



## Discussion Document

**Proposed amendments to the Import Health Standard: 155.02.05 *Importation of Seed for Sowing* and the *Protocol for Testing Seed Imports for the Presence of Genetically Modified Seed*.**

**FOR PUBLIC CONSULTATION**

September 2015



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## Submissions

The Ministry for Primary Industries (MPI) invites comment from interested parties on the proposed changes to the general requirements for the importation of seeds for sowing (Import Health Standard 155.02.05: *Importation of Seeds for Sowing*), and the *Protocol for Testing Seed Imports for the Presence of Genetically Modified Seed*. The proposed changes are supported by this discussion document.

An IHS “specifies requirements to be met for the effective management of risks associated with importing risk goods, including risks arising because importing the goods involves or might involve an incidentally imported new organism” (section 22(1) Biosecurity Act 1993).

MPI seeks comment on the proposed amendments to the IHS: *Seed for Sowing* and the *Protocol for Testing Seed Imports for the Presence of Genetically Modified Seed*. MPI has developed this proposal based on best available scientific evidence and assessment of this evidence. If you disagree with the measures proposed to manage the risks, please provide either data or published references to support your comments. This will enable MPI to consider additional evidence which may change how risks are proposed to be managed.

The following points may be of assistance in preparing comments:

- wherever possible, comments should be specific to a particular change in IHS requirements or a question asked in this document (referencing section numbers or commodity names as applicable);
- where possible, reasons, data and supporting published references to support comments are requested;
- the use of examples to illustrate particular points is encouraged.

**The changes proposed in this discussion document are intended to update the IHS to ensure the current assurance against the importation of unapproved GM plant material is maintained in response to changing scientific and commercial dynamics.**

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](mailto:plantimports@mpi.govt.nz).

However, should you wish to forward submissions in writing, please send them to the following address to arrive by close of business on **08<sup>th</sup> October 2015**.

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Submissions received by the closure date will be considered during the development of the final IHS. Submissions received after the closure 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 the information is commercially sensitive or they wish personal information to be withheld. Any decision to withhold information requested under the OIA is reviewable by the Ombudsman.

# Introduction

## Purpose

- (1) The purpose of this document is to:
  - Clarify the proposed changes to the requirements for genetically modified (GM) testing certificates.
  - Provide a justification for the proposed changes to the *Protocol for Testing Seed Imports for the Presence of Genetically Modified Seed*.
  - Clarify the proposed changes to the general requirements for the importation of seeds for sowing.
  - **Update the IHS to ensure the current assurance against the importation of unapproved GM plant material is maintained in response to changing scientific and commercial dynamics.**

## Background

- (2) MPI is reviewing all standards and guidance documents so that the legal requirements are clear and that information is consistently presented and easy to understand.
- (3) The import health standard 155.02.05: *Importation of Seed for Sowing* has been reviewed and several minor amendments to biosecurity requirements are proposed, which this document outlines. MPI is seeking feedback on the proposed changes.
- (4) A revised and updated version of the *Protocol for Testing Seed Imports for the Presence of Genetically Modified Seed* has also been prepared for consultation (hereafter referred to as the Protocol).
- (5) It is proposed that the name of the Protocol is changed to the *Protocol for Testing for the Presence of Genetically Modified Plant Material* to reflect the scope of testing includes plant material as well as seeds.
- (6) The schedules for *Cucurbita pepo* (squash) and *Linum usitatissimum* (flax, linseed) have been amended to include an option for testing consignments imported into New Zealand for the presence of unapproved GM seeds in an MPI approved laboratory, in addition to the option for a signed exporter/importer non-GM assurance declaration.
- (7) The IHS schedule for *Gossypium hirsutum* (cotton) has been amended to include the requirement for all consignments imported into New Zealand to be tested for the presence of unapproved GM seeds in an MPI- approved laboratory.
- (8) New tests have been added to the Protocol for *Zea mays* (maize, sweetcorn) and *Glycine max* (soybean) seed imported into New Zealand, as new events have been commercialised and are available in the market.

## Context

- (9) GM varieties of organisms, including seeds of plants imported for sowing into New Zealand, are defined as new organisms under the Hazardous Substances and New Organisms (HSNO) Act 1996. The purpose of this Act is to prohibit the importation, development, field-testing or release of any new organism without approval from the Environmental Protection Authority (EPA). The Act is enforced at the New Zealand border under section 28 of the Biosecurity Act 1993.
- (10) Seed importers must take appropriate precautions to ensure consignments of seed for sowing do not contain unapproved GM seed. Plant species with GM varieties grown commercially around the world are tested at the border for the unintentional presence of GM seed.
- (11) Seeds imported for sowing into New Zealand must meet the phytosanitary requirements detailed in the MPI Import Health Standard (IHS): 155.02.05: Importation of Seed for Sowing - <http://www.mpi.govt.nz/importing/plants/seeds-for-sowing/steps-to-importing/>.
- (12) Where possible, phytosanitary import requirements are aligned with international standards, guidelines, and recommendations as per New Zealand's obligations under Article 3.1 of the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (WTO, 1995), and section 23(4)(c) of the Biosecurity Act 1993.

## International

- (13) The WTO and SPS Agreements set in place rules that protect each country's sovereign right to take the measures necessary to protect the life or health of its people, animals, and plants while at the same time facilitating trade. It embodies and promotes the use of science-based risk assessments to manage the risks associated with the international movement of goods.
- (14) In keeping with New Zealand's obligations under the WTO SPS Agreement, the Biosecurity Act 1993, and the International Plant Protection Convention (IPPC), phytosanitary measures must:
  - be justified and can only be for regulated pests. The strength of any phytosanitary measure will depend on the assessment of risk, with an emphasis on the consequences of the pest establishing in New Zealand;
  - not discriminate unfairly between countries or between imported and domestically produced goods;
  - be based on international standards wherever possible, but WTO members can adopt a measure that is more stringent than an international standard, provided the measure is scientifically justified.

## Domestic

- (15) The New Zealand biosecurity system is regulated through the Biosecurity Act 1993. Section 22 of the Act describes an import health standard (IHS) and requires all risk

goods (including plants and plant products) entering New Zealand to be covered by one.

- (16) The Ministry for Primary Industries (MPI) is the government authority responsible for maintaining biosecurity standards for the effective management of risks associated with the importation of risk goods into New Zealand (Part 3, Biosecurity Act 1993).
- (17) Genetically modified organisms are 'new organisms' under the New Zealand Hazardous Substances and New Organisms (HSNO) Act 1996 and require approval by the Environmental Protection Authority before they can legally be imported and released in New Zealand. The HSNO Act is enforced at the New Zealand border under section 28 of the Biosecurity Act 1993 (hereafter referred to as the Act).
- (18) MPI is committed to the principles of transparency and evidence-based technical justification for all phytosanitary measures, new and amended, imposed on importing pathways.

## **Proposed amendments to the current IHS requirements**

### **Format changes**

- (19) The IHS has been revised and migrated into the new MPI Requirements & Guidance format to improve layout and to clarify the legal requirements. Guidance information is now clearly differentiated in 'guidance text boxes' to assist the reader in understanding legal requirements versus guidance.
- (20) Schedules containing repetitive information have been simplified. For example, sections of the seed schedule 'pre-export phytosanitary requirements' and 'phytosanitary certificate additional declarations' have been combined.

### **Phytosanitary certificate**

- (21) The requirements for the Phytosanitary Certificates are summarised now under Part 1.5.2: Phytosanitary certificate. Due to the unequal level of information present on the phytosanitary certificates that are presented at the NZ border, MPI proposes that all phytosanitary certificates must be issued by the exporting country National Plant Protection Office (NPPO) in accordance with ISPM 12: *Guidelines for phytosanitary certificates* and should contain sufficient detail to enable clear identification of the consignment and its component parts.
- (22) As a guidance the following information should be present in the certificate:
  - a) lot number(s);
  - b) number and description of packages;
  - c) country/place of origin of the seed;
  - d) variety names.

### **Genetically modified testing certificate**

- (23) The requirements for GM testing certificates are summarised in Part 1.5.4: Genetically modified testing.



- (24) A number of GM testing certificates have been submitted to border inspectors where it is not clear that the lot being tested for GM seeds is from the same lot imported into New Zealand. MPI proposes making it mandatory for the GM testing certificate to contain the same lot number or unique identifier as stated on all the other import documentation for consignments arriving in New Zealand, to ensure that the documents can be reconciled.
- (25) In addition to the lot number, the name of species tested and sampling method used for each seed line (for example, automatic in-line machine) must be included on the testing certificate.
- (26) MPI welcomes comments on the proposed changes.

## **Declaration for non-genetically modified organisms**

- (27) A declaration for non-GM organisms is currently included in the IHS for *Arabidopsis* and for *Cucurbita pepo* seeds. The Protocol also includes an option for importers of small seed volumes for research, breeding and multiplication which uses a 'quality assurance declaration' that seeds have been produced under a quality assurance system and are not known to include GM seeds. This declaration plus the additional requirements set out in the protocol ensure the risk of accidental importation of unapproved GM seeds is appropriately managed.
- (28) A modified version of the declaration has been developed which includes a section for exporters to complete and sign. In addition, for the seed importer, the 'Exporter/ importer non-GM assurance declaration' is to be used as a template and has been moved to Appendix 3: Declaration Form of the IHS to facilitate the exporter to print and complete the copy to send to the importer. The new declaration allows MPI to request further details from the exporter should they be required.
- (29) This declaration is a requirement for all imports of *Arabidopsis thaliana* seeds.
- (30) The declaration is an option for the crops *Cucurbita pepo* and *Linum usitatissimum*, and for small seed lots as described in the Protocol.
- (31) MPI welcomes comments on this proposed revised declaration.

## **Genetically modified seed testing**

- (32) In addition to phytosanitary requirements, consignments of *Brassica napus var oleifera* (oilseed rape), *Zea mays var. indentata*, *Zea mays var. sacharata*, *Glycine max* and *Medicago sativa* are required to be representatively sampled and tested using the Protocol, and found to be free of unapproved GM seed.
- (33) New GM varieties of *Zea mays* and *Glycine max* have been commercialised in the past few years, and the Protocol has been updated to require additional tests.
- (34) It is proposed that one further crop is added to the Protocol that requires a mandatory border test: *Gossypium hirsutum* – cotton (see Part 2.35 of the IHS).
- (35) Testing has also been added as an option for consignments of *Cucurbita pepo* – squash (see Part 2.26 of the IHS) and *Linum usitatissimum* – flax (see Part 2.43 of the IHS) in addition to the 'Exporter/ importer Non-GM assurance declaration'.

## ***Gossypium***

- (36) It is proposed to update the schedule for *Gossypium* (see Part 2.35 of the IHS) and make testing a mandatory requirement for imported cotton seeds. The field area of GM cotton worldwide in 2013 was of 23.9 million of hectares (70% of the world production) (James, 2013).
- (37) Currently 54 events have been approved in many different countries for cultivation. The main GM traits in cotton are: insect resistance and herbicide tolerance.
- (38) The current *Gossypium* schedule requires importers to apply for a permit to import and to provide MPI with appropriate assurances that the consignment does not contain GM seeds. A permit was initially required to enable MPI to assess import conditions for cotton which included GM testing requirements. It is proposed that the GM Testing Protocol requires compulsory testing for the presence of a GM cotton, as a result the permit is no longer required.
- (39) MPI welcomes comments on the proposal to remove the requirement for a permit to import and include a mandatory test for GM seeds for imports of cotton seeds for sowing.

## ***Cucurbita pepo* and *Linum usitatissimum***

- (40) A non-GM declaration is currently required for these two crops (refer to Appendix 3: Declaration Form of the IHS).
- (41) If the exporter is unable to provide a non-GM declaration, or guarantee its non-GM status, importers will now have the option to have the consignment tested for GM to guarantee that it complies with our current requirements for the crop (refer to Part 2.26 and Part 2.43 of the IHS). It is proposed that testing for GM presence is also given as an option for these crops, alongside the 'Exporter/ importer non-GM assurance declaration (see section: Declaration for non-genetically modified organisms in this document).
- (42) Two GM *Cucurbita pepo* events are currently approved for cultivation in USA and for food in Canada. Events CZW3 and ZW20 have the GM trait of viral disease resistance. Both events had their non-regulated status determined in 1996 (CZW3) and 1994 (ZW20) and are grown in field areas of around 2,000 hectares in the USA (James, 2013).
- (43) Both events are currently commercialised under different variety names in the USA. Although, GM squash production areas are restricted to certain parts of the country, USA is currently our second largest supplier of *Cucurbita pepo* seeds. An updated list of the current commercialized GM varieties of yellow straight neck, yellow crookneck squash and green zucchini is provided under the cucurbitaceae schedule (refer to Part 2.26.3 of the IHS).
- (44) For *Linum usitatissimum*, one event (CDC Triffid Flax) has been approved for cultivation as well as food and feed in USA (1999) and Canada (1996), although it has not been grown commercially in Canada since 2000. CDC Triffid Flax was deregistered in 2001 in Canada, however a report by Booker *et al.*, published in 2014

concluded that low levels of transgenic flax are still prevalent in the production areas of Western Canada.

- (45) For New Zealand, Canada is the second major supplier of flax seeds for sowing according to data from 2011-2014.
- (46) MPI welcomes comments on the review and proposed measures to the current IHS requirements for both crops.
- (47) Importers are reminded of the penalties under the HSNO Act 1996 for importing and releasing unapproved GM crops in New Zealand on the 'Exporter/ importer non-GM assurance declaration form'. If there is doubt as to the status of the seed, importers are encouraged to use the testing option instead for the crop.
- (48) Based on this information for both crops, MPI proposes that New Zealand importers can choose between a voluntary GM testing for their consignments following all the guidelines for sampling and testing in the Protocol or provide a signed 'Exporters/ importers Non-GM assurance declaration' providing assurances that no GM seed is present in the consignment.
- (49) The Protocol and a list of MPI-approved facilities for testing are located on the MPI website: <http://www.biosecurity.govt.nz/regs/imports/plants/gmo>.
- (50) The declaration template is in Appendix 3 in the IHS: Seed for Sowing and Schedule 1 of the Protocol.

## Proposed changes to the GM testing protocol

- (51) For small quantities of seed, the term 'composite sampling' has been replaced with the term 'proportionate sampling'. This more accurately describes how a representative sample needs to be taken.
- (52) Guidance on how to sample each seed line can be found in the Protocol: Schedule 3.
- (53) The Protocol schedules 1, 2 and 3 provide a template for the 'Exporter/ importer Non-GM assurance declaration' (see declaration for non-GM organisms on page 6), Guidance for the minimum consignment size for the proportionate sampling and Guidance on how to calculate for the proportionate sampling (examples included).
- (54) The guidelines for seed testing methods have been removed from the Protocol and added to the MPI laboratory accreditation standard *Approval of Laboratories for Genetically Modified Organism Testing*.
- (55) All GM testing certificates for *Zea mays* and *Glycine max* dated on and after the 01/01/2016 must comply with the new requirements, for example:

Crops	Prior to 31/12/2015	On and after 01/01/2016
<i>Zea mays</i>	tNOS and P35S	tNOS and P35S and DAS-40278-9
<i>Glycine max</i>	P35S and FMV34S or cp4epsps or MON89788	P35S and FMV34S or cp4epsps or MON89788 and DP-305423-1 and MON87701

- (56) MPI welcomes comments on the proposed alterations, new format and content of the new Protocol.

## Testing requirements

- (57) The cost for GM testing ranges from approximately NZ\$210 to \$440 per sample, depending on the laboratory used, number of samples and number of targets.
- (58) New events have been commercialised since this Protocol has been updated.

### ***Glycine max***

- (59) Two new GM soybean events have been commercialised requiring additional laboratory tests (polymerase chain reaction – PCR) to detect them.
- (60) The following two events are proposed to be included in the Protocol:
  - DP-3Ø5423-1 (Treus™, Plenish)
  - MON 87701

### ***Zea mays***

- (61) One new GM event has been commercialised since this Protocol was updated and an additional laboratory test (polymerase chain reaction – PCR) is needed to detect it.
- (62) The following event is proposed to be included in the Protocol:
  - DAS-40278-9 (Enlist™ Maize)

## References and sources of information

James, C. 2013. Global Status of Commercialized Biotech/GM Crops: 2013. *ISAAA Brief* No 46. ISAAA: Itahaca, NY

Booker, H.M., Mischkolz, J.M., St. Louis, M. and Lamb, E.G. (2014) Analysis of the prevalence of CDC Triffid transgenic flax in Canadian grain stocks. *AgBioforum*, 17(1): 75-83.

GRACE – GMO Risk Assessment and Communication of Evidence at <http://www.grace-fp7.eu/> [Assessed on December 2014].

CropLife International at <http://www.biotradestatus.com/results.cfm?CFID=1383068&CFTOKEN=bd2d535c00da4d24-0FE68BEF-D0C8-67D2-5E257C85EAF0C4CD>

Center for Environmental Risk Assessment at <http://cera-gmc.org/GMCropDatabase>