

EXPLANATORY STATEMENT

Issued by Authority of the Director of Biosecurity and the Director of Human Biosecurity

Biosecurity Act 2015

*Biosecurity (Conditionally Non-prohibited Goods) Amendment (2022 Measures No. 1)
Determination 2022*

Legislative Authority

The *Biosecurity Act 2015* (the Act) provides the regulatory framework for the management of diseases and pests that may cause harm to human, animal or plant health or the environment.

The Act also gives effect to Australia's relevant international rights and obligations, including Australia's obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement provides for Australia's obligations with respect to the Appropriate Level of Protection (ALOP), which, for Australia, is a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to a very low level, but not zero.

Subsection 174(1) of the Act provides that the Director of Biosecurity and Director of Human Biosecurity may jointly determine that specified classes of goods must not be brought or imported into Australian territory unless specified conditions (including conditions for administrative purposes) are complied with.

Under subsection 174(3) of the Act, the Director of Biosecurity and the Director of Human Biosecurity must apply the ALOP for Australia in conducting a risk assessment for the purpose of deciding whether to make a determination under subsection 174(1).

Under paragraph 541(4)(a) of the Act, in performing functions or exercising powers under the Act, including making a determination under s174, the Director of Biosecurity must have regard to the objects of the Act, which relevantly include providing for managing biosecurity risks and giving effect to Australia's international rights and obligations.

Purpose

The purpose of the *Biosecurity (Conditionally Non-prohibited Goods) Amendment (2022 Measures No. 1) Determination 2022* (the Amendment Determination) is to amend the *Biosecurity (Conditionally Non-prohibited) Goods Determination 2021* (the Goods Determination) to:

- amend existing alternative conditions for importing or bringing certain goods into Australian territory;
- amend the description and scope of certain goods for which there are existing alternative conditions;
- add new classes of goods for which alternative conditions are now specified;
- add new alternative conditions for existing classes of goods; and
- make minor technical and consequential amendments.

The purpose of the Amendment Determination is to ensure regulatory controls are put in place by specifying conditions for specified classes of goods that must be met to bring or import into Australian territory, in order to continue to manage biosecurity risks to the ALOP for Australia.

Background

The Department of Agriculture, Water and the Environment (the department) and the Department of Health co-administer the Act, which establishes the framework for biosecurity risk management. The detail and specific information requirements for certain activities under the Act are provided for in the *Biosecurity Regulation 2016* and other delegated legislation, including the Goods Determination.

Goods entering Australia carry a risk that they may introduce pests and diseases that could have a negative impact on the environment or human, plant or animal health. To regulate the bringing or importing of goods into Australian territory, the department identifies priority pests and diseases of concern and identifies the measures to be put in place to manage the biosecurity risks associated with specified classes of goods. In determining the appropriateness of the measures, the department evaluates the likelihood of entry, establishment or spread of a pest or disease within Australian territory, as well as the associated potential harm and economic consequences, in accordance with the ALOP for Australia.

Impact and Effect

The Amendment Determination ensures that biosecurity risks associated with certain goods continue to be managed to the ALOP for Australia, while reducing the regulatory impact on importers of those goods where appropriate.

The Amendment Determination ensures that the alternative conditions for specified classes of goods continue to manage the biosecurity risks to the ALOP for Australia. To achieve this, the Amendment Determination:

- clarifies and updates several existing alternative conditions for various goods;
- introduces new classes of goods for which alternative conditions are now specified;
- introduces new conditions for existing classes of goods;
- makes minor technical and consequential amendments, for example, inserting definitions for terms which are used by new or amended items in the Goods Determination;
- amends the description of classes of goods for which alternative conditions are currently specified, such that:
 - some classes of goods are broadened, meaning that more goods are able to comply with those alternative conditions in order to be imported or brought into Australian territories; and
 - the scope of some classes of goods are reduced, meaning that certain goods which could currently be imported without an import permit by complying with the relevant alternative conditions, will now only be able to be imported if covered by a valid import permit.

Some of the amendments reduce administrative burden, for both the department and the importers, without compromising the management of biosecurity risks to facilitate trade, which aligns with the Government's trade agenda.

Where increased or stricter alternative import conditions for certain goods have been specified by the Amendment Determination, the increase in regulatory burden is necessary to appropriately manage the biosecurity risk associated with the goods.

Consultation

The department has prepared the Amendment Determination, taking into account feedback and communication with industry stakeholders, through a number of channels, including alerts and change notices on the Australian Biosecurity Import Conditions system (BICON), and Import Industry Advice Notices. The Amendment Determination reflects the feedback and communication with regulated entities, stakeholders, industry and with various areas of the department.

The Department of Health was consulted on human health-related amendments, such as the amendments in relation to human milk.

The Office of Best Practice Regulation has approved a standing exemption from the Regulatory Impact Statement Preliminary Assessment (RIS) process for minor or technical amendments, or amendments that are in line with the current biosecurity policy setting and do not have more than a minor regulatory impact on industry, to the Goods Determination (ID 23368). Accordingly, a RIS has not been conducted for the Amendment Determination.

Details/Operation

Details of the Amendment Determination are set out in [Attachment](#).

This Amendment Determination is a legislative instrument for the purposes of the *Legislation Act 2003* (the Legislation Act). Subsection 174(5) of the Act provides that the Amendment Determination is not subject to disallowance. It is appropriate for the Amendment Determination to be exempt from disallowance because the decision to make a determination under subsection 174(1) of the Act relies solely on technical and scientifically-based evidence to specify conditions required to be complied with to meet the ALOP for Australia in relation to the bringing in or importation of conditionally non-prohibited goods. The conditions are based on the latest scientific and technical information available, including the absorbed dose of ionising radiation or heat treatment parameters required to inactivate diseases and kill pests posing a biosecurity risk, the health status of an exporting country relevant to goods, or internationally scientific nomenclature. This exemption from disallowance is in accordance with paragraph 44(2)(a) of the Legislation Act. As the Amendment Determination is exempt from disallowance, this also means that a Statement of Compatibility with Human Rights is not required in accordance with paragraph 15J(2)(f) of the Legislation Act and subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

The Amendment Determination commences on the day after the end of the period of 7 days beginning on the day it is registered.

Details of the *Biosecurity (Conditionally Non-prohibited Goods) Amendment (2022 Measures No. 1) Determination 2022*

Section 1—Name

This section provides that the name of the legislative instrument is the *Biosecurity (Conditionally Non-prohibited Goods) Amendment (2022 Measures No. 1) Determination 2022* (the Amendment Determination).

Section 2—Commencement

This section provides that the Amendment Determination commences on the day after the end of the period of 7 days beginning on the day it is registered.

Section 3—Authority

This section provides that the Amendment Determination is made under subsection 174(1) of the *Biosecurity Act 2015*.

Section 4—Schedules

This section provides that each instrument specified in the Schedule to the Amendment Determination is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in the Schedule has effect according to its terms.

Schedule 1—Amendments

Item 1 Section 6

Item 1 inserts three new definitions into section 6 of the *Biosecurity (Conditionally Non-prohibited Goods) Determination 2021* (the Goods Determination) for the following terms:

- **50 kGy of ionising radiation**: goods are treated with **50 kGy of ionising radiation** if the goods are treated with ionising radiation, and the absorbed dose is 50 kGy or more;
- **bioremediation product**, which means a product intended to remove, degrade, neutralise, or otherwise treat contaminants in the environment; and
- **environmental purposes**, which includes use as a bioremediation product or fertiliser. This definition is not intended to be an exhaustive list of environmental purposes.

Item 2 Section 6 (definition of *fish*)

Item 2 repeals the definition of ***fish*** from section 6 of the Goods Determination. The existing definition of ***fish*** is defined as an elasmobranch or a teleost. This definition does not accurately describe all the fish intended to be included, as it excludes jawless fish, cartilaginous fish not within the subclass *elasmobranchii*, and bony fish not within the infraclass *teleostei*.

The effect of this amendment is that the term *fish* in the Goods Determination will now have its ordinary meaning. This is broad enough to encompass elasmobranchs, teleosts, jawless fish, all cartilaginous fish and bony fish, and any other aquatic animal which falls within the ordinary definition of a *fish*.

Item 3 Section 6

Item 3 inserts a new definition into section 6 of the Goods Determination for ***listed microalgae***, which means microalgae of a species that is listed in the List of Microalgae with Alternative Conditions for Import prepared by the Director of Biosecurity and published on the Agriculture Department's website, as existing from time to time.

The note below this definition clarifies that a species of microalgae is listed in this list if the Director of Biosecurity is satisfied that the level of biosecurity risk associated with the microalgae of that species is acceptable.

Item 3 also inserts a new definition in section 6 for ***listed semi-synthetic, fermentation-derived active ingredient***, which means an ingredient that is listed in the Semi-synthetic, Fermentation-derived Active Ingredients List prepared by the Director of Biosecurity and published on the Agriculture Department's website, as existing from time to time.

The note below this definition clarifies that an ingredient is listed in this list if the Director of Biosecurity is satisfied that biosecurity risks associated with the ingredient can be managed to an acceptable level.

The lists outlined in this item will be publicly available on the Agriculture Department's website (<https://www.awe.gov.au/biosecurity-trade/policy/legislation#biosecurity-legislation>).

Item 4 Paragraph 11(2)(c)

Item 4 omits the words 'of animal origin' in paragraph 11(2)(c) of the Goods Determination and substitutes it with 'derived from animals'.

Division 1 of Part 2 of the Goods Determination sets out the alternative conditions applying to certain classes of goods relating to animals, plants, biological material and infectious agents. Section 11 sets out the classes of goods relating to animals, plants, biological material and infection agents to which Division 1 of Part 2 of the Goods Determination applies. Subsection 11(2) lists exceptions to those classes of goods.

The effect of the amendment to paragraph 11(2)(c) is to provide that one of the exceptions is a dye or colouring agent 'derived from animals' that is used on, or is an ingredient of, goods included in a class of goods to which Division 1 of Part 2 applies. The amendments made by this Schedule replace all references in the Goods Determination to 'of animal origin' to 'derived from animals'. This is to align with the best practice for legislative drafting and has no practical change to the alternative conditions and has no effect on the management of biosecurity risk.

Item 5 After paragraph 11(2)(e)

Item 5 inserts a new paragraph 11(2)(ea) after paragraph 11(2)(e) of the Goods Determination to ensure that microscope slides are not a class of goods to which Division 1 of Part 2 of the Goods Determination applies.

Division 1 of Part 2 of the Goods Determination sets out the conditions applying to certain classes of goods relating to animals, plants, biological material and infectious agents. Section 11 of the Goods Determination lists the classes of goods to which this Division applies, including goods containing, or made of, animal material. Subsection 11(2) lists exceptions to those classes of goods.

This amendment provides that microscope slides referred to in new section 52A of the Goods Determination, as inserted by item 57 of this Schedule, is not a class of goods to which Division 1 of Part 2 of the Goods Determination applies. The purpose of this amendment is to ensure that only the new conditions set out in Division 2 of Part 2 of the Goods Determination apply to these microscope slides.

Item 6 Paragraphs 15(1)(b)

Item 6 omits the words ‘use as a bioremedial agent or fertiliser’ in paragraph 15(1)(b) of the Goods Determination and substitutes it with ‘environmental purposes’.

The effect of this amendment is to provide in paragraph 15(1)(b) of the Goods Determination that the alternative conditions in section 15 relating to dead animals, animal parts and related goods do not apply to those goods if they are intended for environmental purposes (instead of the current wording which refers to the intention to use the goods as a bioremedial agent or fertiliser).

‘Environmental purposes’ is defined in section 6 as amended by item 1 of this Schedule to include use as a bioremediation product or fertiliser. ‘Bioremediation product’ is defined as a product intended to remove, degrade, neutralise, or otherwise treat contaminants in the environment. This amendment clarifies that the alternative conditions in section 15 of the Goods Determination do not apply to goods that are intended for use as a bioremediation product or fertiliser.

Item 7 Subsection 15(2) (table item 2, column 2, paragraphs (c) and (d))

Item 7 omits the words ‘gamma irradiation to a level that achieves a minimum of 50 kGray’ from paragraphs (c) and (d) of column 2 of table item 2 under subsection 15(2) of the Goods Determination and substitutes it with ‘50 kGy of ionising radiation’.

Current paragraphs (c) and (d) refer to goods being treated with gamma irradiation to a level that achieves a minimum of 50 kGray, in the context of the alternative conditions that apply to goods made with rawhide.

The effect of this amendment is to provide instead that to meet the alternative condition, the goods made with rawhide must be treated with 50 kGy of ionising radiation. Section 6 as amended by item 1 of this Schedule provides that goods are treated with ‘50kGy of ionising radiation’ if the goods are treated with ionising radiation and the absorbed dose is 50kGy or

more. Ionising radiation covers all ionising radiation methods, and does not limit this to gamma irradiation only. Ionising radiation is identified as an effective measure to manage biosecurity risk. This amendment will allow for any ionising radiation method to be utilised without unnecessarily restricting the method to gamma irradiation.

Item 8 Subsection 15(2) (after table item 12)

Item 8 inserts new table item 12A into subsection 15(2) of the Goods Determination. This new table item sets out the alternative conditions for oyster shells that are not part of manufactured goods. The new alternative conditions require that either:

- the goods have been treated with 50 kGy of ionising radiation at a facility that the Director of Biosecurity is satisfied can treat the goods so that biosecurity risks associated with the goods are managed to an acceptable level, and are accompanied by written evidence stating the matter (subparagraphs (a)(i) and (a)(ii)); or
- the goods are to be treated in accordance with an approved arrangement, while subject to biosecurity control, with one of the following treatments: 50 kGy of ionising radiation; heat treatment in an autoclave at 121°C, 103 kPa for 15 minutes; or heat treatment in an autoclave at 134°C, 214 kPa for 4 minutes (subparagraphs (b)(i), (b)(ii) and (b)(iii)).

Currently, oyster shells that are not part of manufactured products may only be brought or imported into Australian territory if accompanied by an import permit. The biosecurity risk associated with these goods can be managed to an acceptable level with alternative import conditions. The treatments set out in the new alternative import conditions are aimed at reducing the likelihood of entry of pests and diseases associated with oyster shells, or inactivate, or partially inactivate pests and diseases associated with oyster shells to achieve Australia's ALOP, which requires that biosecurity risks are reduced to a very low level, but not zero. Accordingly, it is appropriate for these goods to be brought or imported into Australian territory without an import permit if they meet the relevant alternative conditions.

Item 9 Subsection 15(2) (table item 13, column 1)

Item 9 omits the words 'covered by another item in this table' in column 1 of table item 13 under subsection 15(2) of the Goods Determination, and substitutes 'to which column 1 of another item in this table applies'.

The effect of this amendment is to provide that the alternative condition to allow goods to be brought or imported into Australian territory without an import permit at table item 13 applies to dead animals, animal parts, animal secretions or animal tissue, other than goods to which column 1 of another item in the table applies.

This is a technical amendment which does not change the application of the alternative condition at table item 13 but clarifies that the goods being referred to are those listed in column 1 of another item of the table.

Item 10 Subsection 15(2) (table item 13, column 2, after paragraph (c))

Item 10 inserts a new paragraph (ca) in column 2 of table item 13 under subsection 15(2) of the Goods Determination. This table item specifies alternative conditions for dead animals,

animal parts, animal secretions or animal tissue, other than goods covered by another item in the table.

This item inserts a new alternative condition to allow such goods to be brought or imported into Australian territory without an import permit if the goods have been completely plastinated using curable polymers and are accompanied by a certificate from the laboratory or facility that plastinated the goods stating that fact.

Existing paragraph (d) of this table item requires goods to be in a sealed container and plastinated to meet one of the existing alternative conditions to bring or import the goods into Australian territory without an import permit. The effect of this item is that plastinated goods brought or imported into Australian territory without an import permit are no longer required to be in a sealed container or meet the other requirements outlined in existing paragraph (d) of this table item if they meet the alternative condition in new paragraph (ca). This new alternative condition will be able to manage the biosecurity risk associated with plastinated goods to an acceptable level.

Item 11 Subsection 15(2) (table item 13, column 2, subparagraphs (d)(ii) and (iii))

Item 11 repeals subparagraphs (d)(ii) and (d)(iii) from column 2 of table item 13 under subsection 15(2) of the Goods Determination, and substitutes them with new subparagraphs (d)(ii) and (d)(iii). This table item specifies alternative conditions for dead animals, animal parts, animal secretions or animal tissue, other than goods covered by another item in the table.

The new alternative conditions inserted by this item require that:

- the goods have been preserved or fixed using a method that the Director of Biosecurity is satisfied is appropriate to manage the biosecurity risks associated with the goods to an acceptable level; and
- the goods are accompanied by a certificate from the laboratory or other facility that preserved or fixed the goods stating that the aforementioned condition has been met.

These new alternative conditions must be complied with, in addition to the existing alternative conditions in subparagraphs (d)(i), (d)(iv) and (d)(v), in order to bring or import the goods into Australian territory without an import permit. The existing alternative conditions in subparagraphs (d)(ii) and (iii) limit the number of approved preservation and fixation methods to that listed in the determination. The new substituted alternative conditions address biosecurity risks while also allowing for flexibility in the preservative or fixation method as scientific knowledge improves and acceptable new methods are developed.

Item 12 Subsection 15(2) (table item 13, column 2, paragraph (e))

Item 12 omits ‘(other than bees)’ from paragraph (e) of column 2 of table item 13 under subsection 15(2) of the Goods Determination. This table item provides alternative conditions for dead animals, animal parts, animal secretions or animal tissue, other than goods covered by another item in this table.

The existing alternative condition at paragraph (e) of this table item provides for dead insects or arachnids, but excludes bees. This amendment ensures that the alternative condition

outlined in paragraph (e) also applies to dead bees (as part of dead insects), along with dead insects generally and arachnids.

Item 13 Subsection 15(2) (table item 15, column 2, paragraph (b))

Item 13 omits ‘a health certificate’ in paragraph (b) of column 2 of table item 15 under subsection 15(2) in the Goods Determination and substitutes it with ‘a certificate given by an official of the government of New Zealand’. Table item 15 provides an alternative condition for untanned and partially processed game trophies, hides or skins that are not derived from avian animals and that are from New Zealand.

This amendment clarifies the evidentiary requirements for the relevant goods. There are other government certifications, for example, certificates issued under the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES), that are acceptable as evidence to show that the biosecurity risk associated with the goods from New Zealand have been managed to an acceptable level. This amendment provides greater flexibility for importers to meet this evidentiary requirement.

Item 14 Paragraph 16(1)(b)

Item 14 omits the words ‘use as a bioremedial agent or fertiliser’ in paragraph 16(1)(b) of the Goods Determination and substitutes it with ‘environmental purposes’.

The effect of this amendment is to provide in paragraph 16(1)(b) of the Goods Determination that the alternative conditions in section 16 relating to dead aquatic animals, aquatic animal parts and related goods do not apply to those goods if they are intended for environmental purposes (instead of the current wording which refers to the intention to use the goods as a bioremedial agent or fertiliser).

As with item 6 of this Schedule, all references in the Goods Determination to ‘use as a bioremedial agent or fertiliser’ are being replaced with ‘environmental purposes’, which is defined in section 6 as amended by item 1 of this Schedule to include use as a bioremediation product or fertiliser.

Item 15 Subsection 16(2) (table item 1)

Item 15 repeals table item 1 in subsection 16(2) of the Goods Determination and substitutes it with a new table item 1. Existing table item 1 provides alternative conditions for teleost fish, other than fish of the family Salmonidae or Plecoglossidae. The new table item 1 provides new alternative conditions for bony fish (*Osteichthyes*), other than members of the family Salmonidae or the genus Plecoglossus. This amendment ensures that the alternative conditions manage biosecurity risks associated with the goods to an acceptable level.

To comply with the alternative conditions for these goods, any of the following must be met:

- the goods are eviscerated or processed further than evisceration; are in a quantity of not more than 5 kilograms; and are brought in as baggage (subparagraphs (a)(i), (ii) and (iii)); or
- the goods have been processed into one of the following consumer-ready forms:
 - cutlets (including the central bone and external skin, and excluding fins), each weighing no more than 450 grams (subparagraph (b)(i)); or

- skinless fillets (excluding the belly flap and all bone except the pin bones) of any weight (subparagraph (b)(ii)); or
- skin-on fillets (excluding the belly flap and all bones except the pin bones) each weighing no more than 450 grams (subparagraph (b)(iii)); or
- eviscerated, headless fish, each weighing no more than 450 grams (subparagraph (b)(iv)); or
- eviscerated, headless fish that have been salted, dried or smoked (subparagraph (b)(v)); or
- products that have been processed further than the stage described in subparagraphs (i) to (v) (subparagraph (b)(vi)); or
- the goods are commercially canned; and are shelf-stable (subparagraphs (c)(i) and (c)(ii)); or
- all of the following:
 - the goods have been processed in premises approved by, and under the control of, a body listed in the List of Overseas Authorities—Aquatic Animals for Import (subparagraph (d)(i)); and
 - the goods have been eviscerated, the head and gills removed and internal and external surfaces thoroughly washed (subparagraph (d)(ii)); and
 - the goods have been inspected under the supervision of, or in accordance with systems approved by, a body listed in the List of Overseas Authorities—Aquatic Animals for Import (subparagraph (d)(iii)); and
 - the goods are free from visible lesions associated with infectious disease (subparagraph (d)(iv)); and
 - the goods are accompanied by a certificate from a body listed in the List of Overseas Authorities—Aquatic Animals for Import stating the matters referred to in subparagraphs (i) to (iv) (subparagraph (d)(v)); or
- the goods can be stored at room or ambient temperature and do not need to be refrigerated or frozen before being used; and are for personal use (subparagraphs (e)(i) and (e)(ii)).

Currently, some terminology for fish, for example, teleost fish, is inadvertently creating confusion for importers. This amendment to the goods description is technical in nature to align the terminology to internationally scientific nomenclature and to clarify the genus of goods excluded from this table item.

The existing alternative conditions for the relevant goods do not specify the processing requirements for consumer ready forms of fish. They only require that the goods be processed to an acceptable level to manage biosecurity risks. They also do not specify the health certification requirements for these goods. To ensure clear and consistent compliance with the conditions, it is appropriate to include more detail as to what an acceptable level of processing for this class of fish is, as well as what details are required on the health certification accompanying this class of fish.

The term ***List of Overseas Authorities—Aquatic Animals for Import*** used in this table item is defined in section 6 of the Goods Determination to mean the list with that name prepared by the Director of Biosecurity and published on the Agriculture Department’s website (<https://www.awe.gov.au/biosecurity-trade/policy/legislation#biosecurity-legislation>), as existing from time to time.

Item 16 Subsection 16(2) (cell at table item 2, column 1)

Item 16 repeals the goods description of ‘teleost fish from New Zealand’ in the cell at column 1 of table item 2 under subsection 16(2) of the Goods Determination and substitutes it with bony fish (*Osteichthyes*) from New Zealand, other than members of the family Salmonidae or the genus *Plecoglossus*.

The use of the term ‘teleost fish’ was inadvertently creating confusion for importers. This amendment to the goods description is technical in nature to align the terminology to internationally scientific nomenclature and to clarify the genus of goods excluded from this table item.

Item 17 Subsection 16(2) (table item 4)

Item 17 repeals table item 4 under subsection 16(2) of the Goods Determination. This table item set out the alternative conditions for non-salmonid finfish or finfish product.

Table item 4 is no longer required due to the amendment being made by item 14 of this Schedule, which replaces table item 1 under subsection 16(2) with a new table item 1. It is intended that the goods described in new table item 1 will also cover non-salmonid finfish and finfish product, and the alternative conditions listed for table item 1 will also apply to these goods.

Item 18 Subsection 16(2) (cell at table item 5, column 1)

Item 18 repeals the cell at column 1 of table item 5 under subsection 16(2) of the Goods Determination and substitutes the cell with ‘fish or fish products of the family Salmonidae or the genus *Plecoglossus*, other than roe or caviar; or fish oil.’

The effect of this amendment is to replace the reference to ‘salmon oil’ with a reference to ‘fish oil’. This amendment is technical in nature to clarify the goods description in table item 5. There is no change to the class of goods intended to be covered, and no change to the alternative conditions.

Item 19 Subsection 16(2) (table item 6, column 1)

Item 19 omits the word ‘*Plecoglossidae*’ in column 1 of table item 6 under subsection 16(2) of the Goods Determination and substitutes it with ‘the genus *Plecoglossus*’. Existing table item 6 currently provides alternative conditions for roe or caviar of the family Salmonidae or *Plecoglossidae*.

This is a technical amendment to clarify the genus of goods intended to be covered by this table item.

Item 20 Subsection 16(2) (after table item 7)

Item 20 inserts two new table items after table item 7 under subsection 16(2) of the Goods Determination.

New table item 7A provides new alternative conditions for fish oil from New Zealand, other than fish oil derived from members of the family Salmonidae or the genus Plecoglossus. This amendment ensures that the alternative conditions manage biosecurity risks associated with the goods to an acceptable level.

To comply with the alternative conditions of these goods, all of the following must be met:

- the fish from which the goods were derived were caught in the exclusive economic zone of New Zealand (as defined in the United Nations Convention on the Law of the Sea), or in international waters adjacent to the exclusive economic zone of New Zealand (paragraph (a)); and
- the goods are accompanied by a certificate given by an official of the government of New Zealand stating that the goods were caught as described in paragraph (a) (paragraph (b)); and
- the goods are free from plant or algae material and are accompanied by a declaration by the manufacturer of the goods stating that fact (paragraph (c)); and
- the goods are packaged in containers that are new and are accompanied by a declaration by the manufacturer of the goods stating that fact; or in containers that have been cleaned and inspected for cleanliness and are accompanied by a cleanliness certificate stating that fact (subparagraphs (d)(i) and (d)(ii)).

New table item 7B provides new alternative conditions for fish oil, other than fish oil derived from members of the family Salmonidae or the genus Plecoglossus. This amendment ensures that the alternative conditions manage biosecurity risks associated with the goods to an acceptable level.

To comply with the alternative conditions of these goods, all of the following must be met:

- the goods were not derived from terrestrial or avian animals (paragraph (a)); and
- the goods are free from plant or algae material (paragraph (b)); and
- the goods have been heated to a minimum of 85°C for at least 15 minutes, or 80°C for at least 20 minutes (subparagraph (c)(i) and (c)(ii)); and
- the goods are packaged in containers that are new and are accompanied by a declaration by the manufacturer of the goods stating that fact; or in containers that have been cleaned and inspected for cleanliness and are accompanied by a cleanliness certificate stating that fact (subparagraphs (d)(i) and (d)(ii)); and
- the goods are accompanied by:
 - a certificate from a body listed in the List of Overseas Authorities—Aquatic Animals for Import stating the matter referred to in paragraph (a) (subparagraph (e)(i)); or
 - a declaration by the manufacturer of the goods, endorsed by a body listed in the List of Overseas Authorities—Aquatic Animals for Import, stating the matter referred to in paragraph (a) (subparagraph (e)(ii)); and
- the goods are accompanied by a declaration by the manufacturer of the goods stating the matters referred to in paragraphs (b) and (c) (paragraph (f)).

The term ***List of Overseas Authorities—Aquatic Animals for Import*** used in new table item 7B is defined in section 6 of the Goods Determination to mean the list with that name prepared by the Director of Biosecurity and published on the Agriculture Department's

website (<https://www.awe.gov.au/biosecurity-trade/policy/legislation#biosecurity-legislation>), as existing from time to time.

The biosecurity risks associated with these goods can be managed to an acceptable level with these new alternative import conditions. Accordingly, it is appropriate to include alternative conditions for these goods to achieve Australia's ALOP, which requires that biosecurity risks are reduced to a very low level, but not zero.

Item 21 Paragraph 17(1)(b)

Item 21 omits the words 'use as bioremedial agents or fertiliser' in paragraph 17(1)(b) of the Goods Determination and substitutes it with 'environmental purposes'.

The effect of this amendment is to provide in paragraph 17(1)(b) of the Goods Determination that the alternative conditions in section 17 relating to meat or meat products do not apply to those goods if they are intended for environmental purposes (instead of the current wording which refers to the intention to use the goods as a bioremedial agent or fertiliser).

As with item 6 of this Schedule, all references in the Goods Determination to 'use as a bioremedial agent or fertiliser' are being replaced with 'environmental purposes', which is defined in section 6 as amended by item 1 of this Schedule to include use as a bioremediation product or fertiliser.

Item 22 Subsection 17(2) (table item 2, column 1)

Item 22 inserts "goods that are, or that contain" after "other than" in column 1 of table item 2 in subsection 17(2) of the Goods Determination.

Table item 2 deals with meat or meat products from New Zealand, other than pork or avian meat. This amendment clarifies that goods that are, or that contain, pork or avian meat are excluded from this table item. These products are covered by new table item 2A inserted by item 23 of this Schedule.

Item 23 Subsection 17(2) (after table item 2)

Item 23 inserts new table item 2A after table item 2 under subsection 17(2) of the Goods Determination. New table item 2A provides alternative conditions for meat or meat products from New Zealand that are, or that contain either pork or avian meat.

To comply with the alternative conditions of these goods, all of the following must be met:

- that the animals from which the goods were derived were of Australian or New Zealand origin (paragraph (a)); and
- the animals from which the goods were derived are processed in premises under the supervision of the Ministry of the government of New Zealand with responsibility for primary industries (paragraph (b)); and
- the goods have been retorted (paragraph (c)); and
- the goods are accompanied by a health certificate stating the matters referred to in paragraphs (a) to (c) (paragraph (d)).

These are appropriate alternative conditions for pork and avian meat products from New Zealand to manage the biosecurity risks associated with these goods to an acceptable level.

The term *health certificate* used in new table item 2A is defined in section 6 of the Goods Determination to mean, for an animal or part of an animal that is to be brought or imported into Australian territory from a place outside Australian territory, a certificate for the animal or part of the animal that is in a form approved by the Director of Biosecurity, and has been signed by an official veterinarian from the place outside Australian territory.

Item 24 Subsection 17(2) (table item 8, column 1)

Item 24 omits the words ‘covered by another item in this table’ in column 1 of table item 8 in subsection 17(2) of the Goods Determination, and substitutes ‘to which column 1 of another item in this table applies’.

The effect of this amendment is to provide that the alternative conditions to allow goods to be brought or imported into Australian territory without an import permit at table item 8 applies to meat or meat products, other than goods to which column 1 of another item in the table applies.

This is a technical amendment which does not change the application of the alternative condition at table item 8, but clarifies that the goods being referred to are those listed in column 1 of another item of the table.

Item 25 Paragraphs 18(1)(b) and 19(1)(b)

Item 25 omits the words ‘use as bioremedial agents or fertiliser’ in paragraphs 18(1)(b) and 19(1)(b) of the Goods Determination and substitutes with ‘environmental purposes’.

The effect of this amendment is to provide in paragraphs 18(1)(b) and 19(1)(b) of the Goods Determination that the alternative conditions in section 18 and 19 relating to dairy products and eggs or egg products do not apply to those goods if they are intended for environmental purposes (instead of the current wording which refers to the intention to use the goods as a bioremedial agent or fertiliser).

As with item 6 of this Schedule, all references in the Goods Determination to ‘use as a bioremedial agent or fertiliser’ are being replaced with ‘environmental purposes’, which is defined in section 6 as amended by item 1 of this Schedule to include use as a bioremediation product or fertiliser.

Item 26 Subsection 19(2) (cell at table item 2, column 2)

Item 26 repeals the cell in column 2 of table item 2 under subsection 19(2) of the Goods Determination and replaces it with a new cell in column 2 of table item 2. Table item 2 provides the alternative conditions for egg products, goods that include egg as an ingredient, or goods that contain egg.

This amendment replicates the current alternative conditions applying to these goods, while also adding a third alternative condition for pasta or noodles containing egg or egg product derived from chickens only. The new cell in table item 2 provides that to comply with the

alternative conditions for egg products, goods that include egg as an ingredient or goods that contain egg, any of the following must be met:

- the goods contain less than 10% by weight (other than added water) of egg or egg product, and do not contain discernible pieces of egg (subparagraphs (a)(i) and (a)(ii)); or
- the goods:
 - have been processed so that they are not whole eggs (subparagraph (b)(i)); and
 - are shelf-stable (subparagraph (b)(ii)); and
 - are in a quantity of not more than 1 kilogram or 1 litre (subparagraph (b)(iii)); and
 - are for personal use (subparagraph (b)(iv)); or
- the goods:
 - are pasta or noodles (subparagraph (c)(i)); and
 - contain egg or egg product that was derived from chickens (*Gallus gallus domesticus*) only (subparagraph (c)(ii)); and
 - have been heated to a minimum core temperature of 70°C for at least 8.2 minutes (or equivalent) in a commercial heating process (subparagraph (c)(iii)); and
 - are accompanied by a health certificate, or a declaration from the manufacturer of the goods that has been endorsed by an official veterinarian, stating the matters referred to in subparagraphs (ii) and (iii) (subparagraph (c)(iv)).

The term **health certificate** used in the new alternative conditions set out in table item 2 is defined in section 6 of the Goods Determination to mean, for an animal or part of an animal that is to be brought or imported into Australian territory from a place outside Australian territory, a certificate for the animal or part of the animal that is in a form approved by the Director of Biosecurity, and has been signed by an official veterinarian from the place outside Australian territory.

The effect of this amendment is to provide an alternative condition for pasta and noodles that contain egg or egg products derived from chickens only. This alternative condition manages the biosecurity risks associated with the goods to an acceptable level in a manner to achieve Australia's ALOP, which requires that biosecurity risks are reduced to a very low level, but not zero. Accordingly, it is appropriate for these goods to be able to be brought or imported into Australian territory without an import permit if they meet the relevant alternative conditions.

Item 27 Subsection 19(2) (after table item 2)

Item 27 inserts two new table items after table item 2 in subsection 19(2) of the Goods Determination.

New table item 2A provides alternative conditions for the following goods from New Zealand: egg products, goods that include eggs as an ingredient and goods that contain eggs.

To comply with the alternative conditions of these goods, all of the following must be met:

- the eggs included or contained in the goods, or from which the goods were produced, were derived from chickens (*Gallus gallus domesticus*) that were hatched, raised and continuously resident in New Zealand or Australia (paragraph (a)); and
- the goods were processed in a manufacturing facility that does not handle egg products, or goods that include or contain eggs, other than egg products that are derived from chickens (*Gallus gallus domesticus*) that were hatched and raised and continuously resident in New Zealand or Australia (paragraph (b)); and
- New Zealand is free from highly pathogenic avian influenza and Newcastle disease (paragraph (c)); and
- the egg components of the goods have been heat treated using a method approved by the Director of Biosecurity to manage the biosecurity risks associated with the goods to an acceptable level (paragraph (d)); and
- the goods are accompanied by a certificate given by an official of the government of New Zealand stating the matters referred to in paragraphs (a) to (d) above (paragraph (e)).

There are currently no alternative conditions for commercial imports of egg products from New Zealand specifically. The biosecurity risks associated with these goods can be managed to an acceptable level with these new alternative import conditions. Accordingly, it is appropriate to provide alternative conditions for these goods to achieve Australia's ALOP, which requires that biosecurity risks are reduced to a very low level, but not zero.

Item 27 also inserts new table item 2B, which provides alternative conditions for lysozyme. To comply with the alternative condition for these goods, all of the following must be met:

- the goods were produced from egg white (albumen) that was derived from chickens (*Gallus gallus domesticus*) only (paragraph (a)); and
- the egg white has been treated, resulting in the egg white meeting one of the following:
 - a pH of between 10 and 14 for at least 24 hours and a pH of between 0 and 3.5 for at least 13 hours (subparagraph (b)(i));
 - a pH of between 10.5 and 14 for at least 72 hours and a pH of between 0 and 3.6 for at least 72 hours (subparagraph (b)(ii));
 - a pH of between 0 and 3.5 for at least 15 hours followed by heat treatment of 65°C for at least 5 days (subparagraph (b)(iii)); and
- the goods are accompanied by a health certificate, or a declaration from the manufacturer of the goods that has been endorsed by an official veterinarian, stating the matters referred to in paragraphs (a) and (b) (paragraph (c)).

The term **health certificate** used in the new alternative conditions set out in table item 2B is defined in section 6 of the Goods Determination to mean, for an animal or part of an animal that is to be brought or imported into Australian territory from a place outside Australian territory, a certificate for the animal or part of the animal that is in a form approved by the Director of Biosecurity, and has been signed by an official veterinarian from the place outside Australian territory.

There are currently no alternative conditions for lysozyme derived from eggs specifically. The biosecurity risks associated with these goods can be managed to an acceptable level with these new alternative import conditions. Accordingly, it is appropriate to include alternative

conditions for these goods to achieve Australia's ALOP, which requires that biosecurity risks are reduced to a very low level, but not zero.

Item 28 Section 20 (at the end of the cell at table item 3, column 1)

Item 28 inserts new goods into the cell at column 1 of table item 3 under section 20 of the Goods Determination. These goods are meal or flour mixes, wholefood bars and balls, couscous meal mixes and fruit and seed trail mixes.

The effect of this amendment is that the alternative conditions already outlined in table item 3 under section 20 will apply to meal or flour mixes, wholefood bars and balls, couscous meal mixes and fruit and seed trail mixes, in addition to those already described in this table item. The alternative conditions for table item 3 are that the goods have been commercially prepared and packaged and are ready for retail sale. The biosecurity risks associated with these goods can be managed to an acceptable level with the alternative conditions to achieve Australia's ALOP, which requires that biosecurity risks are reduced to a very low level, but not zero.

Item 29 Section 20 (table item 6)

Item 29 repeals table item 6 under section 20 of the Goods Determination and substitutes it with a new table item 6. This amendment provides alternative conditions for noodles or pasta that contain, or include as an ingredient, meat-based flavouring products.

To comply with the alternative conditions of these goods, the goods must be shelf-stable, for instant use and for personal use.

The term *shelf-stable* used in the new alternative conditions set out in table item 6 is defined in section 6 of the Goods Determination to have the meaning given by section 10, which states that goods are *shelf-stable*, if:

- the goods have been commercially manufactured; and
- the goods have been packaged by the manufacturer; and
- the goods are in that package; and
- the package has not been opened or broken; and
- the goods are able to be stored in the package at room or ambient temperature; and
- the goods do not require refrigeration or freezing before the package is opened.

The meaning of *instant use* is defined in section 6 of the Goods Determination to have the meaning given by section 8, which states that goods for human consumption are for *instant use* if:

- the goods have been commercially manufactured and packaged; and
- the amount in the package is intended to be a single serving; and
- the goods require very little treatment or preparation to be used as intended by the manufacturer.

The effect of this amendment is to remove the reference to noodles or pasta that contain or include eggs or egg products as an ingredient, as this is now covered by table item 2 under subsection 19(2) of the Goods Determination as amended by item 26 of this Schedule. The alternative conditions applying to noodles or pasta that contain, or include as an ingredient,

meat-based flavouring products are the same as previously provide for in table item 6 of section 20 of the Goods Determination.

Item 30 Paragraph 22(1)(b)

Item 30 omits the words ‘use as bioremedial agents or fertiliser’ in paragraph 22(1)(b) of the Goods Determination and substitutes it with ‘environmental purposes’.

The effect of this amendment is to provide in paragraph 22(1)(b) of the Goods Determination that the alternative conditions in section 22 relating to honey and bee products do not apply to those goods if they are intended for environmental purposes (instead of the current wording which refers to the intention to use the goods as a bioremedial agent or fertiliser).

As with item 6 of this Schedule, all references in the Goods Determination to ‘use as a bioremedial agent or fertiliser’ are being replaced with ‘environmental purposes’, which is defined in section 6 as amended by item 1 of this Schedule to include use as a bioremediation product or fertiliser.

Item 31 Section 23 (table item 3, column 2, paragraph (e))

Item 31 omits the words ‘gamma irradiation to a level that achieves a minimum of 50 kGray’ in paragraph (e) of column 2, in table item 3, in section 23 and substitutes it with ‘50 kGy of ionising radiation’.

The effect of this amendment is to provide that the alternative condition in item 3 relating to rawhide chews that are derived from porcine animals and are for consumption by domestic dogs can be met where the goods are treated, while subject to biosecurity control, with 50 kGy of ionising radiation.

As with item 7 of this Schedule, all references in the Goods Determination to ‘gamma irradiation to a level that achieves a minimum of 50 kGray’ are being replaced with ‘50kGy of ionising radiation’. The definition in section 6 as amended by item 1 of this Schedule provides that goods are treated with **50 kGy of ionising radiation** if the goods are treated with ionising radiation and the absorbed dose is 50 kGy or more.

Item 32 Section 23 (after table item 3)

Item 32 inserts new table item 3A in section 23 of the Goods Determination.

New table item 3A sets out alternative conditions for fish oil from New Zealand, other than fish oil derived from members of the family Salmonidae or the genus Plecoglossus.

To comply with the alternative conditions of these goods, all of the following must be met:

- the fish from which the goods are derived are caught in the exclusive economic zone of New Zealand (as defined in the United Nations Convention on the Law of the Sea), or in international waters adjacent to the exclusive economic zone of New Zealand (paragraph (a)); and

- the goods are accompanied by a certificate given by an official of the government of New Zealand stating that the goods were caught as described in paragraph (a) (paragraph (b)); and
- the goods are free from plant or algae material and are accompanied by a declaration by the manufacturer of the goods stating that fact (paragraph (c)); and
- the goods are packaged in containers that are new and are accompanied by a declaration by the manufacturer of the goods stating that fact, or in containers that have been cleaned and inspected for cleanliness and are accompanied by a cleanliness certificate stating that fact (paragraph (d)).

The purpose of this amendment is to provide alternative conditions that manage biosecurity risks associated with fish oil from New Zealand to the appropriate level of protection for Australia. Fish oil derived from fish caught in the exclusive economic zone of New Zealand are generally subject to less stringent conditions than fish oil derived from fish from other countries because the animal health status of New Zealand is generally more closely aligned to that of Australia. Hence, it is appropriate to include new alternative conditions for these goods.

New table item 3B provides alternative conditions for fish oil, other than fish oil derived from members of the family Salmonidae or the genus *Plecoglossus*.

To comply with the alternative conditions of these goods, all of the following must be met:

- the goods are not derived from terrestrial or avian animals (paragraph (a)); and
- the goods are free from plant or algae material (paragraph (b)); and
- the goods have been heated to a minimum of either 85°C for at least 15 minutes or 80°C for at least 20 minutes (paragraph (c)); and
- the goods are packaged in containers that are new and are accompanied by a declaration from the manufacturer of the goods stating that fact, or in containers that are clean and that have been inspected for cleanliness and are accompanied by a cleanliness certificate stating that fact (paragraph (d)); and
- the goods are accompanied by a certificate from a body listed in the List of Overseas Authorities—Aquatic Animals for Import stating the matter referred to in paragraph (a) or a declaration by the manufacturer of the goods, endorsed by a body listed in the List of Overseas Authorities—Aquatic Animals for Import, stating the matter referred to in paragraph (a) (subparagraphs (e)(i) and (e)(ii)); and
- the goods are to be accompanied by a declaration by the manufacturer, stating that the matters referred to in paragraphs (b) and (c) (paragraph (f)).

The term ***List of Overseas Authorities—Aquatic Animals for Import*** used in new table item 3B is defined in section 6 of the Goods Determination to mean the list with that name prepared by the Director of Biosecurity and published on the Agriculture Department’s website (<https://www.awe.gov.au/biosecurity-trade/policy/legislation#biosecurity-legislation>), as existing from time to time.

These alternative conditions manage biosecurity risks associated with the goods to an acceptable level.

Item 33 Section 23 (cell at table item 5, column 1)

Item 33 repeals the goods description at column 1 of table item 5 under section 23 of the Goods Determination and substitutes it with dead bony fish (*Osteichthyes*) (other than members of the family Salmonidae or the genus *Plecoglossus*), or cephalopods, from New Zealand.

The effect of this amendment is to apply the existing alternative conditions in table item 5 to dead bony fish and cephalopods from New Zealand and exclude members of the family Salmonidae or the genus *Plecoglossus* from the relevant goods. The amendment clarifies terminology used for fish, some of which has inadvertently created confusion for importers. This amendment to the goods description is technical in nature to align the terminology to internationally scientific nomenclature and to clarify the genus of goods excluded from this table item.

Item 34 Section 23 (table item 8, column 2)

Item 34 omits the words ‘gamma irradiation to a level that achieves a minimum of 50 kGray’ in column 2 of table item 8 under section 23 of the Goods Determination and substitutes it with ‘50 kGy of ionising radiation’.

The effect of this amendment is to provide that the alternative condition in table item 8 relating to marine molluscs (other than oysters or snails) can be met where the goods are treated in Australian territory, while subject to biosecurity control, with 50 kGy of ionising radiation.

As with item 7 of this Schedule, all references in the Goods Determination to ‘gamma irradiation to a level that achieves a minimum of 50 kGray’ are being replaced with ‘50kGy of ionising radiation’. The definition in section 6 as amended by item 1 of this Schedule provides that goods are treated with **50 kGy of ionising radiation** if the goods are treated with ionising radiation and the absorbed dose is 50 kGy or more.

Item 35 Section 23 (cell at table item 9, column 2)

Item 35 repeals the cell at column 2 of table item 9 under section 23 of the Goods Determination. Table item 9 deals with goods that are food for consumption by pet fish in enclosed aquariums or ponds.

This amendment inserts amended alternative conditions relating to goods that contain listed microalgae and to treatments for the goods. To comply with the alternative conditions of these goods, all of the following must be met:

- the goods do not contain materials derived from terrestrial or avian animals, or fish of the family Salmonidae (subparagraphs (a)(i) and (a)(ii)); and
- the goods do not contain whole seeds, viable plant materials or microalgae, other than listed microalgae (subparagraphs (b)(i), (b)(ii) and (b)(iii)); and
- if the goods contain listed microalgae - none of the following were used in producing the listed microalgae:
 - water sourced from intensive animal production (including an aquaculture system, other than the aquaculture system in which the microalgae was

- produced) or from an animal or human effluent system (subparagraph (c)(i)); or
- material derived from animals (subparagraph (c)(ii)); and
- the goods have been:
 - treated with 50 kGy of ionising radiation at a facility that the Director of Biosecurity is satisfied can treat food for consumption by pet fish so that biosecurity risks associated with the food are managed to an acceptable level (subparagraph (d)(i)); or
 - otherwise treated or processed using a method that the Director of Biosecurity is satisfied is appropriate to manage the biosecurity risks associated with the goods to an acceptable level (subparagraph (d)(ii)); and
- the goods are packed in individual containers of not more than 5 kilograms (paragraph (e)); and
- the goods have been commercially prepared and packaged (paragraph (f)); and
- the goods are ready for retail sale without any further processing (paragraph (g)); and
- the goods are accompanied by a declaration by the manufacturer of the goods stating the matters referred to in paragraphs (a), (b) and (d), and (c) if applicable (subparagraphs (h)(i) and (h)(ii)).

The term *listed microalgae* used in these amended alternative conditions is defined in section 6 of the Goods Determination, as amended by item 1 of this Schedule, to mean microalgae of a species that is listed in the List of Microalgae with Alternative Conditions for Import prepared by the Director of Biosecurity and published on the Agriculture Department's website (<https://www.awe.gov.au/biosecurity-trade/policy/legislation#biosecurity-legislation>), as existing from time to time.

The term *50 kGy of ionising radiation* used in these amended alternative conditions is defined in section 6 of the Goods Determination, as amended by item 1 of this Schedule, to refer to where the goods are treated with ionising radiation, and the absorbed dose is 50 kGy or more.

The purpose of this amendment is to provide new alternative conditions that manage the biosecurity risks associated with food for consumption by pet fish in enclosed aquariums or ponds to an acceptable level to achieve the ALOP for Australia.

Item 36 Section 23 (table item 16, column 2, paragraph (b))

Item 36 omits the words 'of animal origin' in paragraph (b) of column 2 of table item 16 under section 23 of the Goods Determination and substitutes it with 'derived from animals'.

The effect of this amendment is to provide in paragraph (b) of the alternative condition for food or supplements for animals containing *Saccharomyces cerevisiae* that, to meet the condition, the goods must not contain materials derived from animals.

The purpose of this amendment is to ensure that all references in the Goods Determination to 'of animal origin' are replaced with 'derived from animals' (see item 4 of this Schedule for more information).

Item 37 Section 24 (table item 1, column 2, subparagraph (c)(ii))

Item 37 omits the words ‘of animal origin (other than material of animal origin that is covered by an item in a table in this Division)’ in subparagraph (c)(ii) of column 2 of table item 1 under section 24 of the Goods Determination and substitutes it with ‘derived from animals (other than material derived from animals in relation to which alternative conditions are specified in this Division)’.

The effect of this amendment is to provide in the alternative conditions for cosmetics containing biological material for human use that, to meet the conditions, the goods must contain, in total, less than 20% by mass of material derived from animals (other than material derived from animals in relation to which alternative conditions are specified in Division 1 of Part 2 of the Goods Determination).

The purpose of this amendment is to ensure that all references in the Goods Determination to ‘of animal origin’ are replaced with ‘derived from animals’ (see item 4 of this Schedule for more information).

Item 38 Section 24 (table item 2, column 2, paragraph (c))

Item 38 omits the words ‘of animal origin has been added (other than material of animal origin that is covered by an item in a table in this Division)’ in paragraph (c) of column 2 of table item 2 under section 24 of the Goods Determination and substitutes it with ‘derived from animals (other than material derived from animals in relation to which alternative conditions are specified in this Division)’.

The effect of this amendment is to provide in the alternative condition for soap that, to meet the condition, no material derived from animals (other than material derived from animals in relation to which alternative conditions are specified in Division 1 of Part 2 of the Goods Determination) has been added after saponification.

The purpose of this amendment is to ensure that all references in the Goods Determination to ‘of animal origin’ are replaced with ‘derived from animals’ (see item 4 of this Schedule for more information).

Item 39 Paragraph 26(1)(b)

Item 39 omits the words ‘use as a bioremedial agent or fertiliser’ in paragraph 26(1)(b) of the Goods Determination and substitutes it with ‘environmental purposes’.

The effect of this amendment is to provide in paragraph 26(1)(b) of the Goods Determination that the alternative conditions in section 26 relating to miscellaneous plant materials and plant products do not apply to those goods if they are intended for environmental purposes (instead of the current wording which refers to the intention to use the goods as a bioremedial agent or fertiliser).

As with item 6 of this Schedule, all references in the Goods Determination to ‘use as a bioremedial agent or fertiliser’ are being replaced with ‘environmental purposes’, which is defined in section 6 as amended by item 1 of this Schedule to include use as a bioremediation product or fertiliser.

Item 40 Subsection 26(2) (table item 1, column 1)

Item 40 omits the words ‘that are covered by another provision’ in column 1 of table item 1 in subsection 26(2) of the Goods Determination and substitutes it with ‘in relation to which alternative conditions are specified in a provision (other than this item)’.

This is a technical amendment to clarify that the goods in table item 1 do not apply to processed plant products in relation to which alternative conditions are specified in a provision of the Goods Determination other than table item 1 in subsection 26(2) of the Goods Determination.

Item 41 Section 32 (table items 1 and 2)

Item 41 repeals table items 1 and 2 of section 32 of the Goods Determination and substitutes it with a new table items 1 and 2.

New table item 1 deals with any of the following goods, other than goods to which column 1 of another item in the table applies: fruit, vegetables, leaves, herbs and fungi.

To comply with the alternative conditions of these goods, the goods must be:

- free from pests, and diseases, which present an unacceptable level of biosecurity risk (paragraph (a)); and
- have been treated or processed (or both) to ensure that biosecurity risks associated with the goods (including any packaging) have been managed to an acceptable level (paragraph (b)); and
- are accompanied by evidence that the condition referred to in paragraph (b) has been complied with (paragraph (c)).

The amendment removes any ambiguity in the interpretation of what goods are covered by items in column 1 and strengthens the alternative conditions for fruit, vegetables, leaves, herbs and fungi by managing biosecurity risks associated with the goods to an acceptable level. The amendment also provides greater clarity that unprocessed fresh fruit, vegetables, fungi, leaves or herbs, including dried herbs and pickles, are excluded from this item, as these are intended to be covered by new table item 2 inserted by this item.

New table item 2 deals with any of the following goods, other than goods to which column 1 of any of items 3 to 14 applies: unprocessed fresh fruit, unprocessed fresh vegetables, unprocessed fresh leaves, unprocessed fresh herbs, unprocessed fresh fungi.

To comply with the alternative conditions of these goods, all of the following must be met:

- the goods are listed fresh produce for human consumption (paragraph (a)); and
- the goods are free from pests, and diseases, which present an unacceptable level of biosecurity risk (paragraph (b)); and
- the goods are accompanied by a phytosanitary certificate issued by the exporting country’s national plant protection organisation stating that the goods described in the certificate are free from pests and diseases which present an unacceptable level of biosecurity risk (paragraph (c)); and
- the phytosanitary certificate describes the goods, including:

- the botanical name (including genus and species) of the goods (subparagraph (d)(i)); and
- distinguishing marks of the goods, such as the name of the brand or grower (subparagraph (d)(ii)); and
- the quantity, volume and weight of the goods (subparagraph (d)(iii)); and
- the goods have been securely packed in clean and new packaging (paragraph (e)); and
- any information visible on the packaging is not inconsistent with the phytosanitary certificate or with any commercial documentation that accompanies the goods (paragraph (f)).

The term *phytosanitary certificate* is defined in section 6 of the Goods Determination to mean an official paper document, or its official electronic equivalent, issued in accordance with Article V of the International Plant Protection Convention.

The amended alternative conditions clearly provide for unprocessed fresh fruit, vegetables, leaves, herbs or fungi under this item. The biosecurity risks associated with these goods can be managed to an acceptable level with these new alternative import conditions. Accordingly, it is appropriate to include alternative conditions for these goods to be brought or imported into Australian territory without an import permit if they meet the relevant alternative conditions.

Item 42 Section 32 (table item 6, column 1)

Item 42 omits the words ‘covered by item 7’ in column 1 of table item 6 under section 32 of the Goods Determination and substitutes ‘to which column 1 of item 7 applies’.

This is a technical amendment to clarify that the alternative conditions in table item 7 applies to specifies of mushrooms or fungi that are for use for medicinal purposes, other than goods to which column 1 of table item 7 applies.

Item 43 Section 32 (at the end of the table)

Item 43 adds new table items 13 and 14 at the end of the table under section 32 of the Goods Determination.

New table item 13 provides for alternative conditions that apply to unprocessed fresh asparagus that was grown in Mexico or Peru and unprocessed fresh persimmon that was grown in the United States of America.

To comply with the alternative conditions for these goods, all of the following must be met:

- the goods are free from pests, and diseases, which present an unacceptable level of biosecurity risk (paragraph (a)); and
- the goods have been treated, before being exported, for at least 2 hours:
 - at 21 °C or above with at least 32 g of methyl bromide per cubic metre of the goods (subparagraph (b)(i)); or
 - at 16 °C or above with at least 40 g of methyl bromide per cubic metre of the goods (subparagraph (b)(ii)); or
 - at 11 °C or above with at least 48 g of methyl bromide per cubic metre of the goods (subparagraph (b)(iii)); or

- at 10 °C or above with at least 56 g of methyl bromide per cubic metre of the goods (subparagraph (b)(iv)); and
- the goods are accompanied by a phytosanitary certificate issued by the exporting country's national plant protection organisation stating that the goods are free from pests, and diseases, which present an acceptable level of biosecurity risk; and have been treated as mentioned in paragraph (b) (subparagraphs (c)(i) and (ii)); and
- the phytosanitary certificate describes the goods, including the botanical name (including genus and species) of the goods; distinguishing marks of the goods, such as the name of the brand or grower; and the quantity, volume and weight of the goods (subparagraphs (d)(i), (ii) and (iii)); and
- the goods have been securely packed in clean and new packaging (paragraph (e)); and
- any information visible on the packaging is not inconsistent with the phytosanitary certificate or with any commercial documentation that accompanies the goods (paragraph (f)).

The term *phytosanitary certificate* is defined in section 6 of the Goods Determination to mean an official paper document, or its official electronic equivalent, issued in accordance with Article V of the International Plant Protection Convention.

Currently asparagus and persimmon are listed in the List of Fresh Produce for Human Consumption with Alternative Conditions for Import and an import permit is not required. However, it is more effective to include alternative conditions for asparagus and persimmons as described to provide adequate protection from the biosecurity risk posed by pests associated with these goods.

New table item 14 provides for alternative conditions that apply to unprocessed fresh pomegranate that was grown in the United States of America. To comply with the alternative condition for these goods, all of the following must be met:

- the goods are free from pests and diseases, which present an unacceptable level of biosecurity risk (paragraph (a)); and
- the goods have been treated, before being exported, for at least 3 hours at 21 °C or above with at least 40 g of methyl bromide per cubic metre of the goods (paragraph (b)); and
- the goods are accompanied by a phytosanitary certificate issued by the exporting country's national plant protection organisation stating that the goods are free from pests, and diseases, which present an unacceptable level of biosecurity risk, and have been treated as mentioned in paragraph (b) (subparagraphs (c)(i) and (ii)); and
- the phytosanitary certificate describes the goods, including the botanical name (including genus and species) of the goods; distinguishing marks of the goods, such as the name of the brand or grower; and the quantity, volume and weight of the goods (subparagraphs (d)(i), (ii) and (iii)); and
- the goods have been securely packed in clean and new packaging (paragraph (e));
- any information visible on the packaging is not inconsistent with the phytosanitary certificate or with any commercial documentation that accompanies the goods (paragraph (f)).

Currently the item is listed in the List of Fresh Produce for Human Consumption with Alternative Conditions for Import and an import permit is not required. However, it is more

effective to include alternative conditions for pomegranates as described to provide adequate protection from the biosecurity risk posed by pests associated with these goods.

Item 44 Section 33 (table item 1, column 1)

Item 44 omits the words ‘covered by another item in this table’ in column 1 of table item 1 under section 33 of the Goods Determination and substitutes it with ‘to which column 1 of another item in this table applies’.

This is a technical amendment to clarify that the alternative conditions in table item 1 apply to seeds, other than seeds to which column 1 of another item in this table applies.

Item 45 Section 34 (table item 1, column 1)

Item 45 omits the words ‘covered by another item in this table’ in column 1 of table item 1 under section 34 of the Goods Determination and substitutes it with ‘to which column 1 of another item in this table applies’.

This is a technical amendment to clarify that the alternative conditions in table item 1 apply to timber and timber products, other than goods to which column 1 of another item in this table applies.

Item 46 Section 34 (table item 5, column 1, paragraph (b))

Item 46 omits the words ‘use as a bioremedial agent or fertiliser’ from paragraph (b) of column 1 of table item 5 under section 34 of the Goods Determination and substitutes it with ‘environmental purposes’.

The effect of this amendment is to provide in paragraph (b) that the alternative condition in table item 5 applies to sawdust and woodchips of plant origin only, other than goods intended for animal consumption or for environmental purposes (instead of the current wording which refers to the intention to use the goods as a bioremedial agent or fertiliser).

As with item 6 of this Schedule, all references in the Goods Determination to ‘use as a bioremedial agent or fertiliser’ are being replaced with ‘environmental purposes’, which is defined in section 6 as amended by item 1 of this Schedule to include use as a bioremediation product or fertiliser.

Item 47 Subparagraph 36(2)(a)(ii)

Item 47 omits the words ‘use as bioremedial agents or fertiliser’ from subparagraph 36(2)(a)(ii) of the Goods Determination and substitutes it with ‘environmental purposes’.

The effect of this amendment is to provide in subparagraph 36(2)(a)(ii) of the Goods Determination that an alternative condition for highly refined organic chemicals and substances is that the goods are not intended for environmental purposes (instead of the current wording which refers to the intention to use the goods as a bioremedial agent or fertiliser).

As with item 6 of this Schedule, all references in the Goods Determination to ‘use as a bioremedial agent or fertiliser’ are being replaced with ‘environmental purposes’, which is defined in section 6 as amended by item 1 of this Schedule to include use as a bioremediation product or fertiliser.

Item 48 After section 37

Item 48 inserts new section 37A into the Goods Determination after section 37. New section 37A provides alternative conditions for listed semi-synthetic, fermentation-derived active ingredients, which are referred to as the **goods** in new section 37A.

New subsection 37A(1) provides that this section applies to listed semi-synthetic, fermentation-derived active ingredients (the **goods**).

Subsection 37A(2) provides that for the purpose of paragraph 12(1)(b) of the Goods Determination, the alternative conditions for bringing or importing the goods into Australian territory are:

- the goods are intended for human therapeutic use or veterinary therapeutic use (paragraph (a)); and
- the goods have been manufactured without the use of materials of terrestrial animal or avian origin (including the culture media used during fermentation of the goods) (paragraph (b)); and
- the goods do not contain any plant material (other than highly processed and purified plant extracts or oils) and are not on an animal or grain based carrier (paragraph (c)); and
- the goods are derived from a fermentation process that used culture media that was sterilised before use (paragraph (d)); and
- the goods were manufactured to be compliant with:
 - the relevant monograph from at least one of the United States Pharmacopeia, European Pharmacopoeia or British Pharmacopoeia standards (subparagraph (e)(i)); or
 - the specifications approved by the Australian Pesticides and Veterinary Medicines Authority (within the meaning of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*) (subparagraph (e)(ii)); and
- the goods are accompanied by a declaration by the manufacturer of the goods stating the matters referred to in paragraphs (b) to (e) (paragraph (f)).

The term **listed semi-synthetic, fermentation-derived active ingredient** is defined in section 6 of the Goods Determination, as inserted by item 3 of this Schedule, to mean an ingredient that is listed in the Semi-synthetic, Fermentation-derived Active Ingredients List prepared by the Director of Biosecurity and published on the Agriculture Department’s website (<https://www.awe.gov.au/biosecurity-trade/policy/legislation#biosecurity-legislation>), as existing from time to time. An ingredient is listed in this list if the Director of Biosecurity is satisfied that biosecurity risks associated with the ingredient can be managed to an acceptable level.

The standards, as outlined in new paragraph 37A(2)(e), are commonly used in the manufacturing industry. As the conditions relate specifically to the manufacture of the goods,

it could be considered a reasonable expectation that the manufacturers themselves already have access to the standards.

This amendment provides alternative conditions for semi-synthetic, fermentation derived active ingredients for animal and human therapeutic uses. The biosecurity risks associated with these goods can be managed to an acceptable level with these new alternative conditions. Accordingly, it is appropriate for these goods to be brought or imported into Australian territory without an import permit if they meet these alternative conditions.

If the alternative conditions for the goods are not met, subsection 12(1) of the Goods Determination provides that the goods must be covered by an import permit in order to be brought or imported into Australian territory.

Item 49 Subsection 39(4) (table item 10, column headed “Biological material”)

Item 49 omits ‘salmon oil’ from the column headed ‘Biological material’ in table item 10 under subsection 39(4) of the Goods Determination and substitutes it with ‘fish oil derived from members of the family Salmonidae or the genus Plecoglossus’.

This is a technical amendment to align the terminology to internationally scientific nomenclature and to clarify the genus of goods that are ‘biological material’ for the purposes of meeting the alternative conditions in section 39 of the Goods Determination.

Item 50 Section 40 (table item 1, column 1, after paragraph (b))

Item 50 inserts new paragraph (ba) after paragraph (b) in column 1 of table item 1 under section 40 of the Goods Determination. The new paragraph (ba) deals with cosmetics for human use.

Table item 1 provides alternative conditions for gelatine intended for human consumption, human therapeutic use, in-vitro purposes and in-vivo work in laboratory organisms. The alternative condition is that the goods have been commercially prepared.

This amendment includes cosmetics for human use in the class of goods described in column 1 of table item 1. The effect of this amendment is that the alternative condition described for this class of goods at table item 1 also applies to gelatine intended for cosmetics for human use.

This amendment is being made as the biosecurity risks associated with gelatine for cosmetics for human use is no greater than those associated with gelatine for human consumption or human therapeutic use. Accordingly, it is appropriate for this good to be able to be brought or imported into Australian territory without an import permit if it meets the alternative condition.

Item 51 Section 41 (heading)

Item 51 omits the word ‘bioremedial’ in the heading of section 41 of the Goods Determination and substitutes it with ‘bioremediation’.

This is a technical change to reflect the proper scientific term and does not change the substantive effect of the provision.

Item 52 Section 41

Item 52 omits the word ‘bioremedial’ in section 41 of the Goods Determination and substitutes it with ‘bioremediation’.

This is a technical change to reflect the proper scientific term and does not change the substantive effect of the provision.

Item 53 Section 41 (table heading)

Item 53 omits the word ‘bioremedial’ in the table heading under section 41 of the Goods Determination and substitutes it with ‘bioremediation’.

This is a technical change to reflect the proper scientific term and does not change the substantive effect of the provision.

Item 54 Section 41 (table item 1, column 1)

Item 54 omits the word ‘bioremedial’ in column 1 of table item 1 under section 41 of the Goods Determination and substitutes it with ‘bioremediation’.

This is a technical change to reflect the proper scientific term and does not change the substantive effect of the provision.

Item 55 Subparagraph 47(2)(b)(i)

Item 55 omits the words ‘undergone treatment through the application of either gamma irradiation to a minimum of 50 kGray’ in subparagraph 47(2)(b)(i) of the Goods Determination and substitutes it with ‘been treated either with 50 kGy of ionising radiation’.

The effect of this amendment is to provide that the alternative conditions in section 47 relating to equipment that has been in contact with horses may be met where the goods are treated with 50 kGy of ionising radiation at an appropriate facility as specified in that provision.

As with item 7 of this Schedule, all references in the Goods Determination to ‘gamma irradiation to a level that achieves a minimum of 50 kGray’ are being replaced with ‘50kGy of ionising radiation’. The definition in section 6 as amended by item 1 of this Schedule provides that goods are treated with **50 kGy of ionising radiation** if the goods are treated with ionising radiation and the absorbed dose is 50 kGy or more.

Item 56 Paragraph 50(2)(b)

Item 56 repeals paragraph 50(2)(b) in section 50 of the Goods Determination and inserts a new paragraph 50(2)(b). Subsection 50(2) sets out the alternative conditions for goods that are used veterinary equipment other than from New Zealand.

New paragraph 50(2)(b) sets out that such goods must not be brought or imported into Australian territory from a place other than New Zealand unless the goods were, within 72 hours before leaving the exporting country:

- treated with trisodium phosphate (Virkon or Virucidal X) (subparagraph (b)(i)), or
- treated with 50 kGy of ionising radiation (subparagraph (b)(ii)).

This new alternative condition would be in addition to the other existing alternative conditions for these goods as described in subsection 50(2) of the Goods Determination. This new amendment does not substantively change the requirements imposed by the existing alternative conditions, but rather aligns the wording of paragraph 50(2)(b) with the new definition of **50 kGy of ionising radiation**, as inserted by item 1 of this Schedule.

Item 57 After section 52

Item 57 inserts new section 52A into the Goods Determination after section 52. New section 52A provides alternative conditions for microscope slides mounted with biological material, human material, soil or water.

New subsection 52A(1) provides that the class of goods to which this section applies is microscope slides that are mounted with any of the following: biological material, human material to which section 53 or 53A applies (human blood, human tissue and similar goods, or human milk (see item 59 of this Schedule)), soil or water.

Subsection 52A(2) provides that goods included in the class of goods to which this section applies must not be brought or imported into Australian territory unless the goods are covered by an import permit or all of the alternative conditions are complied with.

To comply with the alternative conditions of these goods, all of the following must be met:

- the goods are accompanied by documentation stating that the goods have been prepared using a method that the Director of Biosecurity is satisfied is appropriate to manage the biosecurity risks associated with the goods to an acceptable level (subparagraph (b)(i)); and
- no animal is, or will be, exposed (whether directly or indirectly) to the goods or any derivatives of the goods (subparagraph (b)(ii)); and
- the goods are not intended to be used for isolation or synthesis of viable microorganisms or infectious agents or their homologues (subparagraph (b)(iii)).

The biosecurity risks associated with microscope slides mounted with biological material, human material, soil or water can be managed to an acceptable level with these new alternative conditions. Accordingly, it is appropriate for these goods to be able to be brought or imported into Australian territory without an import permit if they meet the relevant alternative conditions.

Item 58 Paragraph 53(1)(c)

Item 58 adds ‘other than human milk’ at the end of paragraph 53(1)(c) of the Goods Determination.

Existing paragraph 53(1)(c) provides that human secretions, excretions or exudates are part of the class of goods as described by subsection 53(1). The effect of this amendment excludes human milk from the classes of goods to which section 53 (dealing with human blood, human

tissue and similar goods) applies. It is intended that new section 53A, as inserted by item 59 of this Schedule, applies to human milk instead.

Item 59 After section 53

Item 59 inserts new section 53A into the Goods Determination after section 53. New section 53A provides new alternative conditions for human milk.

New subsection 53A(1) provides that the classes of goods to which this section applies is human milk.

New subsection 53A(2) provides that the goods must not be brought or imported into Australian territory unless the goods are covered by an import permit, or all of the alternative conditions are complied with. To comply with the alternative conditions of these goods, all of the following must be met:

- the goods are intended for personal use by one or more children who are under the care of the person bringing in the goods (subparagraph (b)(i)); and
- the goods were not sourced from donors (subparagraph (b)(ii)).

The alternative conditions are intended to cover human milk only intended for personal use by one or more children who are under the care of the person bringing in the goods. Personal use is intended to mean consumption by the child or children. Other uses for human milk (for example, donations) are not intended to be covered by the alternative conditions.

Furthermore, the goods must not have been sourced from donors. Sourced from donors is intended to describe goods sourced from commercial suppliers or from milk banks, which cannot be imported without an import permit. That is, goods will comply with this condition if it is a mother's milk or milk given directly to the carer of the child/children (for example, milk given from a biological parent to a carer).

Previously, human milk brought or imported into Australian territory were part of the class of goods described by subsection 53(1), that is human blood, human tissue and similar goods, for which the alternative conditions set out in subsection 53(2) applies. However, as human milk for consumption is not considered to be for human therapeutic use it is more appropriate to specify separate alternative conditions for human milk as a separate class of goods.

There are a number of people entering Australia with human milk for their infants. The human health risk associated with the goods are managed to an acceptable level with the new alternative conditions.