DRAFT STANDARD – OPEN FOR SUGGESTIONS/ COMMENTS/ OBJECTIONS TILL 30^{TH} SEPTEMBER, 2006

RELEVANT TEXT OF THE WTO NOTIFICATION FORM IS AVAILABLE AT THE END OF THE DRAFT STANDARD

GUIDELINES FOR REGULATING EXPORT, IMPORT & RELEASE OF BIOLOGICAL CONTROL AGENTS & OTHER BENEFICIAL ORGANISMS

Government of India
Ministry of Agriculture
Department of Agriculture and Cooperation
New Dehi

June, 2006

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Endorsement

This standard provides necessary guidance for regulating export, import and release of biocontrol agents and other beneficial organisms. The purpose of this standard is to facilitate safe export, shipment, import and release of biological control agents and beneficial organisms by providing guidelines for all public and private bodies involved in exchange of bio-control agents and other beneficial organisms both for scientific research and commercial use. It describes the need for cooperation between importing and exporting countries so that: the benefits to be derived are achieved without significant adverse effects and practices, which ensure efficient and safe use, while minimizing environmental risks due to improper handling or use are promoted. This standard developed in line with the ISPM No.3 of Food & Agriculture organization.

| This standard is approved for adoption on $\underline{}$ | <u>5.10.06</u> by: |
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| | |
| | |
| | (Ashish Bahuguna) |
| | JS (PP) (Head of NPPO |
| | Department of Agriculture & Cooperation |
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Review and Amendment

This standard would be subject to periodic review and amendment. The next review date for this standard would be November 2006 or any other date as may be considered appropriate by the Department of Agriculture & Cooperation. This standard would be updated and revised if necessary. The standard holders should ensure that the current edition of this standard is being used.

Control & Distribution of the standard

The master copy of this standard shall be held with PPA and controlled copies would be distributed by PPA, Directorate of Plant Protection, Quarantine & Storage, Faridabad to those listed below and to any other organization, to whom the distribution has been approved by the PPA. Any enquiries regarding this standard may be addressed to the PPA, Dte of PPQS, Faridabad-121001.

| Name of Copy Holder | Copy No. |
|--|----------|
| Joint Director (PQ), Dte of PPQ&S, N.H.IV., Faridabad | 1 |
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INTRODUCTION

SCOPE

This standard provides guidelines for regulating the export, import and release of biological control agents and beneficial organisms without undue risk. The standard describes the responsibilities of NPPO of importing country i.e the Department of Agriculture & Cooperation and Dte. of PPQS and exporting countries, other concerned agencies/organizations, importers and exporters; and requirements related to export, import and release of biological control agents (e.g., parasitoids, predators, parasites and pathogens (nematodes, fungi, bacteria and viruses)) and other beneficial organisms both for research and commercial use.

The scope of this standard does not cover any living modified organisms or the formulated biopesticides involving product registration or biological control agents used for the control of vertebrate pests.

BACKGROUND

The scope of the IPPC is based on securing common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control (Article I of the IPPC, 1997). 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).

The IPPC (1997) contains the following provision in relation to the regulation of biological control agents and beneficial organisms. Article VII.1 of the IPPC (1997) 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: ... c) prohibit or restrict the movement of regulated pests into their territories;

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

The structure of this standard broadly follows the structure of the revised ISPM No. 3: Guidelines for export, shipment, import and release of biological control agents and other beneficial organisms'. Its content is based primarily on risk management relating to the use of biological control agents and beneficial organisms. It is recognized that the existing standards on pest risk analysis (ISPM No. 2: Guidelines for pest risk analysis and ISPM No. 11: Pest Risk Analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004) provide the appropriate 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.

Moreover it should be recognized that in some situations, biological control agents and other beneficial organisms might act as a carrier or pathway for plant pests. In this sense only, 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: Guidelines for a phytosanitary import regulatory system.

Therefore, certain provisions of this standard are based on the presumption that a biological control agent or other beneficial organism may be a potential pest, 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.

REFERENCES

Guidelines for export, shipment, import and release of biological agents and other beneficial organisms, 2004. ISPM No. 3 (Rev.), FAO, Rome.

Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.

Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.

Guidelines for phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.

Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.

International Plant Protection Convention, 1997. FAO, Rome.

Pest reporting, 2002. ISPM No. 17, FAO, Rome.

Pest Risk Analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11 (Rev.), FAO, Rome.

DEFINITIONS & TERMS¹

| 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 [ISPM N° 3, 1996] |
|--------------------------------|---|
| area | An officially defined country, part of a country or all or parts of several countries [FAO, 1990; revised FAO, 1995; CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures] |
| 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 Standard. |
| beneficial organism* | Any species, strain or biotype of plant, micro-organism or animal beneficial under specific circumstances to plants or plant products |
| biological control** | Pest control strategy making use of living natural enemies, antagonists or competitors and other biotic entities. [formerly <i>biological control (biocontrol)</i>] |
| biological control agent** | A natural enemy, antagonist or competitor, and other biotic entity, used for pest control. |
| classical biological control** | The intentional introduction of a non-indigenous biological agent for long-term pest control. |
| competitor | An organism which competes with pests for essential elements (e.g. food, shelter) in the environment.[ISPM N° 3, 1996] |
| consignment | A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) [FAO, 1990; revised ICPM, 2001] |

¹ Terms marked with an (*) are new, terms marked with an (**) are revised

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contaminant** Any foreign organism present or associated with the consignment of a

regulated article such as biological control agent or other beneficial organism

not constituting infestation.

control (of a pest) Suppression, containment or eradication of a pest population [FAO, 1995]

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 [IŠPM N° 3, 1996].

entry (of a consignment)

Movement through a point of entry into an area [FAO, 1995]

establishment Perpetuation, for the foreseeable future, of a pest within an area after entry.

(agreed

interpretation)**

Agreed interpretation: the term establishment can apply equally to any organism, whether considered to be a pest or not. This is not adequately reflected in the definition found in Article II of the IPPC (1997).

host range** Species capable, under natural conditions, of sustaining a specific pest or other

organism

introduction The entry of a pest resulting in its establishment.

(agreed

interpretation)**

Agreed interpretation: the term introduction can apply equally to any organism, whether considered to be a pest or not. This is not adequately reflected in the definition found in Article II of the IPPC (1997).

infestation (of a commodity of a living pest of the plant or plant product commodity)

Presence in a commodity of a living pest of the plant or plant product concerned. Infestation includes infection [CEPM, 1997; revised CEPM, 1999].

inundative release** The release of large numbers of a mass-produced biological control agent or

beneficial organism without necessarily achieving continuing impact and, in the case of biologic al control agents, with the expectation of achieving a rapid effect.

IPPC International Plant Protection Convention, as deposited in 1951 with FAO in

Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001].

legislation Any act, law, regulation, guideline or other administrative order promulgated by a

government [ISPM N° 3, 1996].

micro-organism A protozoan, fungus, bacterium, virus or other microscopic self-replicating biotic

entity [ISPM N° 3, 1996].

National Plant

Protection

Organization (NPPO)

Official service established by a government to discharge the functions specified by the IPPC[FAO, 1990; formerly Plant Protection Organization (National)].

natural enemy** An organism which lives at the expense of another organism and which may help

to limit the population of that organism. This includes parasitoids, parasites,

predators, phytophagous organisms and pathogens.

naturally occurring A component of an ecosystem or a selection from a wild population, not altered

by artificial means [ISPM N° 3, 1996].

organism** Any biotic entity capable of reproduction or replication in its naturally occurring

state.

parasite An organism which lives on or in a larger organism, feeding upon it [ISPM N° 3,

1996].

parasitoid** An organism, most commonly an insect, parasitic usually only in its immature

stages, killing a single host individual in the process of its development.

Micro-organism capable of causing disease. pathogen**

pest Any species, strain or biotype of plant, animal or pathogenic agent injurious to

plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997].

Phytosanitary Certificate

Certificate patterned after the model certificates of the IPPC [FAO, 1990]

phytosanitary measure (agreed interpretation)

technique (SIT)*

Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests [FAO, 1995; revised IPPC, 1997;

ICPM, 2002]

offspring.

The agreed interpretation of the term phytosanitary measure accounts for the relationship of phytosanitary measures to regulated non-quarantine pests. This relationship is not adequately reflected in the definition found in Article II of the IPPC (1997).

predator A natural enemy that preys and feeds on other animal organisms, more than one

of which are killed during its lifetime [ISPM N° 3, 1996].

quarantine** Official confinement of regulated articles or regulated organisms for observation

and research or for further inspection, testing and/or treatment.

reference collection* Individual specimen(s) from a specific population deposited in a publically

available collection(s), as well as reference culture collection(s).

regulated organism* An organism deemed to require phytosanitary measures

release (into the Intentional liberation of an organism into the environment (see also

environment) "introduction" and "establishment") [ISPM N° 3, 1996].

sterile insect* An insect that, as a result of an appropriate treatment, is unable to produce viable

sterile insect Method of pest control using area-wide inundative release of sterile insects to

reduce fertility of a field population of the same species.

OUTLINE OF REQUIREMENTS

This standard is intended to facilitate the safe export, shipment, import and release of biological control agents and beneficial organisms. This standard prescribes the responsibilities of NPPOs of importing/exporting countries and other relevant agencies or organizations, importers and exporters on risk management related to the export, shipment, import and release of biological control agents and beneficial organisms.

The Directorate of Plant Protection, Quarantine & Storage, on behalf of the NPPO, shall carry out pest risk analysis of intended import of biological control agents and beneficial organisms prior to allowing the import and before recommending for inundative release; ensure to hold them under containment facilities, while under quarantine testing before granting clearance for release into the environment; and maintain appropriate records relevant to import and release of biological control agents and beneficial organisms.

The NPPO of exporting country should ensure that the regulations of importing country are complied with, while certifying for exports; and provide appropriate documentation requirements relevant to the export inspection, certification and shipment.

The exporter must ensure that the consignment of biological control agents and beneficial organisms exported are complied with regulations of importing country; securely packed and appropriately labeled prior to export; providing appropriate documentation related to export of specific biological control agents and beneficial organisms and relevant information to facilitate carrying out pest risk analysis.

The importer must ensure to provide appropriate documentation and relevant information related to import of specific biological control agents and beneficial organisms, ensure timely referring imported consignments for quarantine inspection and where required establish appropriate containment facilities as per guidelines prescribed by the Department of Agriculture & Cooperation.

1. General Requirements

1.1. Designation of Authority

The Directorate of Plant Protection, Quarantine & Storage (Dte of PPQS), established under the Department of Agriculture & Cooperation of Ministry of Agriculture has been mandated with the responsibility of implementing the regulations relating to the import of biological control agents or other beneficial organisms both for scientific research & commercial use.

1.2. Regulatory Requirements

The import of insects, microbial cultures including mushrooms and algae or biological control agents regulated by 'Plant Quarantine (Regulation of Import into India) Order, 2003 issued under the Destructive Insects & Pests Act, 1914 and amendments issued thereunder. As per the provision of clause 7 (1) of the above said Order, no import of insects or microbial cultures including mushrooms and algae or biological control agents shall be permitted without a valid permit issued by the Plant Protection Adviser.

Every Application for a permit to import insects or microbial cultures including mushroom spawns and algae or biological control agents should be made to the Plant Protection Adviser in form PQ 12 at least two months in advance along with prescribed registration fee. PPA would issue permit in form PQ 13 along with blue/violet tag in form PQ 14 (clause 7 (2)).

All the applications for first import of insects or microbial cultures including mushrooms and algae or biological control agents will be subject to a review by a Technical Committee established under the chairmanship of JS(PP), Department of Agriculture & Cooperation and permit for first import should only be issued based on the recommendations of the Technical Committee.

The technical panel will comprise of the following:

- Plant Protection Adviser (PPA), Dte of PPQS, N.H-IV, Faridabad-121001;
- Assistant Director General (Plant Protection), ICAR, New Delhi;
- Director, Project Directorate of Biological Control, Bangalore;
- Director, National Centre of Integrated Pest Management, New Delhi;
- Director, Biological Control, Forest Research Institute, Dehradun; and
- Director, National Bureau of Plant Genetic Resources, New Delhi-110012;
- Director (IPM), Dte of PPQS, N.H-IV, Faridabad-121001;
- Head, Division of Entomology, IARI, New Delhi-110012.
- Head, Division of Nematology, IARI, New Delhi-110012
- Head, Division of Plant Pathology, IARI, New Delhi-110012; and
- Joint Director (PQ), Dte of PPQS, N.H-IV, Faridabad-121001;

As per clause 3(14) of the PQ order, the import of live insects or microbial cultures including mushrooms and algae or biological control agents shall only be permitted through NPQS, New Delhi and RPQS, Amritsar, Chennai, Kolkata, Mumbai and Bangalore.

The consignments of beneficial organisms shall be accompanied by a certificate issued by NPPO at the country of origin with additional declarations for freedom from specified parasites or parasitoids or pathogens and the biological control agents free from natural enemies or hyper parasites or pathogens. The consignments of biological control agents or beneficial organisms shall be subjected to post-entry quarantine by the Department of Agriculture & Cooperation.

1.3. Responsibilities of NPPO of Exporting Country

The NPPO of the exporting country, in association with the exporter (see section 1.6), to the extent possible, should:

 ensure that regulations of the importing country are followed and that phytosanitary certificates, where required by the importing country for consignments of biological control agents or other beneficial organisms, if these are considered as potential pests or pathways for plant pests, are issued in accordance with ISPM No. 12: Guidelines for phytosanitary certificates;

follow the appropriate elements of this standard, where the importing country has no legislation specifically concerning the import of biological control agents or other beneficial organisms; and

Where appropriate may permit and collaborate in carrying out the research/experimental trials with biological control agents or other beneficial organisms by the importing country prior to exportation of bio-control agents or other beneficial organisms.

1.4. Responsibilities of NPPO of Importing Country (Dte of PPQS)

Prior to import, the Dte PPQS on behalf of the NPPO, shall:-

- promote awareness of, and compliance with this standard and use specific powers or introduce necessary phytosanitary measures to regulate the import, shipment and release of biological control agents or other beneficial organisms in its country, and make provision for effective enforcement;
- evaluate the documentation on the pest specified in section 1.7 and on the biological control agent or other beneficial organisms supplied by the importer in relation to the level of acceptable risk;
- establish measures for importation, shipment, quarantine facilities or release of biological control agents or other beneficial organisms appropriate to the assessed risk;
- issue regulations and/or import permits stating measures to be fulfilled by the exporter and importer. As appropriate, these may include the:
 - requirements to ensure authoritative identification in quarantine, and provision and storage of a reference specimen

- specified source of the biological control agent or other beneficial organism(s), including origin and/or point of production where relevant
- precautions to be taken against inclusion of natural enemies of the biological control agent or other beneficial organism
- measures required for the exclusion of contaminating pest(s)
- guidelines for minimal acceptable packaging for shipment
- measures to validate documentation
- measures to allow validation of the contents of the material
- conditions under which the package may be opened
- point(s) of entry
- person or organization to receive the consignment
- facilities in which the biological control agent or beneficial organisms may be held.

On import, the Dte PPQS should:

- ensure that procedures are available for the documentation of the importation (identity, origins), release (numbers/quantities, dates, localities), potential impact of each particular biological control agent or other beneficial organism in each country and of any other data relevant to assessing the outcome, and make records available to the scientific community and the public, as may be appropriate, while protecting any proprietary rights to the data;
- ensure entry and, where required, processing through quarantine facilities. If necessary, importation through an intermediate quarantine station in a third country recognized by the Dte of PPQS should be considered;
- where possible, ensure the deposition in appropriate collections of authoritatively identified reference specimens of the imported biological control agent or other beneficial organism (and host(s) where appropriate) where they will be available for reference and study in a publicly accessible collection. In the case of sterile insect technique (SIT), the sterile insect should be marked to different iate it from the wild insect;
- consider the necessity to require culturing of imported biological control agents or other beneficial organisms in quarantine before release. Culturing for one generation can help in ensuring purity of the culture, authoritative identification, and freedom from hyperparasites and pathogens or associated pests. This is especially advisable when biological control agents or other beneficial organisms are collected from the wild;
- consider, through the pest risk assessment process (consistent with the principles of necessity and minimal impact), if, after a first import, further imports of the same biological control agent or other beneficial organism can be exempted from some or all of the requirements for import.

1.5. Responsibilities of other Agencies/Organization

The other agencies such as Customs, port and postal authorities should cooperate with Plant Quarantine Authorities at designated point of entry in quickly referring the consignments of biological control agents or other beneficial organisms on arrival at the point of entry for quarantine inspection and ensure that the packages are not opened except in secured quarantine facility. The Dte of PPQS shall on behalf of the NPPO maintain effective communication with the above agencies for effecting timely forwarding of the same for quarantine inspection.

1.6. Responsibilities of Exporter

The exporter of biological control agents or other beneficial organisms should ensure that:

- all conditions specified in the regulations of the importing country or on the import permit are complied with;.
- consignments, upon export, are accompanied by appropriate documentation;
- packaging is secure in order to prevent escape of the contents;
- the sterile insects have been irradiated with the required minimum absorbed dose suitable for sterile insect technique (SIT) purposes and appropriately marked to recognise from natural population;

Exporters of biological control agents or other beneficial organisms for commercial purpose or inundative release further should:

- take all necessary steps to ensure that exported biological control agents or other beneficial organisms conform to import regulations specified and to relevant international agreements;
- provide documentation on measures undertaken to ensure that acceptable levels of contaminating organism(s) are not exceeded.

1.7. Responsibilities of Importer

Prior to the first importation, the importer of biological control agents or other beneficial organisms for any purpose should prepare documentation for submission to the Dte of PPQS, with the information on the targeted pest (s) to be controlled, including:

- accurate identification of the target pest (s), its world distribution and probable origin, its known biology and ecology;
- assessment of its economic importance and environmental impact;
- consideration of possible benefits of the target and conflicting interests surrounding its use;

• its known natural enemies, antagonists and other biological control agents or competitors already present or used in the proposed release area or in other parts of the world:

Prior to first importation, the importer of biological control agents or beneficial organisms for any purpose should coordinate with the exporter to prepare documentation with information for submission to the Dte of PPQS on candidate biological control agent or beneficial organism including:

- accurate identification or, if not available, sufficient characterization of the biological control agent or beneficial organism to allow its unambiguous recognition;
- a summary of all available information on its origin, distribution, biology, natural enemies and impact in its area of distribution;
- available information on host specificity of the biological control agent or beneficial organism and any potential hazards posed to non-target hosts;
- description of natural enemies or contaminants of the agent and procedures required for their elimination from laboratory colonies including, if appropriate, procedures to identify accurately and, if necessary, eliminate from the culture the host upon which the biological control agent or beneficial organism was cultured. Information on any measures taken prior to shipment should also be provided;

Prior to first importation, the importer of biological control agents or beneficial organisms, for any purpose, should also prepare documentation for presentation to the relevant authority that:

- identifies potential hazards and analyses the risks posed, such as for those who may be handling biological control agents or beneficial organisms under laboratory, production and field conditions:
- documents emergency actions or procedures, should the biological control agent or beneficial organism display unexpected adverse properties.

On importation, the importer of biological control agents or other beneficial organims should: ensure to file an application with PQ officer at concerned point of entry for quarantine inspection and clearance in form PQ 16 along with a copy of attached documents.

1.8. Requirements of Import Risk Analysis

Where appropriate, pest risk assessment should be undertaken prior to release (see section 14), in accordance with ISPM No. 2 (*Guidelines for pest risk analysis*) and/or stage 2 of ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004) as considered appropriate.

However, in respect of import of biocontrol agents and beneficial organisms intended for scientific research and evaluation shall only be permitted after undertaking full PRA in accordance with ISPM No.

11, (Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004) will be completed prior to release.

1.9. Accreditation of Quarantine Facilities

The importer of biological control agents or other beneficial organisms, where appropriate, should establish quarantine facilities to hold the consignments of biological control agents or other beneficial organisms under quarantine or confinement, while undertaking research and evaluation prior to release as per guidelines for accreditation of facilities established by the Plant Protection Adviser.

1.10. Requirements for Scientific Research

The import of biological control agents or other beneficial organisms for scientific research should only be permitted after securing information on the nature of material proposed for importation and detailed description of the security of facility, which includes level of containment and the competency/qualification of staff managing the facility.

1.11. Requirements for Commercial Importation (for inundative release)

The commercial importation of biological control agents or other beneficial organisms for inundative release should be limited to classical biological control. Such importation should be permitted only after ensuring that the imported biological control agents or beneficial organisms strictly confirm to regulations of importing country and in agreement with relevant international agreements and are free from natural enemies with acceptable level of contaminants.

2. Specific Requirements

2.1. Export Requirements

2.1.1. Inspection & certification prior to shipment

The NPPO or any responsible authority at the country of origin or export should inspect the consignment of biological agents or beneficial organisms prior to shipment to ensure free from natural enemies or acceptable level of contaminants and issue appropriate certificates. Such inspection should include verification of documentation and regulatory requirements of importing country and laboratory testing.

2.1.2. Shipment/labeling Requirements

The consignment of biological control agents or beneficial organisms should be securely packed to prevent causing any escape and appropriately labeled indicating common/scientific name of organism, taxon, life stage of the organism and host species, if any. The package should carry out appropriate declaration to the effect that the imported organism is not a living modified

organism or a biopesticide requiring product registration or biological control agent for controlling vertebrate pest.

2.2. Import Requirements

2.2.1. Inspection at the point of entry

All the consignments of biological control agents or other beneficial organisms upon import at the concerned point of entry should be referred for inspection at a specified quarantine facility.

2.2.2. Quarantine clearance

The PQ officer at concerned point of entry should allow certain biological control agents or beneficial organisms to be granted quarantine clearance directly for release, if appropriate and provided that all conditions have been complied with (see section 1.4) and required documentary evidence is made available (section 1.7).

2.2.3. Temporary holding in Quarantine

Where the import of biological control agents or beneficial organisms is made for the first time from the specified origin, the PQ officer should ensure that biological control agents or beneficial organisms are cultured in quarantine for at least one generation in appropriate post-entry quarantine facility established by the importer, to ensure free from natural enemies or hyper parasites or pathogens.

2.2.4. Notification of Non-compliance

The Dte of PPQS shall promptly inform concerned/appropriate authority in the event of detection of presence of natural enemies or should the biological control agent or beneficial organism display unexpected adverse properties or contaminants exceeded the level of acceptance or the regulations of importing country not met with.

2.3. Requirements of Field Release & Certification

2.3.1. Limited/Experimental trials

Where import of biological control agents or beneficial organisms are made for the first time, the Dte of PPQS may grant permission for carrying out evaluation studies under confinement or in isolated fields. After evaluating the performance of limited/experimental trials, the Dte of PPQS may grant permission for inundative release. PPA may consult the technical panel before granting permission for inundative release

2.3.2. Monitoring and evaluation

The Dte of PPQS shall ensure the monitoring of the release of biological control agents or beneficial organisms in order to assess the impact on the target and non-target organisms. Where appropriate, it should include a marking system to facilitate recognition of the biological control agent (e.g. sterile insects) or beneficial organism in contrast to the wild organism.

2.3.3. Corrective action

Where problems are identified (i.e. unexpected deleterious incidents), the Dte of PPQS shall consider appropriate measures to ensure that corrective action is taken and that all relevant parties are informed.

2.3.4. Communication

The Dte of PPQS shal take action, where relevant, to inform and educate local suppliers of biological control agents or beneficial organisms, farmers, farmer organizations and other stakeholders on their appropriate application and use.

2.3.5. Reporting

The Dte of PPQS shall abide by any reporting obligations under the IPPC (as contained in ISPM No. 17: *Pest Reporting*), e.g. where an organism used as a biological control agent by one country may be considered as a pest by another country.

2.3.5. Certification of Release

The Dte of PPQS shall perform, manage, supervise or, at minimum, audit or review any official requirements related to the release of biological control agents or beneficial organisms, e.g. requirements related to release only in specific areas in consultation with technical panel established for the said purpose.

RELEVANT TEXT OF THE WTO NOTIFICATION ON GUIDELINES FOR IMPORT / EXPORT OF BENEFICIAL ORGANISMS

1. Products covered (provide tariff item number(s) as specified in national scheduled deposited with the WTO; ICS numbers should be provided in addition where applicable):

Guidelines for regulating export, import and release of biological control agents and other beneficial organisms

2. Regions or countries likely to be affected, to the extent relevant or practicable :

All trading partner countries, exporting biological control agents and other beneficial organisms into India.

3. Title, language and number of pages of the notified document:

Title – Plant Quarantine (Regulation of Import into India) Order, 2003. Language – English/ Hindi Number of pages – 17

4. **Description of content:**

The draft guidelines prescribe the detailed requirements and procedures for imports and exports of biocontrol agents and other beneficial organisms and their mode of release. The purpose of these guidelines is to facilitate safe export, import, transport and release of biological control agents and beneficial organisms, both for scientific research and commercial use, wih a view to maximize the benefits from such trade and minimizing the possible adverse effects thereof, including health and environmental risks.

These guidelines are in consonance with ISPM 3 of the International Plant Protection Convention (IPPC). The details can be seen at the website www.plantquarantineindia.org or can be obtained from the National Enquiry Point – Mr. Amand Shah, Director, Plant Protection, Department of Agriculture & Cooperation, Ministry of Agriculture, Room No. 233, Krishi Bhavan, New Delhi – 110 011, INDIA.

Tele/Fax: 91-11-23389441

E-mail: amandshah@hotmail.com/ dac.sps@nic.in/ amand@krishi.nic.in /

5. Objective and rationale: [] food safety, [] animal health, [] plant protection

| [] protect humans from animal/ plant pest or disease, | | |
|--|--|--|
| [] protect territory from other damage from pests.6. international standard, guideline or recommendation : | | |
| [] Codex Alimentarius Commission, [] Office International des | | |
| Epizooties | | |
| [] International Plant Protection Convention, [] None | | |
| if an international standard, guideline or recommendation exists, give the | | |
| appropriate reference and briefly identify deviations: | | |
| The contents of this guidelines are in consonance with the International Standards on | | |
| Phytosanitary Measures No. 3 of Food and Agriculture Organisation. | | |
| 7. Relevant documents and language (s) in which these are available: | | |
| English and Hindi | | |
| 8. Proposed date of adoption: 30.10.2006 | | |
| 9. Proposed date of entry into force: 30.10.2006 | | |
| 10. Final date for comments: 15.09.2006 | | |
| Agency or authority designated to handle comments: | | |
| National Enquiry Point : Amand Shah, Director, Plant Protection, Department of | | |
| Agriculture & Cooperation, Ministry of Agriculture, Room No. 233, Krishi Bhavan, New | | |
| Delhi – 110 011, INDIA. | | |
| Tele/Fax: 91-11-23389441 | | |
| E-mail: amandshah@hotmail.com | | |
| dac.sps@nic.in | | |
| amand@krishi.nic.in | | |
| 11. Texts available from : | | |
| Website of the Department of Agriculture and Cooperation, Ministry of Agriculture, Government of India [http://agricoop.nic.in and [www.plantquarantineindia.org.in] And | | |
| National Enquiry Point : Amand Shah, Director, Plant Protection, Department of | | |
| Agriculture & Cooperation, Ministry of Agriculture, Room No. 233, Krishi Bhavan, New | | |
| Delhi – 110 011, INDIA. Tele/Fax: 91-11-23389441 | | |
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