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INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

CODE OF CONDUCT FOR THE IMPORT AND RELEASE OF EXOTIC BIOLOGICAL CONTROL AGENTS

Secretariat of the International Plant Protection Convention
Food and Agriculture Organization
of the United Nations
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CONTENTS

Endorsement

International standards for phytosanitary measures are prepared by the Secretariat of the International Plant Protection Convention as part of the United Nations Food and Agriculture Organization's global programme of policy and technical assistance in plant quarantine. This programme makes available to FAO Members and other interested parties these standards, guidelines and recommendations to achieve international harmonization of phytosanitary measures, with the aim to facilitate trade and avoid the use of unjustifiable measures as barriers to trade.

The following standard was endorsed by the 28th Session of the FAO Conference in November 1995.

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Director-General
Food and Agriculture Organization of the United Nations

Review and amendment

International standards for phytosanitary measures are subject to periodic review and amendment. The next review date for this standard is 2001, or such other date as may be agreed upon by the Commission on Phytosanitary Measures.

Standards will be updated and republished as necessary. Standard holders should ensure that the current edition of this standard is being used.

Distribution

International standards for phytosanitary measures are distributed by the Secretariat of the International Plant Protection Convention to all FAO Members, plus the Executive/Technical Secretariats of the Regional Plant Protection Organizations:

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- Comité Regional de Sanidad Vegetal para el Cono Sur
- Comunidad Andina
- European and Mediterranean Plant Protection Organization
- InterAfrican Phytosanitary Council
- North American Plant Protection Organization
- Organismo Internacional Regional de Sanidad Agropecuaria
- Pacific Plant Protection Organization.

INTRODUCTION

SCOPE

This standard describes the Code of Conduct for the Import and Release of Exotic Biological Control Agents. It lists the responsibilities of the authorities of governments, and the responsibilities of the exporters and importers of biological control agents.

The Code addresses the importation of exotic biological control agents capable of self-replication (parasitoids, predators, parasites, phytophagous arthropods and pathogens) for research and/or release into the environment including those packaged or formulated as commercial products.

Governments that are already fulfilling the objectives of this Code by regulation or other equivalent means may consider adapting their existing systems in the light of this Code.

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[1] The terms and definitions published in 1996 in this standard conform to this edition of the *Glossary of phytosanitary terms*.

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DEFINITIONS AND ABBREVIATIONS

Antagonist	An organism (usually pathogen) which does no significant damage to the host but its colonization of the host protects the host from significant subsequent damage by a pest.
Area	An officially defined country, part of a country or all or parts of several countries.
Authority	The National Plant Protection Organization, or other entity or person officially designated by the government to deal with matters arising from the responsibilities set forth in the Code.
Biological control (Biocontrol)	Pest control strategy making use of living natural enemies, antagonists or competitors and other self-replicating biotic entities.
Biological control agent	A natural enemy, antagonist or competitor, and other self-replicating biotic entity, used for pest control.
Biological pesticide (Biopesticide)	A generic term, not specifically definable, but generally applied to a biological control agent, usually a pathogen, formulated and applied in a manner similar to a chemical pesticide, and normally used for the rapid reduction of a pest population for short-term pest control.
Classical biological control	The intentional introduction and permanent establishment of an exotic biological agent for long-term pest control.
Competitor	An organism which competes with pests for essential elements (e.g. food, shelter) in the environment.

Ecoarea	An area with similar fauna, flora and climate and hence similar concerns about the introduction of biological control agents.
Ecosystem	A complex of organisms and their environment, interacting as a defined ecological unit (natural or modified by human activity, e.g. agroecosystem), irrespective of political boundaries.
Establishment (of a biological control agent)	The perpetuation, for the foreseeable future, of a biological control agent within an area after entry.
Exotic	Not native to a particular country, ecosystem or ecoarea (applied to organisms intentionally or accidentally introduced as a result of human activities). As this Code is directed at the introduction of biological control agents from one country to another, the term "exotic" is used for organisms not native to a country.
Import permit (of a biological control agent)	An official document authorizing importation (of a biological control agent) in accordance with specified requirements.
Introduction (of a biological control agent)	The release of a biological control agent into an ecosystem where it did not exist previously (see also "establishment").
Inundative release	The release of overwhelming numbers of a mass-produced, invertebrate biological control agent in the expectation of achieving a rapid reduction of a pest population without necessarily achieving continuing impact.
IPPC	International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended.
Legislation	Any act, law, regulation, guideline or other administrative order promulgated by a government.
Micro-organism	A protozoan, fungus, bacterium, virus or other microscopic self-replicating biotic entity.

National Plant Protection Organization (NPPO)	Official service established by a government to discharge the functions specified by the IPPC.
Natural enemy	An organism which lives at the expense of another organism and which may help to limit the population of its host. This includes parasitoids, parasites, predators and pathogens.
Naturally occurring	A component of an ecosystem or a selection from a wild population, not altered by artificial means.
Organism	Biotic entity capable of reproduction or replication; vertebrate or invertebrate animals, plants and micro-organisms.
Parasite	An organism which lives on or in a larger organism, feeding upon it.
Parasitoid	An insect parasitic only in its immature stages, killing its host in the process of its development, and free living as an adult.
Pathogen	Micro-organism causing disease.
Pest	Any species, strain or biotype of plant, animal, or pathogenic agent, injurious to plants or plant products.
Predator	A natural enemy that preys and feeds on other animal organisms, more than one of which are killed during its lifetime.
Quarantine (of a biological control agent)	Official confinement of biological control agents subject to phytosanitary regulations for observation and research, or for further inspection and/or testing.

Release (into the environment)	Intentional liberation of an organism into the environment (see also "introduction" and "establishment").
Specificity	A measure of the host range of a biological control agent on a scale ranging from an extreme specialist only able to complete development on a single species or strain of its host (monophagous) to a generalist with many hosts ranging over several groups of organisms (polyphagous).

OUTLINE OF THE CODE

The Code is concerned with the importation of exotic biological control agents capable of self-replication (e.g. parasitoids, predators, parasites, phytophagous arthropods and pathogens) for research, and field release of control agents used in biological control and those used as biological pesticides. Currently used formulations of live pathogens are included because they possess the potential for multiplication and persistence in the environment. Naturally occurring strains (genetically, if not morphologically distinct entities) of natural enemies may show notable differences in specificity and infectivity, for example strains of *Bacillus thuringiensis* (Bt), and if exotic, fall within the terms of reference of this Code.

It is recognized that it may often be difficult to know whether the agent in a biological pesticide is exotic or not. For that reason many biological pesticides may have to be treated as though they were exotic.

The Code does not deal with other pest control techniques, that are also sometimes referred to as "biological controls", notably, autocidal methods, resistant host plants, as well as behaviour-modifying chemicals and other novel biological products. For toxic products of microbes used as pesticides which cannot reproduce and which are similar to conventional chemical pesticides, refer to the FAO International Code of Conduct on the Distribution and Use of Pesticides where they are covered in detail.

Procedures governing the handling and release into the environment of strains of organisms created artificially by genetic engineering are currently being examined by various international organizations and by national programmes. If required this Code could be applied to these organisms.

It is possible that this Code, after due evaluation, could also be applied to the introduction of exotic biological agents to control pests affecting human or animal health or the conservation of natural habitats.

Thus the Code deals with:

- the import of exotic biological control agents for research,
- the import and release of exotic biological control agents for biocontrol,
- the import and release of exotic biological control agents for use as biological pesticides where those products incorporate organisms which can multiply.

It does this by:

- identifying the three main groups involved in importing and releasing biological control agents: authorities (as the organizations representing government); exporters and importers;
- describing three responsibility phases of the process of import and release: the responsibilities of those involved before export; those before and upon importation; and those after importation.

CODE OF CONDUCT FOR THE IMPORT AND RELEASE OF EXOTIC BIOLOGICAL CONTROL AGENTS

1. Objectives of the Code

1.1 The objectives of the Code are to:

- facilitate the safe import, export and release of exotic biological control agents by introducing procedures of an internationally acceptable level for all public and private entities involved, particularly where national legislation to regulate their use does not exist or is inadequate;

- describe the shared responsibility of the many segments of society involved and the need for cooperation between importing and exporting countries so that:

  - benefits to be derived are achieved without significant adverse effects,
  - practices which ensure efficient and safe use while minimizing health and environmental concerns due to improper handling or use are promoted.

Standards are described that:

- encourage responsible and generally accepted trade practices,
- assist countries to design regulations to control the suitability and quality of imported exotic biological control agents and to address the safe handling, assessment and use of such products;
- promote the safe use of biological control agents for the improvement of agriculture, and human, animal and plant health;
- allow all those involved in the import or release of exotic biological control agents to determine if, in the context of the International Plant Protection Convention and other relevant conventions and legislation, their proposed actions and the actions of others constitute acceptable practices.

1.2 Responsibilities are outlined for the entities which are addressed by this Code, including governments, individually or in regional groupings; international organizations; research institutes; industry, including producers, trade associations, and distributors; users; and public-sector organizations such as environmental groups, consumer groups and trade unions. All references in this Code to a government or governments shall be deemed to apply equally to regional groupings of governments for matters falling within their areas of competence.

2. Designation of authority responsible

2.1 Governments should designate the competent authority empowered (normally the National Plant Protection Organization) to regulate or otherwise control and, where appropriate, issue permits for the importation and release of biological control agents. The authority may exercise its powers by using an internationally accepted standard (such as this Code) for guidance or by applying national legislation (which should be aligned with this Code). Importations of biological control agents should only be carried out with the consent of the authority.

2.2 The authority needs to:

2.2.1 Consider the legislation and regulations for the import and release of biological control agents.

2.2.2 Establish procedures for the assessment of the dossiers specified in section 4 and for establishing conditions appropriate to the assessed risk for the importation of biological control agents either with confinement in quarantine or directly to the importing agent without such requirement.

2.2.3 Maintain appropriate communication with and advise affected parties, including, where appropriate, other authorities on:
- despatch and handling procedures,
- release and evaluation of agents,
- distribution, trade and advertising factors,
- labelling, packaging and storage,
- information exchange, and
- occurrence of unexpected and/or deleterious incidents, including remedial action taken.

3. Responsibilities of authorities prior to import

3.1 The authority of an importing country should:

3.1.1 Endeavour to promote compliance with the Code or use specific powers or introduce necessary legislation to regulate the import, distribution and release of biological control agents in their countries, and make provision for effective enforcement.

3.1.2 Evaluate the dossiers specified in section 4 on the pest and the candidate biocontrol agent supplied by the importer in relation to the degree of acceptable risk and establish conditions for importation, containment or release appropriate to the assessed risk.

3.1.3 Issue regulations and/or import permits stating conditions to be fulfilled by the exporter and importer. As appropriate, these should include the:

- requirements to ensure authoritative identification of the agent,
- specified source of the biocontrol agent,
- precautions to be taken against inclusion of natural enemies of the agent,
- measures required for the exclusion of contaminants (especially quarantine pests),
- nature of the packaging to provide appropriate security,
- measures to allow inspection without escape of contents,
- point of entry,
- person or organization to receive the consignment,
- conditions under which the package may be opened,
- facilities in which the biological control agent may be held.

3.1.4 Ensure that procedures are available for the full documentation of the importation (identity, origins), release numbers/quantities, dates, localities), impact of each particular biological control agent in each country and any other data relevant to assessing the outcome, and make records are available to the scientific community and the public, as may be appropriate, while protecting any proprietary rights to the data.

3.1.5 If appropriate, ensure entry and, where required, processing through quarantine facilities or consider where a country does not have secure quarantine facilities, the importation through an accredited intermediate quarantine station in a third country.

3.1.6 Ensure the deposition in appropriate collections of authoritatively identified voucher specimens of the pest(s) and imported biological control agent where they will be available for reference and study.

3.1.7 Consider the necessity to require culturing of imported control agents in quarantine before release. Culturing for one generation can help in ensuring purity of the culture, authoritative identification, freedom from hyperparasites and pathogens or associated pests. This is especially advisable when wild collected agents are involved.

3.1.8 Decide if after a first import, further imports of the same biological control agent can be exempted from some or all of the requirements for import.

3.1.9 Maintain appropriate communication with and advise affected parties, including, where appropriate, other authorities on:

- despatch and handling procedures,
- release and evaluation of agents,
- distribution, trade and advertising factors,
- labelling, packaging and storage,

- information exchange, and
- occurrence of unexpected and/or deleterious incidents, including remedial action to be taken.

3.1.10 Ensure, in the case of repeat imports of a biological control agent for use in biocontrol or as a biopesticide, that documentation of the certification system permitting entry and release is such that only imports of at least equivalent standard to the approved import are released.

3.1.11 Take action to inform and educate local suppliers of biological control agents, farmers, farmer organizations, agricultural workers' unions, and other interested parties on the appropriate use of biological control agents.

3.1.12 Consult with authorities in neighbouring countries within the same ecoarea and with relevant regional organizations to clarify and resolve any potential conflicts of interest that may arise between countries.

3.2 The authority of an exporting country, to the extent possible, should:

3.2.1 Ensure that regulations of the importing country relevant to the Code are followed in the export from their countries of biological control agents.

3.2.2 Follow, where the exporting country has no or limited legislation concerning the import of biological control agents, the elements of the Code concerning the export of agents.

3.2.3 Ensure that arrangements are made for the taking and storing of voucher specimens of the exported material.

4. Responsibilities of importer prior to import

4.1 At the first importation, the importer of biological control agents for any purpose should prepare dossiers for submission to the authority with information on the pest to be controlled, including:

4.1.1 Accurate identification of the target pest, its world distribution and probable origin,

4.1.2 Assessment of its importance,

4.1.3 Its known natural enemies, antagonists or competitors already present or used in the proposed release area or in other parts of the world.

4.2 At the first importation, the importer of biological control agents for any purpose should prepare dossiers with information on the candidate biological control agent including:

4.2.1 Accurate identification or, where necessary, sufficient characterization of the agent to allow its unambiguous recognition,

4.2.2 A summary of all available information on its origin, distribution, biology, natural enemies and impact in its area of distribution,

4.2.3 An analysis of the host specificity of the biological control agent and any potential hazards posed to non-target hosts,

4.2.4 Natural enemies or contaminants of the candidate agent and procedures required for their elimination from laboratory colonies including, if appropriate, procedures to accurately identify and, if necessary, eliminate from the culture the host upon which the agent was cultured.

4.3 At the first importation, the importer of biological control agents for any purpose should also prepare a dossier for presentation to the authority which identifies potential hazards analyses the risks posed thereby and proposes mitigating procedures with respect to:

- those who may be handling biological control agents under laboratory, production and field conditions,
- human and animal health following introduction.

4.4 The importer of candidate biological control agents proposed for research in quarantine only should include information on the above points, plus the:

- nature of the material proposed for importation,
- security of quarantine (based on a description of the facilities and the qualifications of the staff).

4.5 The importer of biological control agents for import and release and use as biological pesticides should include in the dossier specified in 4.3 above, an analysis of the risks posed to possible non-target organisms and to the environment generally and should detail available emergency procedures should the biological control agent after release display unexpected adverse properties. The dossier should also contain a report detailing laboratory tests, and/or field observations and any other appropriate data to indicate the known or probable host range of the candidate agent. Testing should be based on recommended procedures and approved by the authority. These tests should relate to the candidate agent only and different procedures should apply to any additives used in formulations of products which contain biological control agents.

5. Responsibilities of exporter prior to export

5.1 Exporters of biological pesticides and other biological control agents for inundative release should:

5.1.1 Take all necessary steps to ensure that exported biological control agents conform to relevant regulations of importing countries, FAO and World Health Organization specifications concerning labelling, packaging and advertising, in particular the International Code of Conduct on Distribution and Use of Pesticides, as applicable, and this Code.

5.1.2 Ensure that biological control agents used in biological pesticides and for inundative release are evaluated for safety as provided for in section 4.3.

5.1.3 Ensure that all biological pesticides and other biological control agents for inundative release are evaluated for safety to human health and the environment and freedom from contaminating organisms.

5.2 The exporter of biological control agents for any purpose should ensure that:

5.2.1 All conditions specified in the regulations of the importing country or on the import permit are complied with.

5.2.2 Consignments, upon export, are accompanied by appropriate documentation:
- specifying that the contents are in compliance with the legislative provisions of the importing country and the permit provisions for that consignment,
- including information on the identity and recognition, safety, rearing or culture, and handling methods of the agent, and on possible contaminants, their recognition and elimination.

5.2.3 Packaging be sufficiently robust and consists of inert material secured in such a way that it can be inspected without escape of the contents. Wherever possible, organisms should be transported without their hosts (to reduce quarantine risks) and/or when they are in a dormant, inactive stage that is least likely to escape from packaging.

5.3 The exporter of biological control agents for research or classical biological control should also ensure that:

5.3.1 The import permit and all other documentation required in association with it are available prior to dispatch of the agent.

5.3.2 Packages are properly labelled in the official language of the importing country as to their contents and handling both in transit and on receipt in the receiving country. The information should include instructions to

handlers and officials at the point of entry on how the package should be treated to avoid damage to the contents and on action to be taken if the packaging is breached. It should also indicate whether it may be opened for customs inspection or must be sent directly into quarantine before opening.

5.3.3 Advance notice with full details of routing is provided to the receiver to minimize delays and to alert officials at the point of entry.

6. Responsibilities of authorities upon import

6.1 Authorities should:

6.1.1 Ensure that, where required (see section 3.2.5), all imports of classical biological control agents for research or biological control, after completion of import requirements at the point of entry, are taken directly to the specified quarantine facility for inspection or other required procedure. All dead, diseased or contaminated material, as well as extraneous material and packaging material, should be sterilized or destroyed in quarantine.

6.1.2 Ensure that biological control agents for which it is considered necessary (see section 3.2.6) are cultured in quarantine as long as has been specified by the authority.

6.1.3 Allow certain biological control agents to be passed directly for release providing all conditions have been complied with and appropriate documentary evidence is made available (see section 3). In all cases where identification or compliance is to be checked, this should be undertaken in a secure laboratory (i.e. a closed room with facilities for sterilizing or autoclaving extraneous or suspect materials).

7. Responsibilities of authorities before and upon release

7.1 Authorities should:

7.1.1 *If not already agreed under the terms of the import permit:*
Consider for approval for release following critical assessment of the submitted dossier on the agent and the establishment of appropriate conditions to reduce the assessed risk to an acceptable level. Assessments should be made using the types of procedures established in the ISPM *Guidelines for pest risk analysis* (e.g. to assess risks to non-target organisms and to identify risk-mitigating procedures). This may require information from specified additional tests.

7.1.2 Ensure full documentation of novel importations and their release programme as to identities, origins, numbers/quantity released, localities, dates, location of voucher specimens and any other data relevant to assessing the outcome, and maintenance of records of appropriate information with regard to other repeated releases of the same species.

7.1.3 Encourage the monitoring of the release of biological control agents in order to assess the impact on the target and non-target organisms.

7.1.4 Where problems (i.e. unexpected deleterious incidents) are identified, consider, and where appropriate, ensure corrective action is taken and inform all relevant interested parties.

8. Responsibilities of importer after import and release

8.1 The importer should:

8.1.1 Ensure that persons involved in distribution of their biological control agents are trained adequately, such that they are capable of providing a user with advice on efficient use.

8.1.2 Make information relating to the safety and environmental impact of biological control agents publicly available, and maintain a free and frank exchange of information, not subject to commercial confidentiality, with exporters, authorities other importers and operators of programmes involving the control agents.

8.1.3 Consider publication of the results of each first importation and release programme in an international journal. Such publication should include details of the programme and its economic and environmental impact as soon as practicable after the release of the agent.

8.1.4 Notify the authorities when problems occur and voluntarily take corrective action and, when requested by authorities, help to find solutions to difficulties.

8.1.5 Ensure application of the provisions of Article 11 of the International Code of Conduct on the Distribution and Use of Pesticides with respect to the advertising of commercial preparations of biological control agents for sale to the public.

9. Observance of the Code

9.1 This Code should be observed through collaborative action on the part of: governments, individually or in regional groupings; international organizations;

research institutes; industry, including producers, trade associations, and distributors; users; and other organizations such as environmental groups, consumer groups and trade unions.

9.2 The Code should be interpreted so that the requirements of other relevant codes or treaties are respected.

9.3 All parties addressed by this Code should observe this Code and promote the principles and ethics expressed, irrespective of other parties' ability to observe the Code.

9.4 The parties involved in providing biological control agents should maintain an active interest in following their products, keeping up to date with major users and with the occurrence of problems arising in the use of their products.

9.5 FAO Members should periodically review the relevance and effectiveness of the Code. The Code should be considered a dynamic text which must be brought up to date as required, taking into account technical, economic and social progress.

9.6 Authorities should monitor the observance of the Code and report on progress made to the Director-General of FAO.

For further information on international standards, guidelines and recommendations concerning phytosanitary measures, and the complete list of current publications, please contact the:

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