Ministry for Primary Industries
Manatū Ahu Matua

Risk Management Proposal:
Research samples (excluding animal and human samples)

Prepared for public consultation
by the Animal and Plant Health Directorate

March 2021

New Zealand Government

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Contents

Page

Submissions

The Ministry for Primary Industries (MPI) invites comment from interested parties on the proposed new import health standard (IHS) for import of "Research samples (excluding animal and human samples)", which is supported by this risk management proposal.

An import health standard 'specifies requirements that must be met to effectively manage risks associated with importing risk goods' (Section 22 of the Biosecurity Act 1993 (the Act)).

MPI is seeking comment on the risk management measures for the importation of research samples (excluding animal and human samples).

MPI encourages respondents to forward comments electronically. Please include the following in your submission:

- The title of the consultation document in the subject line of your email;
- Your name and title (if applicable);
- Your organisation's name (if applicable); and
- Your address.

Send submissions to: plantimports@mpi.govt.nz.

However, should you wish to forward submissions in writing (hard copy), please send them to the following address to arrive by close of business on 14 May 2021.

Plant Product Imports
Animal & Plant Health Directorate
Biosecurity New Zealand
Ministry for Primary Industries
PO Box 2526
Wellington 6140
New Zealand

Submissions received by the closing date will be considered during the development of the final IHS. Submissions received after the closing date may be held on file for consideration when the issued IHS is next revised/ reviewed.

Official Information Act 1982
Please note that your submission is public information, and it is MPI policy to publish submissions and the review of submissions on the MPI website. Submissions may also be the subject of requests for information under the Official Information Act 1982 (OIA). The OIA specifies that information is to be made available to requesters unless there are sufficient grounds for withholding it, as set out in the OIA. Submitters may wish to indicate grounds for withholding specific information contained in their submission, such as information being commercially sensitive or personal information. Any decision to withhold information requested under the OIA is reviewable by the Ombudsman.

1. General information

1.1 Purpose

(1) The purpose of this risk management proposal is to outline the rationale for proposed measures to effectively manage the biosecurity risks associated with the importation of research samples (excluding animal and human samples) (referred to as 'research samples' in this document).

1.2 Background

(2) A range of research samples are regularly imported into New Zealand. Currently, the import requirements for research samples are spread across eight different import health standards (IHSs) (Appendix 1).

(3) MPI has received feedback that the biosecurity requirements for research samples have not been centralised. On some occasions, importers need to meet the requirements of more than one IHS for a single type of research sample. This has the potential to cause unnecessary complexity and confusion for importers trying to understand what goods are allowed into the country and the requirements they must meet.

(4) MPI is proposing to centralise all the requirements for research samples into one IHS: *Research Samples (excluding animal and human samples)*. In general, the draft IHS does not propose different measures than are currently required for different research samples. Instead, the draft IHS aims to reduce complexity and streamline requirements.

1.3 Commodity description

(5) Materials addressed in this draft IHS must be for the purpose of either testing, analysis, sensory evaluation, or teaching (referred to as 'research' in this document).

(6) The proposed scope of research samples includes the importation of samples derived from plants, plant materials, inorganic matter and water. There is a wide variety of risk goods that falls within this scope, including, but not limited to:

a) Samples derived from plants or plant samples, in fresh or dried forms (e.g. cells, tissue cultures, seeds, fruits, vegetables, cuttings, bulbs, flowers, tubers, foliage, wood, pulp, timber);
b) herbarium specimens from four kingdoms (Plantae, Mycenae, Protista and Cyanobacteria);
c) material that may contain viable microorganisms (e.g. filters, test kits containing viable microorganisms: diagnostic kits, biological indicators, research kits, and controls and calibrators);
d) organic matter (excluding animal and human matter)
e) inorganic matter; and
f) water.

(7) The following items are out of the scope of the draft IHS. They are eligible for import under other IHSs:

a) Test kits that do not contain viable microorganisms
b) Lab specimens of animal origin (including invertebrates)
c) Human samples
d) Axenic culture of microorganisms

2. Biosecurity risk associated with research samples

(8) Research samples are regularly imported into New Zealand each year. Imported research samples can introduce foreign pests and diseases that could be detrimental to New Zealand's environment, agriculture and economy. Biosecurity risks associated with research samples range from very low (e.g. microscopic slides) to high (e.g. new organisms imported into containment under a Hazardous Substances and New Organisms (HSNO) Act approval).

(9) It is impossible to identify the associated pests and pathogens in any degree of detail for research samples imported under the draft IHS due to:

a) the wide range of materials that can be imported for research purposes; and
b) the large number of unknown microorganisms potentially present within these materials.

(10) Instead, consideration is limited to controlling the introduction into New Zealand of unwanted organisms, new organisms (including genetically modified organisms), regulated pests, and organisms listed as 'entry prohibited' in plants biosecurity index (PBI) into New Zealand where they could pose risk to New Zealand biosecurity, plant health and environment.

(11) A high-level hazard identification process was undertaken by MPI (MPI, 2019)[1]. The risk organisms were grouped according to the type of the organism and their life cycle traits including means of transmission and physical characteristics of the organism. The following hazard groups have been determined to be associated with research samples:

a) plant pathogens (viruses, viroids, phytoplasmas, bacteria, fungi, oomycetes) and nematodes that are transmissible;
b) plant pathogens (viruses, viroids, phytoplasmas, bacteria, fungi, oomycetes) and nematodes that are stable (naturally persistent), have resting bodies or are a risk in association with nonviable material;
c) genetically modified organisms, new organisms or unwanted organisms;
d) invertebrates that are associated with fresh/viable plant material and fungi;
e) invertebrates that are associated with dried or processed plant material and fungi; and
f) organisms that are contamination/hitchhikers or are associated with contamination/hitchhikers.

3. Risk mitigation measures

(12) The draft IHS includes risk mitigation measures to manage any risk organisms that could be present with the imported research samples.

(13) It is recognised that the specific purpose of research samples can mean common phytosanitary measures, such as requiring particular forms of treatment, or phytosanitary inspection and certification, are not applicable. This is because measures such as treatment may change or damage the nature of the research samples, thereby negating their purpose. In addition, these samples may carry known or unknown pests and pathogens, with no visible signs or symptoms.

(14) The following matters were considered during the assessment of risk management options:

a) the type and level of risk that research samples pose to New Zealand's biosecurity and plant health;
b) whether research samples would pose biosecurity risk if unintentionally introduced or released into the New Zealand environment;

[1] MPI, 2019: Scientific technical advice on risks associated with laboratory specimens of plant origin, Biosecurity Science & Risk Assessment, Biosecurity New Zealand, 2019

c) whether research samples can receive biosecurity clearance or whether they must remain contained in a containment facility or transitional facility upon import into New Zealand;
d) what type of facility is appropriate to handle and contain research samples;
e) options for packaging and labelling suitable for the importation of research samples; and
f) whether any additional conditions on the use and/or transfer of research samples are necessary once they are imported into New Zealand.

(15) Given the potential risks associated with imported research samples, several measures are proposed to mitigate these risks and a combination of them may apply for import of each research samples. These measures include:

a) the requirement to hold a permit for imported samples;
b) secure packaging;
c) direction to transitional facility or containment facility;
d) inspection on arrival;
e) document verification;
f) quantity limitation; and
g) restricted use of risk goods.

4. Rational for proposed risk mitigation measures

(16) For the purpose of the draft IHS, research samples have been grouped into the following categories:

a) laboratory specimens;
b) herbarium specimens; and
c) trade samples.

(17) The rational for the proposed measures for each category is explained in this section.

4.1 Proposed measures for import of laboratory and herbarium specimens

(18) Proposed risk mitigation measures and the reason why they are considered appropriate to manage the biosecurity risks associated with both laboratory specimens and herbarium specimens are outlined below.

4.1.1 Restricted use of imported laboratory and herbarium specimens

(19) Laboratory and herbarium specimens are eligible for import under the draft IHS only for the purpose of research, analysis, teaching and testing.

4.1.2 Permit

(20) The draft IHS requires laboratory and herbarium specimens to be imported under a valid permit.

(21) As explained above, the draft IHS outlines general import requirements for importation of all research samples. However, it does not set out specific import requirements for each individual commodity that may be imported for research. Therefore, a permit is required in order to assess and specify any special conditions considered necessary to meet the import requirements of the draft IHS for each research sample.

(22) For each permit, MPI will assess the biosecurity risks associated with research samples in order to determine:

a) if the research sample poses a risk to New Zealand's biosecurity:

- whether direction to a transitional facility or containment facility is required; and
- whether pre-export or post-entry requirements (e.g. packaging, freezing or heating treatment, etc) are necessary.

b) if the risk of the research sample is negligible:

- whether the research sample is eligible for biosecurity clearance.

4.1.3 Packaging

(23) Secure packaging prevents any accidental loss of contents, escape of risk organisms or cross contaminations during transportation.

(24) The draft IHS requires triple packaging for laboratory and herbarium specimens that contain high risk organisms. This packaging must comply with international standards and ensures that the integrity of this packaging remains secure during transport. This is required for any sample that knowingly contains:

a) an unwanted organism;
b) a regulated pest;
c) an organism which is listed as "entry prohibited" in the PBI;
d) an unidentified organism;
e) a new organism (including genetically modified organism).

(25) To keep the packaging intact during transportation, documentation is required to be attached to the outside of the package so that the primary package does not have to be opened to access it. In this way, the integrity of the packaging will not be compromised in order to access documentation.

4.1.4 Document verification and inspection of samples on arrival

(26) All required import documents need to be inspected on arrival to verify they comply with requirements of the draft IHS.

(27) On-arrival inspection of laboratory and herbarium specimens is prohibited. These samples may harbour (intentionally or unintentionally) pests and diseases. Opening their secure packaging on arrival, in order to conduct an inspection, will increase the risk of spreading the quarantine pests associated with them. The draft IHS states that the primary packaging of the laboratory and herbarium specimens must not be opened on arrival; instead, these samples should be directed to the facility listed on the permit to contain any possible risk associated with them.

4.1.5 Direction of laboratory and herbarium specimens into transitional or containment facilities

(28) The majority of imported research samples are not eligible for biosecurity clearance and must be directed to an appropriate transitional or containment facility where they can be securely held. This requirement will be set during the import permit process and will be based on the type of sample that is being imported and the purpose of the research.

(29) It is possible that some research samples imported into a transitional facility may receive biosecurity clearance should it be rendered non-viable. Organisms imported into containment facilities will not receive biosecurity clearance except where that organism has been approved for release by the Environmental Protection Authority.

(30) Transitional and containment facilities must be approved and must operate under facility standards. The following are transitional and containment facility standards which relate to the use of imported research samples:

a) *TF-GEN - Transitional facilities for general unclear goods*

This standard allows for the importation of samples deemed to have a low-risk profile. Examples of items that are directed into this type of transitional facility include water samples imported for chemical and physical analysis.

b) *154.02.17 - Transitional Facilities for Biological Products*

This standard allows for the importation of samples deemed to have a greater risk. Examples of items that are directed into this type of transitional facility include: samples that may have quarantine pests, for example, those that could contain mobile insects or sporulating fungi.

c) *154.03.02 - Facilities for Microorganisms and Cell Cultures: 2007a*

This standard allows for the importation of microorganisms, or materials containing microorganisms, not deemed present in New Zealand.

In addition, some samples must go to a specific physical containment (PC) level[2]. A brief summary of these containment levels is below:

- Physical containment level 1 (PC1)

  Suitable for work with microorganisms that fall under Risk Group 1 category[3]. Work may be carried out on the open bench, and laboratory staff can be adequately protected by standard laboratory practice, and no containment equipment is required.

- Physical containment level 2 (PC2)

  Suitable for work with microorganisms that fall under Risk Group 2 category[4]. PC2 incorporates all the requirements of a PC1 laboratory but with additional requirements relating to staff training, safety equipment and access to the facility.

d) *Containment facilities for plants: 2007*

This standard applies to plants that are new organisms. That is, those plant species (including genetically modified plants), that have not been approved for release into the New Zealand environment under the HSNO Act but where HSNO Act approval has been given for them to be held in containment subject to controls.

(31) It is considered that propagation of plant research samples meeting the requirements of *Facilities for microorganisms and cell cultures: 2007a* or *Containment facilities for plants: 2007* will mitigate biosecurity risks associated with them. The type and level of these facilities will be specified on the permit after assessing the type of sample for intended research.

(32) If MPI assesses that propagation of/from research samples should not be allowed, this will be specified on the permit.

4.1.6 Destruction of laboratory specimens

(33) Upon completion of research, laboratory specimens and any material originating from the research sample must be:

a) destroyed in accordance with the relevant facility standard, any approval, and/or permission granted; or

b) rendered non-viable.

Non-viable material is eligible for biosecurity clearance.

[2] More information regarding physical containment levels can be found in Australian/New Zealand Standard 2243.3: 2010: Safety in Laboratories Part 3: Microbiological safety and containment, Sixth edition 2010 (AS/NZS 2243.3:2010)

[3] Risk Group 1 is a microorganism that is unlikely to cause human, plant or animal disease (definition from http://www.absa.org/riskgroups/).

[4] Risk group 2 is a microorganism that can cause human, animal or plant disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause infection, but effective treatment and preventive measures are available, and the risk of spread is limited (definition from http://www.absa.org/riskgroups/).

(34) Not all laboratory specimens must be destroyed or rendered non-viable upon completion of research. Plant samples may receive biosecurity clearance upon completion of research only if plant samples meet the requirements specified in the IHSs for the importation of nursery stock (155.02.06) or seed for sowing (155.02.05), which will mean that the risks associated with the plant samples are mitigated.

4.2 Proposed measures for import of trade samples

(35) Trade samples are goods imported for sensory evaluation, assessment and testing. Due to their evaluative nature and limited scale, it is not feasible to require that trade samples comply with the phytosanitary measures that are in place for large commercial trade of the same type of commodity under other relevant IHSs.

(36) The following risk management measures are considered appropriate to manage the biosecurity risks associated with trade samples of grains, seeds, fruit, vegetables and coco peat.

4.2.1 Restricted use of trade samples

(37) Trade samples are only eligible for import for the purpose of sensory evaluation, assessment and testing.

4.2.2 Packaging

(38) Secure packaging of the trade sample is required to prevent any accidental loss of contents, escape of organisms or cross-contamination during transportation.

(39) Documentation must be attached to the outside of the package so that the package does not have to be opened to access the documents on arrival.

4.2.3 Quantity limitation

(40) The draft IHS sets a quantity limit for the import of trade samples of fruit, vegetables and coco peat. By limiting the quantity of these samples per consignment, the potential risk of spreading pests associated with the samples will be minimised.

(41) The proposed limits are up to 30 kilograms of a particular fruit or vegetable per consignment and up to 5 kilograms of coco peat per consignment. These limits are considered to be manageable for mitigating any risks associated with these samples.

(42) Only one package of the imported trade samples can be opened and evaluated at any one time. In this way, if any quarantine pests are present on the samples or in the package, they can be appropriately managed.

(43) There is no quantity limit for trade samples of seeds and grain because the types of biosecurity risks associated with these trade samples are considered manageable by ensuring that trade samples are handled within a transitional facility.

4.2.4 Document verification and inspection of trade samples on arrival

(44) The required import documents need to be inspected on arrival to verify they comply with requirements of the IHS.

(45) In the draft IHS, trade samples are subject to inspection to verify freedom from quarantine pests, other extraneous material and any signs of pathogens or pests. Inspection is to occur in an approved transitional facility to minimise the chance of pests escaping.

(46) For trade samples of fruit and vegetables, the following actions will be taken:

a) any units with signs or symptoms of pest infestation or disease infection will be removed and destroyed;

b) an MPI-approved treatment will be applied if any quarantine insect pest (other than fruit fly) is detected in the consignment;

c) the entire consignment will be destroyed if any fruit flies are detected.

(47) The draft IHS proposes removing two current measures that require documentation. MPI believes that the proposed measures outlined in the draft IHS effectively manage the risk and no further documentation is required. Therefore, MPI proposes removing the following requirements:

d) a letter of approval to accompany the trade samples of fruit and vegetables (currently required under Part 4.13 of the 152.02: Importation and Clearance of fresh fruit and vegetables into New Zealand); and

e) a permit to accompany the trade samples of grain and seeds (currently required under Part 1.7 of the GCFP.IHS: Grain and seeds for consumption, feed or processing).

4.2.5 Direction of trade samples into a transitional facility

(48) Trade samples of grain, seeds, fruit and vegetables are not eligible for biosecurity clearance and must be directed to a transitional facility. These facilities need to be approved for holding or processing that type of commodity under the Standard *TF-GEN - Transitional facilities for general uncleared risk goods*.

(49) Trade samples of coco peat are a significantly lower biosecurity risk. Depending on the processing, storage and packaging, the only risks are likely to be hitchhikers that become associated with the products during storage (MPI, 2008)[5]. Trade samples of coco peat do not require direction to a transitional facility and are eligible for biosecurity clearance if they are free from viable seeds and other contaminants.

4.2.6 Destruction of trade samples

(50) Trade samples of grain and seeds and their packaging must be destroyed or rendered non-viable upon completion of research.

(51) Trade samples of fruit and vegetables and their packaging must be destroyed within 48 hours of importation. This will mitigate the risk of escaping pests that may be associated with the trade samples and were not detectable during inspection of samples on arrival (e.g. larvae in fruit).

5. Feasibility and Practicality of Measures

(52) MPI has also considered the feasibility and practicality of the proposed measures. The risk management measures specified in Part 4 of this document have been successfully applied and operated for importation of research samples for several years. These measures have proven to be practical and effective in the management of risk associated with research samples.

(53) If the draft IHS is approved, the other IHSs (listed in Appendix 1) will be amended to remove the research sample requirements as appropriate.

[5] MPI, 2008: Risk discussion document for the importation of coco peat, MAF Biosecurity New Zealand Paper No. 2008/02.

Appendix 1:

List of current import health standards that cover the requirements for import of the research samples

Research samples	Relevant import health standards
Dried herbarium specimens Seeds (not for propagation) Other plant material Preserved plant material for research	PLANTMATERIAL.IHS: Dried and Preserved Plant Material, and Plant Material for Research (Part 5.1, 5.2, 5.3 and 5.4)*
Seeds (where propagation is a part of research)	155.02.05: Seeds for Sowing (Part 1.8) *
Soil Water	IHS.SOWTR: Soil, Rock, Gravel, Sand, Clay and Water (Part 2.1) *
Biological products (non-viable products derived from living organisms[6])	BIOPRODIC.ALL: Biological Products (including samples)
Viable microorganisms Products containing viable microorganisms	MICROIC.ALL: Microorganisms from all countries
Trade samples of grains and seeds	GCFP.IHS: Grain and seeds for consumption, feed or processing (Part 1.7) *
Trade samples of fruits and vegetables	152.02: Importation and Clearance of fresh fruit and vegetables into New Zealand (Part 4.13) *
Trade samples of coco peat	IHS.FERTGRO: fertilisers and growing media of plant origin (Part 2.4(7)) *

* Following issuing the Research Samples IHS, specified Parts of the relevant IHSs will be removed.

[6] For the purpose of the BIOPRODIC.ALL IHS, biological products are non-viable (not capable of living, replicating, reproducing or developing) products derived from living organisms, including samples of animal origin. (Note: Biological products derived from humans are not subject to this IHS.)