International Plant Protection Convention
Protecting the world's plant resources from pests

Feb
2016

ENG

Overview on International Standards for Phytosanitary Measures (ISPMs) and their application to living modified organisms (LMOs)

Prepared by the Secretariat of the International Plant Protection Convention

CONTENTS

1. INTRODUCTION

This publication provides an overview on International Standards for Phytosanitary Measures (ISPMs) and their application to living modified organisms (LMOs).

The Commission on Phytosanitary Measures (CPM), the governing body of the International Plant Protection Convention (IPPC) agreed that plant pest risks associated with LMOs / products of modern biotechnology fall within the scope of the IPPC. In particular, the CPM endorsed the results of an Open-Ended Exploratory Working Group[1] (OEWG) on the Phytosanitary Aspects of Genetically Modified Organisms (GMO), Biosafety and Invasive Species. The OEWG noted that, consistent with the IPPC mandate to protect plant health, plant pest concerns that may be presented by LMOs/products of modern biotechnology fall within the scope of the IPPC. The group agreed that IPPC risk analysis and management systems are appropriate for assessing and managing, if necessary, the direct or indirect risks of pests to cultivated and wild flora and plant products that may be presented by LMOs/products of modern biotechnology. It was also agreed that IPPC systems and procedures are relevant to, and adequate for, managing the risks posed by LMOs/products of modern biotechnology as they relate to the protection of plant health. Existing national mechanisms and structures for phytosanitary systems may form a basis or a model for developing other practical approaches to managing risks associated with LMOs/products of modern biotechnology. Finally, the group noted that plant pest risks associated with LMOs/products of modern biotechnology fall clearly within the scope of the IPPC.

This publication highlights where existing ISPMs provide guidance on plant pest risk analysis (PRA) of LMOs. The international standards discussed in this document can be found on the International Phytosanitary Portal[2]. It should be noted that ISPMs are guidelines, and each contracting party interprets and applies these guidelines in the manner that best suits their infrastructure, capabilities and needs. ISPMs allow for a flexible approach to PRA and are intentionally open and flexible to allow for different approaches depending on need and application, while still ensuring members remain true to the principles of the IPPC and hence the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO-SPS). The application of these guidelines to LMOs does not exclude consideration of the unique risks presented by LMOs.

2. ISPMS

ISPM 1: *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*

This standard describes the various principles reflected in the text of the IPPC.

Basic principles include:

- sovereignty
- necessity
- managed risk
- minimal impact
- modification
- transparency
- harmonization
- equivalence

[1] Held in 2000-06

[2] IPPC Standards: https://www.ippc.int/en/core-activities/standards-setting/ispms/

Operational principles include:

- pest free areas and areas of low pest prevalence
- pest risk analysis
- pest listing
- surveillance
- phytosanitary certification
- dispute settlement
- prompt action
- emergency measures
- notification of non-compliance
- information exchange
- technical assistance

ISPM 1 reflects the purpose of the IPPC-- to secure common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote measures for their control—while ensuring that measures imposed are the least trade restrictive measures available. The development and adoption of new ISPMs has strong ties to the principles identified in ISPM 1. Risk analysis and managed risk are the key principles that apply to plant pest risks of LMOs.

ISPM 2: *Framework for pest risk analysis*

ISPM 2 applies to both quarantine and regulated non-quarantine pests. The standard elaborates on the steps for conducting PRA: initiation, risk assessment and risk management. The initiation stage (**Section 1**) involves identifying the pests or pathways for which further analysis is needed. The second step is the assessment of the likelihood of entry, establishment and spread of a pest, and the potential economic importance. Risk management is the evaluation of various options for mitigating or reducing the risk. The PRA is usually applied to a specific area, the "PRA area", which may be a country, part of a country, or parts or all of several countries.

Living modified organisms are discussed in Section 1.2.4.

"Types of LMOs for which a PRA may be conducted include:

- plants for use in agriculture, horticulture or silviculture, bioremediation of soil, for industrial purposes, or as therapeutic agents (e.g. LMO plants with an enhanced vitamin profile)
- biological control agents and other beneficial organisms modified to improve their performance
- pests modified to alter their pathogenic characteristics.

The modification may result in an organism with a new trait that may now present a pest risk beyond that posed by the non-modified recipient or donor organisms, or similar organisms. Risks may include:

- increased potential for establishment and spread
- those resulting from inserted gene sequences that may act independently of the organism with subsequent unintended consequences
- potential to act as a vector for the entering of a genetic sequence into domesticated or wild relatives of that organism, resulting in an increase in the pest risk of that related organism
- in case of a modified plant species, the potential to act as a vector for the entering of an injurious genetic sequence into relatives of that species.

PRA is usually concerned with phenotypic rather than genotypic characteristics. However, genotypic characteristics should also be considered when assessing the pest risks of LMOs.

Predictive indicators more specific to LMOs include intrinsic attributes such as:

- phenotypic similarities or genetic relationships to known pest species

- introduced changes in adaptive characteristics that may increase the potential for introduction or spread
- phenotypic and genotypic instability.

For LMOs, identification requires information regarding the taxonomic status of the recipient and the donor organism, and description of the vector, the nature of the genetic modification, and the genetic sequence and its insertion site in the recipient genome.

Further potential risks of LMOs are outlined in Annex 3 to ISPM 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004). A PRA may be carried out to determine whether the LMO is a pest, and subsequently assess the pest risk."

ISPM 11: *Pest risk analysis for plants as quarantine pests*

- Annex 1: Comments on the scope of the IPPC in regard to environmental risks
- Annex 2: Comments on the scope of the IPPC in regard to pest risk analysis for living modified organisms
- Annex 3: Determining the potential for a living modified organisms to be a pest
- Annex 4: Pest risk analysis for plants as quarantine pests

This standard describes the PRA process for "quarantine pests". A **quarantine pest** is defined as "a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled."

Many of the same issues that arise for ISPM 2 with respect to LMOs also apply to ISPM 11 and specific considerations for LMOs have been integrated into ISPM 2 and marked with a "*S2*" in the left margin of the text. In particular initiation of the PRA for an LMO would most likely be considered to be "pest initiated" if the LMO was being evaluated as a potential plant pest. Likewise, the introduction potential of the LMO would be established. However, ISPM 11 provides considerably more guidance than ISPM 2 in parts of the assessment stage. In particular, **Section 2.2.1.5** discusses the probability of transfer to a suitable host, including dispersal mechanisms (including vectors), intended use of commodity and risks from by-products—each of which may be applicable to examining the pest potential of an LMO. **Section 2.2.2** also provides extensive guidance on evaluating probability of establishment, taking into account such factors as availability of suitable hosts, alternate hosts, and vectors in the PRA area, suitability of the environment, cultural practices, reproductive strategy of the pest, and genetic adaptability. This last factor may be especially applicable to the evaluation of the pest potential of LMOs.

Section 2.3 discusses the assessment of potential economic consequences. As with ISPM 2, a pest must have the potential to cause economic harm. However, certain indirect effects of an LMO (e.g. effects on non-target organisms) may be difficult to quantify economically. Nonetheless, **Section 2.3.1.1** and **Section 2.3.1.2** discuss direct and indirect pest effects, respectively, and include assessment of environmental effects as well as assessing the potential for crop losses.

The IPPC recognizes that uncertainty is a component of PRA and provides guidance on accounting for the nature and degree of uncertainty in the overall analysis (ISPM 2, Section 3.1; ISPM 11, Section 2.4). Care is taken to document areas of uncertainty and the degree of uncertainty in any analysis, and to indicate where expert judgement has been used, including in examining risk management options. It should be stressed that phytosanitary measures are intended to account for uncertainty and should be designed in proportion to the assessed risk."

Section 3 provides guidance on management options. **Section 3.4.1** discusses risk management options for consignments, including pre- and post-entry quarantine, specified conditions for the consignment and restrictions on end use, all of which may be applied to LMOs.

Annex 1 of ISPM 11 outlines how environmental harm might be considered in a PRA. It is Attachment 1 to this document. Annex 2 and Annex 3 of ISPM 11 outline how the IPPC applies to risks associated with LMOs and

the criteria for determining the potential for a living modified organism to be a pest. They are Attachment 2 and Attachment 3, respectively, to this document.

ISPM 5: *Glossary of phytosanitary terms*

The development and use of internationally agreed terminology under the auspices of the IPPC has served the phytosanitary community since the IPPC was originally adopted. This terminology is recognized by national, regional and international organizations as the appropriate terms to use with respect to matters related to plant protection and has been incorporated in national legislation and regulations throughout the world. Many terms overlap significantly with concepts currently under the CBD and the Cartagena Protocol on Biosafety. The Cartagena Protocol on Biosafety carries with it the need for the application of specific terms and definitions for consistency. In some instances, terms developed and used under the IPPC could be applied to situations relevant to the CBD, while in other cases, certain IPPC terms are characteristic to phytosanitary issues and situations (e.g. regulated non-quarantine pest; area of low pest prevalence).

The term "**pest**" refers to "any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products". The ICPM "Open-ended exploratory working group on the phytosanitary aspects of GMOs, biosafety and invasive species" asserted that the scope of the Convention applies to wild flora and as such "plants" includes non-cultivated plants as well as cultivated plants. It also agreed that in cases where LMOs have the potential to cause harm to plant life or health, they could be considered "pests" and treated as such.

The term "potential economic importance" is an important element of the definition of quarantine pest and one to which considerable emphasis is placed in the PRA process. ISPM 5, Supplement 2 provides background information and other relevant information to clarify the meaning of this term within the IPPC and ISPMs. The Supplement clarifies that "potential economic importance" can include impacts expressed in both monetary and non-monetary terms, that markets are not the sole indicator of pest consequence, and that members maintain the right to adopt phytosanitary measures with respect to pests for which the damage caused to plants, plant products or ecosystems within an area cannot easily be quantified. The Supplement further explains that economic effects should not be interpreted to mean only market effects but is intended to provide a broad framework in which a wide variety of effects including also environmental and social effects may be analysed."

ISPM 6: *Guidelines for surveillance*

The scope of this standard is "the components of survey and monitoring systems for the purpose of pest detection and the supply of information for use in pest risk analyses, the establishment of pest free areas, and where appropriate, the preparation of pest lists." Surveillance for LMOs may be a key component to the use and management of LMOs, including the management of risks associated with LMOs. The standard distinguishes between general and specific surveillance. **Section 1** (General surveillance) states that the information obtained through general surveillance may be used to support NPPO declarations of pest freedom, for early detection of pests, and other types of information exchange. The information may also be used to establish host and commodity pest lists and distribution records.

Section 2 (Specific surveillance) describes the components of specific survey programmes designed to obtain information on pests on specific sites over defined periods of time. Like general surveillance, specific surveillance can aid in the early detection of new pests (**Section 2.1**). This section also describes how sites for specific surveys are determined, including:

- previously reported presence and distribution of the pest
- biology of the pest
- distribution of host plants of the pest and especially of their areas of commercial production, and
- climatic suitability of sites for the pest.

Section 2.2 describes the determination of survey sites for "commodity or host surveys". Finally, **Section 2.3** discusses the uses of targeted and random sampling, stating that some random sampling should be done to "detect unexpected events". This is especially important to the detection of pests which may affect natural environments (rather than areas under cultivation). However, the relevance of this statement to detecting unpredicted spread of an LMO is important, and demonstrates that surveillance may also be an important component in the assessing and managing plant pest risks of LMOs.

Section 5 outlines the type of information that should be included in pest records (see also ISPM 8). Besides such information as scientific name and collection information, "additional information" may also be appropriate. This may be "nature of host relationship, infestation status, growth stage of plant affected, or found only in greenhouses". For LMOs, additional information describing the genetic modifications should be included in the records.

Monitoring, "an official ongoing process to verify phytosanitary situations", is considered to be a part of surveillance. The use of monitoring surveys may therefore be an important component to the permitting process for the release of LMOs into the environment. For instance, monitoring may be used after the release of an LMO plant to determine if the LMO has itself become weedy, has outcrossed to wild relatives to produce new weeds, or is otherwise producing some sort of detrimental effects on plants or the environment.

ISPM 9: *Guidelines for pest eradication programmes*

ISPM 9 provides guidance on how countries may undertake to eradicate both quarantine and non-quarantine pests from an area. The procedures outlined in this standard may also be applicable to conducting PRAs for LMOs. One aspect of managing risks associated with LMOs is the development of emergency plans if the LMO unexpectedly causes some problem (outcrossing to wild relatives to create new weeds, becoming weedy or invasive, etc.). **Section 1** describes the formulation of "contingency plans" which is especially important in the management of plant pest risks of LMOs. In particular it specifies that such plans are advantageous in saving time during emergency outbreak situations. Likewise, **Section 2** describes reasons for undertaking an eradication programme, and provides guidance on how an NPPO would carry out the eradication programme. It includes the same types of information that may be used in a pest risk analysis, including pest biology, distribution, potential hosts, potential for spread, possible impacts, and what sort of eradication strategies might be expected to work. ISPM 9, therefore, may be considered to be especially important in formulating management strategies for LMOs in cases where an LMO unexpectedly becomes a pest.

ATTACHMENT 1 - Comments on the scope of the IPPC in regard to environmental risks (Annex 1 to ISPM 11)

The full range of pests covered by the IPPC extends beyond pests directly affecting cultivated plants. The coverage of the IPPC definition of plant pests includes weeds and other species that have indirect effects on plants, and the Convention applies to the protection of wild flora. The scope of the IPPC also extends to organisms which are pests because they:

- *directly affect uncultivated/unmanaged plants*

Introduction of these pests may have few commercial consequences, and therefore they have been less likely to be evaluated, regulated and/or placed under official control. An example of this type of pest is Dutch elm disease (*Ophiostoma novo-ulmi*).

- *indirectly affect plants*

In addition to pests that directly affect host plants, there are those, like most weeds/invasive plants, which affect plants primarily by other processes such as competition (e.g. for cultivated plants: Canada thistle (Cirsium arvense) [weed of agricultural crops], or for uncultivated/unmanaged plants: Purple loosestrife (Lythrum salicaria) [competitor in natural and semi-natural habitats]).

- *indirectly affect plants through effects on other organisms*

Some pests may primarily affect other organisms, but thereby cause deleterious effects on plant species, or plant health in habitats or ecosystems. Examples include parasites of beneficial organisms, such as biological control agents.

To protect the environment and biological diversity without creating disguised barriers to trade, environmental risks and risks to biological diversity should be analyzed in a PRA.

ATTACHMENT 2 - Comments on the scope of the IPPC in regard to pest risk analysis for living modified organisms (Annex 2 of ISPM 11)

Phytosanitary risks that may be associated with a living modified organism (LMO) are within the scope of the

International Plant Protection Convention (IPPC) and should be considered using pest risk analysis (PRA) to make decisions regarding pest risk management.

The analysis of LMOs includes consideration of the following:

- Some LMOs may present a phytosanitary risk and therefore warrant a PRA. However other LMOs will not present a phytosanitary risks beyond those posed by related non-LMOs and therefore will not warrant a complete PRA. For example, modifications to change the physiological characteristics of a plant (e.g. ripening time, storage life) may not present any phytosanitary risk. The pest risk that may be posed by an LMO is dependent on a combination of factors, including the characteristics of the donor and recipient organisms, the genetic alteration, and the specific new trait or traits. Therefore, part of the supplementary text (see Annex 3) provides guidance on how to determine if an LMO is a potential pest.
- PRA may constitute only a portion of the overall risk analysis for import and release of a LMO. For example, countries may require the assessment of risks to human or animal health, or to the environment, beyond that covered by the IPPC. This standard only relates to the assessment and management of phytosanitary risks. As with other organisms or pathways assessed by an NPPO, LMOs may present other risks not falling within the scope of the IPPC. When an NPPO discovers potential for risks that are not of phytosanitary concern it may be appropriate to notify the relevant authorities.
- Phytosanitary risks from LMOs may result from certain traits introduced into the organism, such as those that increase the potential for establishment and spread, or from inserted gene sequences that do not alter the pest characteristics of the organism but that might act independently of the organism or have unintended consequences.
- In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term "pest" should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk.
- The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. However, genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs.
- Potential phytosanitary risks that may be associated with LMOs could also be associated with non-LMOs. It may be useful to consider risks associated with LMOs in the context of risks posed by the non-modified recipient or parental organisms, or similar organisms, in the PRA area.

ATTACHMENT 3 - Determining the potential for a living modified organism to be a pest (Annex 3 of ISPM 11)

This annex is relevant for living modified organisms (LMOs) only where there is potential for phytosanitary risks from the LMO associated with some characteristic or property related to the genetic modification. Other phytosanitary risks associated with the organism should be assessed under other appropriate sections of ISPM 11 or under other appropriate ISPMs. The information requirements outlined in section 1.3 may be needed in determining the potential for an LMO to be a pest.

Potential phytosanitary risks for LMOs

Potential phytosanitary risks for LMOs may include:

a. Changes in adaptive characteristics which may increase the potential for introduction or spread, for example alterations in:

- tolerance to adverse environmental conditions (e.g. drought, freezing, salinity etc.)
- reproductive biology
- dispersal ability of pests
- growth rate or vigour
- host range
- pest resistance
- pesticide (including herbicide) resistance or tolerance.

b. Adverse effects of gene flow or gene transfer including, for example:

- transfer of pesticide or pest resistance genes to compatible species
- the potential to overcome existing reproductive and recombination barriers resulting in pest risks
- potential for hybridization with existing organisms or pathogens to result in pathogenicity or increased
- pathogenicity.

c. Adverse effects on non-target organisms including, for example:

- changes in host range of the LMO, including the cases where it is intended for use as a biological control agent or organism otherwise claimed to be beneficial
- effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and
- microflora, nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects)
- capacity to vector other pests
- negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants.

d. Genotypic and phenotypic instability including, for example:

- - reversion of an organism intended as a biocontrol agent to a virulent form.

e. Other injurious effects including, for example:

- phytosanitary risks presented by new traits in organisms that do not normally pose phytosanitary risk
- novel or enhanced capacity for virus recombination, trans-encapsidation and synergy events related to the presence of virus sequences
- phytosanitary risks resulting from nucleic acid sequences (markers, promoters, terminators, etc.) present in the insert.

The potential phytosanitary risks identified above can also be associated with non-LMOs. The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. However, genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs.

If there is no indication that new traits resulting from genetic modifications have phytosanitary risks, the LMO may require no further consideration.

It may be useful to consider potential risks in the context of risks posed by the non-modified recipients or parental organisms, or similar organisms, in the PRA area.

In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term "pest" should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk.

Factors that may result in the need to subject a LMO to stage 2 of the PRA include:

- lack of knowledge about a particular modification event
- the credibility of information if it is an unfamiliar modification event
- insufficient data on the behaviour of the LMO in environments similar to the PRA area
- field experience, research trials or laboratory data indicating that the LMO may pose phytosanitary risks (see sub-sections a. to e. above)
- where the LMO expresses characteristics that are associated with pests under ISPM 11
- existing conditions in the country (or PRA area) that may result in the LMO being a pest
- where there are PRAs for similar organisms (including LMOs) or risk analyses carried out for other purposes that indicate a pest potential
- experience in other countries.

Factors that may lead to the conclusion that an LMO is not a potential pest and/or requires no further consideration under ISPM 11 include:

- where the genetic modification in similar or related organisms has previously been assessed by the NPPO (or other recognized experts or agencies) as having no phytosanitary risk
- where the LMO is to be confined in a reliable containment system and not be released
- evidence from research trials that the LMO is unlikely to be a pest under the use proposed
- experience in other countries.