

INTERNATIONAL GUIDELINES FOR THE EXPORT, SHIPMENT, IMPORT, AND RELEASE OF BIOLOGICAL CONTROL AGENTS AND OTHER BENEFICIAL ORGANISMS (INTERNATIONAL STANDARD FOR PHYTOSANITARY MEASURES NO. 3)

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ABSTRACT

This paper describes the development and review of the International Standard for Phytosanitary Measures (ISPM No. 3) which provides guidelines for risk management relating to the export, shipment, import and release of biological control agents and other beneficial organisms. The standard lists the related responsibilities of contracting parties to the International Plant Protection Convention (IPPC) ('contracting parties'), of National Plant Protection Organizations (NPPOs) or of other responsible authorities, importers and exporters. ISPM No. 3 addresses biological control agents capable of self-replication (including parasitoids, predators, parasites, nematodes, phytophagous organisms, and pathogens such as fungi, bacteria and viruses), sterile insects and other beneficial organisms (such as mycorrhizae and pollinators), including those packaged or formulated as commercial products. Provisions are also included for importation of non-indigenous biological control agents and other beneficial organisms for research in quarantine facilities.

INTRODUCTION

Phytosanitary standards (ISPMs) are developed under the auspices of the International Plant Protection Convention (IPPC) and provide a framework within which national plant protection organisations (NPPOs) can develop regulations to provide for plant protection. The level of phytosanitary protection that is considered appropriate for any given country, is for that particular country to decide. The finalization and adoption of the IPPC occurred after the first publication of ISPM No. 3 (FAO 1996b). In the 1980's onwards there was an increasing volume (both number of species and number of individual specimens) of biological control agents moved internationally, particularly classical biological control agents and those

used for inundative release. Prior to 1995, there was no agreed international guidance for the trans-boundary movement of these live organisms, hence FAO developed ISPM No. 3 to address a specific need. It was decided that the most appropriate place for such an international guideline was within the framework of the IPPC. The FAO Conference adopted ISPM No. 3 in 1995, before the revision of the IPPC (which was adopted in 1997) and the finalization of the World Trade Agreement on the Application of Sanitary and Phytosanitary Measures. There have also been many scientific developments in the knowledge of biological control agents since 1995. It is within this context that ISPM No. 3 was developed and now been revised.

The primary support standard to ISPM No. 3 was ISPM No. 2 (FAO 1996a). More detailed guidance on Pest Risk Analysis is provided in other ISPMs, particularly ISPM No. 11 (FAO 2004a) and ISPM No. 21 (FAO 2004c).

At the second session of the ICPM (October 1999) issues wider than agriculture, such as the impact on the environment and other relevant international agreements, were considered in the context of the IPPC (e.g., the Convention on Biological Diversity). The ICPM established an expert working group to consider this and other relevant issues. An output of the working group was that the recommendation that ISPM No. 3 be amended “to include consideration of risk of spread of biological control organisms to other countries”.

Prior to revision, the scope of ISPM No. 3 was relatively narrow and primarily applicable to classical biological control agents. Although conceptually it encompassed the principles of the IPPC and SPS Agreement and could in practice be applied more widely, it was not explicit on a number of important phytosanitary issues e.g. pest risk analysis. Therefore, the scope of ISPM No. 3 was broadened to encompass the principles and articles of IPPC, in particular Article VII 2 (g) “*Contracting parties may make provisions, with adequate safeguards, for the importation for purposes of scientific research or education, of plants and plant products and of specimens of plant pests. Adequate safeguards likewise need to be taken when introducing biological control agents and organisms claimed to be beneficial.*” Hence the revised standard has incorporated guidelines that cover other beneficial organisms with particular reference to sterile insects as well as biological control agents.

In addition, ISPM No. 3 was considered by the ICPM for possible review in 2001 (five years after adoption, as is standard for all adopted ISPMs) and issues such as the rapid increase in the use of, and trade in biological control agents, as well as developments in biological control practices meant there was a need to update this standard. The standard also needed to be made consistent with other more recently developed ISPMs and phytosanitary concepts within the framework of the IPPC. The revision of ISPM No. 3 was placed on the IPPC work programme and the revision commenced as soon as funding became available.

REVIEW OF ISPM NO. 3

Given the above context and to ensure that all relevant issues were addressed in this process, the ICPM Standards Committee drafted specifications for the review of ISPM No. 3. According to IPPC Specification No. 4 the review needed to include the consideration of:

- Revision of title and text;
- Pest risk analysis procedures appropriate for biological control agents;
- Regulatory guidance developed by the OECD since publication of the standard;
- Issues relating to the transport and handling of biological control agents;
- Possibilities for clarification and emphasis with regards to invasive species and other impacts on the environment, and
- Issues relating to pre and post release monitoring.

Other matters to be considered and addressed where appropriate were:

- Sterile insect technique (SIT) issues;
- Beneficial organism issues, and
- The use of biological control agents that had been genetically modified using modern biotechnology techniques.

An expert working group (including nine independent experts plus the IPPC Secretariat) met in December 2003 at FAO Headquarters in Rome to revise ISPM No. 3. The outcome was a revised draft ISPM No. 3 that was reviewed by the Standards Committee in May 2004. The draft ISPM No. 3 was released for country consultation in June 2004. Many comments were received and all comments from all interested parties had to channel their comments through the NPPOs. Comments provided by the NPPOs were considered by the Standards Committee and the necessary adjustments made to the draft. The final version of the standard was submitted to the seventh session of the ICPM (in April 2005) for consideration. After minor modifications it was adopted as ISPM No. 3 (FAO 2005a and 2005c).

The Standard states that it is “*intended to facilitate the safe export, shipment, import and release of biological control agents and other beneficial organisms. Responsibilities relating to this are held by contracting parties, NPPOs or other responsible authorities, and by importers and exporters.*” However it does not include reference to living modified organisms, issues related to registration of biopesticides, or microbial agents intended for vertebrate pest control.

“Contracting parties, or their designated authorities, should consider and implement appropriate phytosanitary measures related to the export, shipment, import and release of biological control agents and other beneficial organisms and, when necessary, issue related import permits.”

As described in this standard, NPPOs or other responsible authorities should:

- *“Carry out pest risk analysis of biological control agents and other beneficial organisms prior to import or prior to release;*
- *Ensure, when certifying exports, that the phytosanitary import requirements of importing contracting parties are complied with;*

- *Obtain, provide and assess documentation as appropriate, relevant to the export, shipment, import or release of biological control agents and other beneficial organisms;*
- *Ensure that biological control agents and other beneficial organisms are taken either directly to designated quarantine facilities or mass-rearing facilities or, if appropriate, passed directly for release into the environment;*
- *Encourage monitoring of release of biological control agents or beneficial organisms in order to assess impact on target and non target organisms.*

Responsibilities of, and recommendations for, exporters include ensuring that consignments of biological control agents and other beneficial organisms comply with phytosanitary import requirements of importing countries and relevant international agreements, packaging consignments securely, and providing appropriate documentation relating to biological control agents or other beneficial organisms.

Responsibilities of, and recommendations for, importers include providing appropriate documentation relating to the target pest(s) and biological control agent or other beneficial organisms to the NPPO or other responsible authority of the importing country.”

DISCUSSION

A primary objective of the revision of ISPM No. 3 was to ensure consistency with the IPPC (FAO 1997) and that it was harmonized with relevant IPPC phytosanitary terms (FAO 2005b).

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OBJECTIVES OF THE STANDARD

The objectives of the standard are to:

- *“Facilitate the safe export, shipment, import and release of biological control agents and other beneficial organisms by providing guidelines for all public and private bodies involved, particularly through the development of national legislation where it does not exist;*
- *Describe the need for cooperation between importing and exporting countries so that:*
 - i. benefits to be derived from using biological control agents or other beneficial organisms are achieved with minimal adverse effects;*
 - ii. practices which ensure efficient and safe use while minimizing environmental risks due to improper handling or use are promoted.”*

Guidelines in support of these objectives are described that:

- *“Encourage responsible trade practices*
- *Assist countries to design regulations to address the safe handling, assessment and use of biological control agents and other beneficial organisms*

- *Provide risk management recommendations for the safe export, shipment, import and release of biological control agents and other beneficial organisms*
- *Promote the safe use of biological control agents and other beneficial organisms.*

SCOPE OF THE IPPC

The International Plant Protection Convention (IPPC) is based on securing common and effective action to prevent the spread and introduction of pests of plants and plant products, and the promotion of appropriate measures for their control. In this context, the provisions of the IPPC extend to any organism capable of harbouring or spreading plant pests, particularly where international transportation is involved (Article I of the IPPC, 1997). A pest is defined as “*any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products*”.

The IPPC (1997) contains the following provision in relation to the regulation of biological control agents and other beneficial organisms. Article VII.1 states:

“With the aim of preventing the introduction and/or spread of regulated pests into their territories, contracting parties shall have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may:

- d) prohibit or restrict the movement of biological control agents and other organisms of phytosanitary concern claimed to be beneficial into their territories.”*

Section 4.1 of ISPM No. 20 (FAO 2004b) contains a reference to the regulation of biological control agents; it states:

“Imported commodities that may be regulated include articles that may be infested or contaminated with regulated pests. ... The following are examples of regulated articles: ... pests and biological control agents.”

The revised ISPM No. 3 provides international guidelines relating to phytosanitary measures, as well as recommending guidelines for the safe use of biological control agents and other beneficial organisms claimed to be beneficial. Phytosanitary concerns with regards to biological control agents include the possibility that newly introduced biological control agents, or organisms claimed to be beneficial may introduce pests or diseases which affect the agent, hence reduce the effect of a biological control program or may severely disrupt an existing biological control program; or may significantly affect non-target organisms, such that there are harmful effects on plant species or plant health. This standard does not alter in any way the scope or obligations of the IPPC itself as contained in the New Revised Text (1997) or conflict with any of the other ISPMs.

Most of the standard is based on the premise that a biological control agent or other beneficial organism may be a potential pest itself, and in this sense Article VII.1c of the IPPC (1997) applies because contracting parties may prohibit or restrict the movement of regulated pests into their territories. In some situations, biological control agents and other beneficial organisms may act as a carrier or pathway for plant pests, hyperparasitoids, hyperparasites

and entomopathogens. In this sense, biological control agents and other beneficial organisms may be considered to be regulated articles as described in Article VII.1 of the IPPC (1997) and ISPM No. 20 (FAO 2004b).

ISPM No. 3 does not specifically cover genetically modified organisms (GMOs). Although GMOs are specifically excluded, the principles of pest risk analysis for assessment of risk and implementation of an appropriate level of protection are still applicable. In addition, this standard does not cover pesticide registration. Pesticide registration is an independent set of processes that differ between countries. The extent to which organisms covered in ISPM No.3 are involved in these registration processes depends on individual countries. In some instances the processes and information required are coincident with the requirements of ISPM No.3. However, the objectives of pesticide registration are different as a whole from those of the IPPC/ISPM No.3, although there may be similar elements.

STRUCTURE

The structure of this revised standard broadly follows that of the original ISPM No. 3, and its content is based primarily on risk management relating to the use of biological control agents and other beneficial organisms. Based on in-country experience, the previous format of ISPM No. 3 was very easy to understand and popular in the field, and so as much of the content and format as possible was retained.

PEST RISK ANALYSIS

The existing standards on pest risk analysis (ISPM No. 2 (FAO 1996a), ISPM No. 11 (FAO 2004a) and ISPM No. 21 (FAO 2004c)) provide the appropriate fundamental processes for carrying out pest risk assessments for biological control agents and other beneficial organisms. In particular, ISPM No. 11 includes provisions for pest risk assessment in relation to environmental risks, and this aspect covers environmental concerns related to the use of biological control agents. Implicit in the development of the output of a risk analysis is the development of risk management plans for organisms being considered.

The IPPC (1997) takes into account internationally approved principles governing the protection of the environment (Preamble). Its purpose includes promoting appropriate phytosanitary measures (Article I.1). Therefore, in carrying out pest risk analyses in accordance with this and other appropriate ISPMs, and in developing and applying related phytosanitary measures (i.e., pest risk management), contracting parties should consider the potential for broader environmental impacts resulting from releasing biological control agents and other beneficial organisms (e.g., the impact on non-target invertebrates).

ISSUES/CHANGES

The content of ISPM No. 3 was not consistent with that of more recent ISPMs in that it included a significant amount of technical implementation details, as well as having a significantly different functional layout and terminology (e.g., see Table 1 for a summary of terminology changes). The revision removed the technical details and adjusted the layout of the text to align more closely with that of other standards.

Table 1. A summary of ISPM No. 3 terminology changes.

Term	New	Modified	Deleted
Authority		x	
Beneficial Organism	x		
Biological Control		x	
Biological Control Agent		x	
Biological Pesticide (biopesticide)		x	
Classical Biological Control Agent		x	
Contamination	x		
Control (of a pest)	x		
Ecoarea			x
Entry (of a consignment)	x		
Establishment		x	
Exotic			x
Import Permit (of a biological control agent)			x
Host Range	x		
Infestation (of a commodity)	x		
Introduction		x	
Inundative Release		x	
Natural Enemy		x	
Organism		x	
Parasitoid		x	
Pathogen		x	
Phytosanitary Measure	x		
Quarantine		x	
Reference Specimens	x		
Regulated Organism	x		
Specificity		x	
Sterile Insect	x		
Sterile Insect Technique	x		

It is recognized that much of the information removed was useful to various parties involved in the practical processes of import and release of biological control agents and other organisms claimed to be beneficial. It is intended that the technical implementation details will be compiled into a set of technical explanatory documents in support of the standard. These documents will not be obligatory, have no official status under the ICPM, and will not be considered official interpretations of ISPM No. 3. However, they may provide examples

of processes and methodologies that could be followed when implementing the standard. According to the IPPC, such explanatory documents need to be developed under the auspices of the IPPC secretariat (otherwise they do not have ISPM explanatory document status).

The general arrangement of ISPM No. 3 (FAO 2005a) is as follows: “designation of responsible authority and description of general responsibilities; pest risk analysis; responsibilities of contracting parties prior to import, documentary responsibilities of importer prior to import; responsibilities of exporter; responsibilities of NPPO or other responsible authority of the importing contracting party upon import; responsibility of the NPPO or other responsible authority before, upon and following release.

The implementation of the guidelines is the responsibility of the contracting parties (usually the NPPO’s) or other responsible authorities. Previously, ISPM No. 3 included details and obligations for organisations (e.g., exporters, researchers and importers) that are beyond the scope of the IPPC.

These guidelines are not legally binding under the IPPC, but are indirectly binding through the WTO/SPS Agreement. Advice for parties other than NPPOs, such as exporters, is provided. This advice is for guidance on appropriate process and is not obligatory. The obligations of non-NPPO parties are those contained in the regulations of countries within which they operate. These regulations should have been developed by the NPPO within the framework of ISPM No.3, hence align with the ISPMs objectives.

Reference is made to other international agreements where appropriate, but such references are intentionally vague to ensure it is not implied the IPPC is infringing or interpreting such agreements.

The revision of ISPM No. 3 should improve the understanding of the processes associated with the import and release of biological control agents and/or beneficial organisms, and facilitate the safe trade in such organisms while protecting the environment. This ISPM continues to provide a framework for countries to establish their own phytosanitary measures for biological control agents and/or beneficial organisms i.e., it is not a prescriptive standard that details phytosanitary measures that should be applied in all countries around the world.

Further information on ISPM No. 3 (or any other ISPM or the IPPC) can be obtained from the IPPC Secretariat (ippc@fao.org) or: IPPC Secretariat, FAO-AGPP, Vialle delle Terme di Caracalla, 00100 Rome, Italy.

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