represent a biosecurity risk to New Zealand. Commercial packaging should therefore not be required.

Recommendation

(4) The RMP proposes that highly processed inedible collagen/protein products may be imported from any country provided the following requirements are met:

a) The product is not for use as animal feed; and
b) The product is commercially manufactured.

6.5 Other non-food animal products

(1) The *IHS INEPROIC.ALL* contains the following provision:

a) Clause 6.24: commercially packaged animal skin/hide glue or size from any country.

(2) This is a long-standing requirement that present a very low risk to New Zealand and thus is eligible for biosecurity clearance.

(3) Animal skin/hide glue or size, when commercially manufactured, do not represent a biosecurity risk to New Zealand. Commercial packaging should therefore not be required.

Recommendation

(4) The RMP proposes that the requirements remain unchanged, except that the requirement 'commercially packaged' for and animal skin/hide glue or size, is replaced with 'commercially manufactured'.

6.6 Specified Porcine Enzymes

(1) Cause 6.14 of the *IHS INEPROIC.ALL* has the requirements for the porcine enzymes pancreatin and pepsin from Australia, Canada, and the USA, which may be given clearance provided the product is commercially packaged.

(2) The *IHS PORENZIC.NAM* also has requirements for four specified porcine enzymes: lipase, pancreatin, pepsin and trypsin from Canada and the USA. The IHS requires the product is commercially packaged and hermetically sealed, and a manufacturer's declaration which states:

a) The product was derived from pigs born, raised and slaughtered in with Canada or the USA; and
b) that the pigs have passed veterinary ante-mortem and post-mortem inspection; and
c) that the pigs were processed in meat packing premises inspected by and registered with the government veterinary authority of the country of origin of the pigs.

(3) For the purpose of preventing post-processing contamination, tamperproof sealing is deemed as equivalent as hermetic sealing.

(4) The *IHS PORENZIC.NAM* also requires veterinary certification stating that African swine fever, foot and mouth disease, hog cholera (classical swine fever), rinderpest, and swine vesicular disease has not occurred in the country of origin of the pigs during the twelve months prior to the date of departure of the

product for New Zealand. Note that rinderpest had been globally eradicated in 2011 so certification of this disease is not required.

(5) Requirements for the porcine enzymes pancreatin and pepsin from Canada, and the USA have been duplicated in the *IHS INEPROIC.ALL* and *PORENZIC.NAM.* The requirements in the *IHS PORENZIC.NAM* should prevail as it provides New Zealand a higher level of protection.

Recommendation

(6) The RMP proposes that the requirements for the porcine enzymes pancreatin and pepsin from Australia remain unchanged.

(7) The RMP proposes that specified porcine enzymes may be imported from Canada and the United States of America provide they meet the following requirements:

a) The porcine enzymes is lipase, pancreatin, pepsin or trypsin.
b) The product is commercially packaged with tamperproof seals applied to bags.
c) The product is accompanied by a manufacturer's declaration stating:

   i) The product was derived from pigs born, raised and slaughtered in Canada, or the United States of America.; and
   ii) that the pigs have passed veterinary ante-mortem and post-mortem inspection; and
   iii) that the pigs were processed in meat packing premises inspected by and registered with the government veterinary authority of the country of origin of the pigs.

d) The product is accompanied by a veterinary certificate stating that African swine fever, foot and mouth disease, hog cholera (classical swine fever), and swine vesicular disease has not occurred in the country of origin of the pigs during the twelve months prior to the date of departure of the product for New Zealand.

7 Recommendations for other animal products

7.1 Dietary Supplements, Supplemented Foods and Therapeutic Products for Human Use

(1) Cordyceps are non-viable caterpillars that have been parasitized by a fungus. The fungus has several scientific names that are synonymous to each other: *Cordyceps sinensis, Metacordyceps chlamydosporia, Ophiocordyceps sinensis,* and *Verticillium chlamydosporium*. The fungus has been deemed by the New Zealand Environmental Protection Agency (EPA) as being present in New Zealand. So as long as cordyceps are non-viable and free from visible contamination, they are eligible for importation.

(2) Clause 6.1 of the *IHS INEPROIC.ALL* has the requirements for health supplements/Chinese and Oriental medicines containing animal products, which may be imported from any country provided all the following requirements are met:

a) The product shall be commercially manufactured and compounded into pills, tablets, capsules, liquids, syrups, oils or medicated plasters.
b) The product shall be shelf-stable (i.e. not require refrigeration)
c) The packaging or appearance of the packaging shall not indicate that the product is intended for animal use.
d) If the product is a liquid, it shall be contained within sealed packaging.

(3) Sub-clause d) does not add to risk mitigation.

(4) The commodity title 'health supplements/Chinese and Oriental medicines containing animal products' does not sufficiently describe the commodity. To align with other New Zealand legislations, 'Dietary supplements, supplemented foods and therapeutic products (including Chinese and Oriental medicines)', each have their own specific definition under the Dietary Supplements Regulations 1985 administered by MedSafe, the New Zealand Food (Supplemented Food) Standards 2016, and Section 4 of the Medicines Act 1981, will be used.

(5) The CTOd 2017 064 gives the ability for bulk health supplements/Chinese and Oriental medicines containing animal products to be directed to a transitional facility for further processing (i.e. commercial manufacturing and compounding of the bulk product into pills, tablets, capsules, liquids, syrups, oils or medicated plasters) to occur before biosecurity clearance may be given. This provision will be added to the IHS.

(6) Clause 6.2 of the *IHS INEPROIC.ALL* has the requirements for homeopathic medicines containing animal products, which may be imported from any country provided all the following requirements are met:

a) The product shall be commercially packaged
b) The product shall be labelled as being a homeopathic medicine
c) The product packaging shall indicate that the medicine is intended for human use.

Recommendation

(7) RMP proposes that dietary supplements, supplemented foods and therapeutic products (including Chinese and Oriental medicines) containing animal products from any country may be imported provided they meet the following requirements:

a) The product is commercially manufactured and compounded into pills, tablets, capsules, liquids, syrups, oils or medicated plasters; or the product must be directed to a transitional facility for further processing into pills, tablets, capsules, liquids, syrups, oils or medicated plasters.
b) The product does not require refrigeration before the package is opened.
c) The packaging indicates that the product is intended for human use.

(8) The RMP proposes that the requirements for homeopathic medicines containing animal products remain unchanged.

Schedule 1 – F03 Time and Temperature

(1) Equivalent time/temperature combinations to achieve an F0 value of 3:

Temperature at the slowest heating point of the product (°C)	Process time (min)	Temperature at the slowest heating point of the product (°C)	Process time (s)
110	40	127	46
111	32	128	37
112	25	129	29
113	20	130	23
114	16	131	18
115	13	132	15
116	11	133	12
117	9	134	9
118	7	135	7
119	6	136	6
120	5		
121	3		
122	3		
123	3		
124	3		
125	2		
126	1		