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European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes

PM 6/2 (3)

Safe use of biological control
Sécurité de la lutte biologique

PM 6/2 (3) Import and release of non-indigenous biological control agents

Specific scope

This Standard gives guidelines for the import, release and required application procedures for non-indigenous biological control agents (BCAs).

Specific approval and amendment

Revision approved in 2010–09.
Second revision approved in 2014–09.

Introduction

Non-indigenous organisms, including biological control agents, may pose risks to agricultural and natural ecosystems if they establish in the environment. Their introduction into countries should be done with great care after assessment of the risks. The release ('Intentional liberation into the environment'; IPPC, 1995) of a non-indigenous biological control agent often follows a period in which relevant research has been carried out. The first import, for research, should have been carried out following the notification procedure of EPPO Standard PM 6/1 *First import of exotic biological control agents for research under contained conditions*, and the research will have provided information in support of the safety and efficacy of the organism when it is in due course released. This guideline is mainly concerned, therefore, with the release of biological control agents after a period of research, either in the importing country, or in another country, provided the EPPO-recommended notification procedure has been respected by the importer.

The above sequence is not, however, always followed, and biological control agents are sometimes imported directly for release. They may have been mass-reared in another country and then imported. In this case, provided the mass rearing was carried out to fulfil IOBC (International Organization for Biological and Integrated Control of Noxious Animals and Plants) or equivalent quality control standards, the notification procedure of EPPO Standard PM 6/1 may be used by the importer. Alternatively, if they have not been reared to fulfil IOBC or equivalent quality-control standards, or in particular if they have been collected in the wild, the import should not only be notified by the procedure of EPPO Standard PM 6/1, but also the organisms should be held in quarantine in order to verify their identity and eliminate contaminants and/or hyperparasites.

The requirements for release of a biological control agent are more severe than for first import for research purposes. If the organism is to be released for classical biological control, it is intended that it should establish itself and control one or more pests, possibly permanently. If it is intended to be used for inundative release or for seasonal establishment, it will be released on an experimental scale first, then repeatedly at full scale[1] and the risks arising from this release should be estimated according to this Standard. The relevant precautions apply whatever the scale of the first release, as undesirable consequences may be irreversible.

ISPM No. 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*) states that Governments should designate a National Authority responsible for implementation. For the purpose of import and release of non-indigenous biological control agents, this National Authority should institute an appropriate official procedure. Each country should decide what type of administrative system is appropriate (notification, approval or authorization), taking into account official policies in support of biological control.

Preparation of dossier

Import

If the organism is to be imported for mass-rearing or research before release, the notification procedures of EPPO Standard

[1]However, it should be noted that, for microorganisms, regular use of a marketed product is covered in many EPPO countries by the registration requirements for plant protection products, and so not by this Standard. This applies particularly to the EU Member States (through EU Directive 1107/2009).

PM 6/1 should first be followed. This specifies, in brief, details on the name and address of the organization concerned, the purpose of the research, the containment facilities proposed for the research, accurate identification of the agent, details on the proposed import, etc. For full details, see the EPPO Standard concerned, which also outlines general safeguards. The application form (see Appendix 1[2]) can be used in these situations and parts 1, 2, 4 and 5 should be completed.

Release

If the organism has already been imported and is currently being held in containment, or if the organism is being imported directly for release, the applicant should prepare a dossier for submission to the National Authority. The application form (see Appendix 1) is recommended to be used and all parts should be completed. It should include:

Part 1. Application information
- (A) Information on the applicant
- (B) Purpose of the application and use

Part 2. Information for indigenous and non-indigenous BCAs
- (A) Taxonomy and origin
- (B) Product information

Part 3. Information requirements for intentional release of a non-indigenous BCA with reference to:
- (A) Biology and ecology
- (B) Assessment of risks and benefits
  - (a) Establishment
  - (b) Host specificity
  - (c) Dispersal
  - (d) Non-target effects

Part 4. Submission of forms and signature
- (A) Submission details
- (B) Agreement: safeguards and signature

Part 5. Appendices, if appropriate

Appendix 2 provides guidelines for the completion of the application form for the import, shipment, rearing and release of invertebrate biological control agents in EPPO countries.

Evaluation of the dossier

The National Authority should determine whether an organism is required to be subjected to pest risk analysis (PRA) before release. Pest risk assessment should be conducted in accordance with ISPM No. 2 (*Framework for pest risk analysis*) and ISPM No. 11 (*Pest risk analysis for quarantine pests*) as appropriate, taking into account uncertainties, and potential environmental consequences, as provided for in those Standards. EPPO Standard PM 5/3(5) (*Guidelines on Pest-Risk Analysis*) provides detailed instructions for the successive stages of PRA. In addition to conducting pest risk assessment, the National Authority should also consider possible impacts on the environment, such as impacts on non-target invertebrates. Furthermore, all relevant national and international regulations (for example on the safeguard of natural resources or the movement of rare or endangered organisms) should be respected. After the dossier has been examined, the National Authority will make a decision within a previously agreed period of time as to whether to grant a permit (licence). The permit to import and/or release will be valid for a fixed period of time, assigned by the National Authority, after which a renewal may be sought.

The National Authority may propose precautions or restrictions in the manner of release, or may recommend that the organism should not be imported or released.

Supervision of the release

The organization undertaking the release proceeds under the appropriate supervision of the National Authority, taking account of the following:

(1) All appropriate safety procedures should be put in place. In particular, all contaminants and hyperparasites should be absent;
(2) The release programme should be fully documented concerning identity, origin, numbers/quantity released, dates, localities and any other data relevant to assessing the outcome;
(3) Evaluation of the releases should be planned in advance, to assess the impact of the organism on the target pest and non-target organisms;
(4) Authoritatively identified reference (voucher) specimens of the pests and natural enemies involved should be deposited in appropriate collections, where they should be available for reference and study;
(5) Any problems encountered in post-release monitoring should be reported.

The procedure described in this Standard is intended to be used for first release of an organism. Under certain circumstances, it may be necessary to repeat it for later releases.

General safeguards

(1) Any relevant information on undesirable side effects should be reported to the National Authority;
(2) Biodiversity conventions and intellectual property rights should be respected.

References

EC Directive (2008) 2008/61/EC establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 2000/29/ECmay be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections: see http://eur-lex.europa.eu/LexUriServ/ LexUriServ.do?uri=CELEX:31995L0044:EN:HTML

Eilenberg J, et al. (2001) Suggestions for unifying the terminology in biological control. *Biocontrol* **46**, 387–400.

[2]The application form was developed in the EU-funded REBECA project. This project aimed to review possible risks of biocontrol agents and propose efficient regulation procedures.

EPPO (2010) List of biological control agents widely used in the EPPO region http://archives.eppo.org/EPPOStandards/biocontrol_web/bio_list.htm

IPPC (1995) *Code of Conduct for the Import and Release of Exotic Biological Control Agents*. ISPM no. 3. IPPC Secretariat, FAO, Rome (IT).

IPPC (2007) ISPM No. 3, 2005; ISPM No. 5, 2007 http://www.ippc.int/:

van Lenteren JC, Babendreier D, Bigler F, Burgio G, Hokkanen HMT, Kuske S, et al. (2003) Environmental risk assessment of exotic natural enemies used in inundative biological control. *BioControl* **48**, 3–38.

van Lenteren JC, Bale J, Bigler F, Hokkanen HMT & Loomans AJM. (2006) Assessing risks of releasing exotic biological control agents of arthropod pests. *Annual Review of Entomology* **51**, 609–634.

Appendix 1 – Application form for the import, shipment, rearing and release of invertebrate BCAs in EPPO countries

Information required to complete this form

This application form and related information requirements for the release of non-indigenous BCAs contains 5 parts (numbered 1–5) and is structured in a step-by-step way: depending on the origin of the organism and the purpose of the application, the sequence of assessments and level of information required is related to the perceived level of risk. An application for any specified organism should include the following information:

Part 1. Application information
- (A) Information on the applicant
- (B) Purpose of the application and use

Part 2. Information on indigenous and non-indigenous BCAs
- (A) Taxonomy and origin
- (B) Product information

Part 3. Information requirements for intentional release of a non-indigenous BCA with reference to:
- (A) Biology and ecology
- (B) Assessment of risks and benefits
  - (a) Establishment
  - (b) Host specificity
  - (c) Dispersal
  - (d) Non-target effects

Part 4. Submission of forms and signature
- (A) Submission details
- (B) Agreement: safeguards and signature

Part 5. Appendices, if appropriate

Sections of the form to be completed

This form can be used for the import and release of all BCAs. Depending on the purposes of use, either some or all parts of the form must to be completed.

1. Renewal of a previous application	Parts 1, 4 and 5
2. First application	
Import only	Parts 1, 2, 4 and 5
Release of indigenous BCAs	Parts 1, 2, 4 and 5
Release of non-indigenous BCAs	Parts 1, 2, 3, 4 and 5

Part 1. Application information

(A) Information about the applicant

1.1 Who will apply for the permit?

- Name of organization
- Name of applicant (only a legally authorized person is allowed to apply[3])
- Affiliation of applicant
- Address
- Post code
- City
- Phone
- Fax
- E-mail
- Chamber of Commerce number

1.2 Who is the contact person?

- Name of contact person (research manager and/or quarantine officer)
- Affiliation of contact person
- Visiting address
- Post code
- City
- Phone
- Fax
- E-mail

(B) Purpose of the application and use

1.3 Information about the application

Application type	Renewal ☐	First Application ☐

- Renewal (application number and expiry date) _____

Listed on EPPO PM 6/3	Yes ☐	No ☐

- Relation with previous/other applications_____
- Application or registration elsewhere in EPPO region

	Yes ☐	No ☐

- License period requested ___/___/_____ (mm/dd/year)

1.4 Purpose of use

Import	Research ☐	(Mass) rearing ☐
Release	Trials ☐	Commercial[4] ☐

[3]Include confirmation of the person's authorization and a copy of a valid identification card with the application

[4]To include full scale release of a classical biocontrol agent

- Type of biocontrol programme
- Type of area where BCA will be released

1.5 Facilities and procedures

Describe how the risks, in particular probability of escape and possible extent into the wild for import/rearing of non-indigenous organisms will be managed.

- Address
- Post code
- Location
- Facility
- Contingency plan
- Standard Operating Procedures
- Quality control management
- Accreditation

1.6 Information about the target organism(s)

Give a description of the biology and ecology of the target pest(s), including weeds.

- Target host taxon
- Names of target pests
- Original area of distribution of the pests
- Biology of pests
- Target crops hosting the pest

Part 2. Information regarding indigenous and non-indigenous BCAs

(A) Taxonomy and origin

2.1 Identity

For what species/organism is the application made? Indicate which species is involved (a single species per application) and full scientific name and taxonomy.

- Class
- Order
- Family
- Genus
- Species
- Sub-species
- Common names
- Alternative names
- Associated organisms
- Indicate means, methods of ID confirmation and reference (voucher) specimen.

  Authority
  Methodology
  Reference (voucher) specimen deposits

2.2 Characterization of BCA

Specify life-stages, strains or taxonomic constraints.

- Diagnostic descriptions
- Specific characteristics
- Taxonomic characteristics

2.3. Origin and distribution BCA

What is the immediate source of the organism? Include details of the origin and distribution of the BCA (species or lower taxon).

Origin	Indigenous ☐	Non-indigenous ☐

- Field collected
- Laboratory culture
- Producer/supplier
- Original area and distribution
- Areas where introduced before

(B) Product information

2.4 Product information

- Product/trade name
- Producer/supplier
- Method of supply
- Life stages
- Label information
- Storage
- Method of use

2.5 Product composition

- Co-formulants
- Contaminants

2.6 Particular situations

In the case of:

- A renewal of a previously successful application (section 1.3) OR
- The species or population being indigenous to the country or ecoregion OR
- The BCA being imported for research or rearing only OR
- The BCA's mention on the EPPO list of biological control agents widely used in the EPPO region (PM 6/3, Appendix 1 or 2) in the intended area of release, no further information is required and only the submission details in 4(A) and (B) and Appendices (Part 5) need to be completed. For other applications, such as the release of a non-indigenous species, the information requirements in Part 3 must be supplied.

Part 3. Information requirements for intentional release of a non-indigenous BCA

(A) Biology and ecology

3.1 Information regarding biology and ecology

Give a description of the biology and ecology of the BCA

- Life cycle – generations/year
- Developmental biology

- Mechanisms of survival
- Mechanisms of dispersal
- Climatic conditions
- Habitat range
- Host range
- Natural enemies

(B) Assessment of risks and benefits

3.2 Safety and health effects

Potential hazards of BCA, product or any co-formulants, and measures taken to limit operator exposure, with emphasis on

- Human health
- Animal health
- Measures of prevention

3.3 Information about environmental risk assessment

All fields should normally be completed (but see exemptions listed below), but may be weighted differently in the evaluation of risks

- History of previous releases or introductions
- Outcome of previous risk assessments

3.3.1 Potential for establishment

When outdoor establishment of the BCA is very unlikely and is predicted to die out rapidly (as indicated by the data provided), the subsequent fields need not be completed, and no further risk assessments are necessary

- Physical constraints
- Resource constraints
- Survival data and methods used
- Evidence of establishment

3.3.2 Host range assessment

When outdoor establishment of the BCA is necessary or likely to occur, host range information is essential for the risk assessment

- Known hosts
- Organisms tested
- Procedures used for host range testing
- Effects on plants used by target and non-target hosts

3.3.3 Dispersal

Dispersal test results are not required for releases in protected structures which restrict escape (e.g. glasshouse), but should be provided when BCAs are released into open fields or structures that do not restrain escape (e.g. polytunnels). In fields and polytunnels large numbers of organisms are released augmentively and have the potential to disperse into the wider environment before populations decline and die out.

- Ability to disperse

3.3.4 Direct and/or indirect non-target effects

A summary of known direct and indirect non-target effects should always be given, irrespective of whether host range and/or dispersal have been assessed.

- Summary of available information and conclusions on risks

3.4 Efficacy and benefits of the BCA

Assessment of efficacy, economic and environmental benefits

- Method(s) to determine efficacy
- Results of efficacy trials
- Economic benefits
- Environmental benefits

Part 4. Submission of forms and signature

(A) Submission details

4.1 Appendices

Check for completeness of application.

- Information requirements ☐
- Literature reference copies ☐
- Identification of applicant ☐
- Chamber of Commerce ☐
- Authorization payment ☐

4.2 Where to submit the application

- Name organization
- Bureau
- Address
- Post code
- City

4.3. General safeguards

The applicant or authorized user undertaking the release proceeds under the conditions of the authorization for release, taking into account the following requirements:

- All appropriate safety procedures should be put in place
- Any relevant information on adverse effects, which might relate to the released BCA, should be reported immediately to the National Authority
- Information on sites and dates of supply or release of the BCA should be made available to the National Authority, if requested
- Information requirements have been supplied according to the most recent knowledge, and that the conditions made by the National Authority will be respected

4.4. Signature[5]

- Date
- Applicant's name
- Signature

[5]completed by a legally authorized person.

Part 5. Appendices

Appendix 2 – Guidelines for the completion of an application form for import and release of BCAs[6] in EPPO countries

Using this guidance

This appendix provides guidance on how to complete the application form for a permit for the release of an invertebrate Biological Control Agent (BCA) and other beneficial organisms. This form may also be used to apply for an import permit (including labelling, packaging and storage in transit) and mass-rearing. The dossier to be submitted to the National Authority must include information on the following parts of the application form:

Part 1. Information about the applicant (A) and purpose of the application and use (B)

Part 2. Information regarding the invertebrate biological control agent: identity, specific characteristics, origin and distribution (A), and product information (B)

Part 3. Information relating to intentional release of a non-indigenous BCA: biology and ecology of the BCA (A) and an assessment of risks and benefits of the release (B)

Part 4. Information on where to send the application (A) and conditions (B)

Part 5. Appendices

Parts 1–5 of this guidance document are divided into different sections and sub-sections. The title and number of each part, section and sub-section referred to in this document correspond to the same parts, sections and sub-sections of the application form. In the case of renewal of an application, parts 1, 4 and 5 have to be completed. In the case of a first application, parts 1, 2, 4 and 5 must be completed by all applicants, including applications for the release of indigenous species, when required by the National Authority. For applications to release a non-indigenous species, part 3 of the application form must also be completed.

Note that **information should be submitted by the applicant.**

Part 1. Application information

(A) Information about the applicant

Provide information (including contact details) on:

1.1 Who will apply for the permit[7]; include confirmation of the person's authorization and a copy of a valid identification card with the application

1.2 The contact person, research manager and/or quarantine officer.

(B) Purpose of application and use

1.3 Information about the application

- Indicate whether this is a first application or a renewal of a previous application. In the case of a renewal, include a dossier reference number and expiry date and highlight any changes introduced since the first application
- Is the organism on the EPPO List of biological control agents widely used in the EPPO region (appendices 1 and 2, EPPO Standard PM 6/3)
- Has an application for this organism been submitted elsewhere in Europe, or has the organism or a product containing the organism been registered elsewhere in Europe? Specify in which country and provide contact details, and information on when the application was submitted and the outcome
- Is there a relationship with other applications currently submitted or previously licensed with other BCAs or beneficial organism(s) in the same product?
- For what period is the permit requested (within the range allowed by the relevant National Authority)?

1.4 Purpose of use

Indicate the purpose of the application and use of the organism:

- Indicate whether the application is made for (i) import for research and/or (mass) rearing, or (ii) direct release.[8] Indicate whether a release is intended in the country of application or not
- When releases are intended, indicate whether the applications are for trial purposes or for full field releases, in commercial and/or classical programmes
- Type of biological control programme: classical biological control, augmentative biological control, or weed biocontrol
- For direct release in field trials or for commercial release, indicate whether permanent establishment is intended (classical release) or not (augmentative release)
- Provide details of area of application (e.g. protected, semi-protected glasshouse, open field, natural environment).

1.5 Facilities and procedures

The research/production facilities and procedures: describe how the risks, in particular the probability of escape and possible extent into the wild will be managed (*for import of non-indigenous organisms only*). This can usually be done by means of one or more waivers.

- Address (physical), post code, location (city)
- For imported material, provide details of labelling, packaging and storage during transit
- Facility: describe the types of facilities used (greenhouses, laboratories, climate rooms or cabinets)
- Levels of containment: is a permit to work with quarantine organisms under for instance the provisions of Directive 2008/61/EC. If not, justify why the levels of containment proposed for transport, rearing or research are appropriate to avoid

[6]Any organism directly or indirectly advantageous to plants or plant products including biological control agents (IPPC, 2007)

[7]Only a legally authorized, registered person is allowed to apply.

[8]Release: intentional liberation of an organism into the environment (see ISPM No. 3, 2005).

escape and spread; where feasible, a contingency plan to prevent undesired environmental effects should be provided

• Quality control management system: give a description of the measures, methods and intervals to ensure quality and purity of the BCA (species/strain), and methods for periodic control of purity and identity of mass-rearing, including Standard Operating Procedures for:

○ Life stage and numbers (amount) to be imported

○ Methods and materials to be used for shipping (e.g. sealed container, host mummies, prey to be included, plant material included, etc.)

○ Procedures to eliminate any contaminants of the imported agent that are of concern

○ Procedures to dispose of used research materials, including shipping materials

○ A plan for detecting escape and undesired environmental effects

○ Any other procedures specific to this importation (i.e. not part of standard procedures)

• Accreditation: is your organization certified and/or accredited for processes and/or activities (ISOs) as developed by the International Organization for Standardization.[9] Relevant Standards include ISO 9001 for 'Quality management' (general procedures) and ISO/IEC 17025 for 'General requirements for competence of test and calibration laboratories'. Provide details of the ISO Standard(s) and activities for which you have certification and/or accreditation.

1.6 Information about the target organism(s) and area of application

• Name(s) of pest(s) to be controlled (order, family, genus, species and author), including weeds

• Origin of the pest(s)/weeds and the natural occurrence in the area of release

• Biology of pests: life cycle(s) of pests/weeds released against

• Crops: damage inflicted on target crops or vegetation; crops or vegetation on which releases will be made.

Part 2. Information regarding indigenous and non-indigenous BCAs

(A) Taxonomy and origin

2.1 Identity and ID confirmation

(a) For what species/organism is the application made? Indicate which species is involved (a single species per application) and full scientific name and taxonomy. Give an accurate identification of the BCA or, where necessary, sufficient characterization to allow its unambiguous recognition, such as:

• Order, family, genus, species and author, and, where appropriate, sub-species, strain, or biotype; include common names and synonyms

• Include the name of micro-organisms directly associated with the BCA, e.g. identity of the symbiotic bacteria in entomopathogenic nematodes

[9]For details, see http://www.iso.org/iso/home.htm

(b) ID confirmation. Indicate means, methods of ID confirmation and reference (voucher) specimen:

• Authority: by which expert or institute has the organism been identified?

• By what method: if available, include a letter from a scientific expert, recognized by the National Authority, stating the identity of the organism at the species or strain (where possible) level; any appropriate method (e.g. morphological or molecular) can be used for identification of the species

• Supply evidence of deposition of reference (voucher) specimens, with identity confirmed, in a recognized collection facility (these depositions must be made before the agent is released); include the name and location of institution(s) where reference (voucher) specimens are deposited

• Where cultures are refreshed, confirmation of identity should be sought at regular intervals and additional reference (voucher) specimen should be deposited accordingly

• Include the accurate identity of the symbiotic bacteria associated with entomopathogenic nematodes used as a BCA.

2.2 Characterization of BCA

Specify life-stages, strains or taxonomic constraints:

• General diagnostic descriptions of all life stages of the BCA that are relevant for its use in biological control, highlighting details of any taxonomic characteristics and difficulties with the group (e.g. species complexes, cryptic species, poorly studied group)

• Where appropriate, describe particular characteristics of the population(s)/strain(s)/isolate(s), such as:

○ Cold-hardiness (winter survival, diapausing abilities)

○ Known pesticide resistance (if yes: for which pesticide)

○ Information on differences from the parent wild strain.

• Where appropriate, molecular information (e.g. unique micro-satellite markers) used for diagnosis, especially for population identification, species complexes or cryptic species.

2.3 Origin and distribution

What is the immediate source of the organism? Include details of the origin and distribution of the BCA (species or lower taxon) as follows:

(a) Indicate whether indigenous or non-indigenous;

(b) If field-collected, provide information on collection sites and dates, including:

• Geographic area (approximate latitude, longitude and altitude of site)

• Description of the original habitat(s) and host(s) from which the collection was made.

(c) If from laboratory culture or production facility, provide information as indicated in (a) and in addition, the history of the culture stock, including:

• The immediate source of the organism (i.e. where it is produced), giving the name and address of the manufacturer, including the location of the production facility

• Any other source from which the culture has been collected or supplied

• Frequency and origin of additional wild stock used to refresh laboratory cultures.

(d) Current distribution, including:

- Known areas of original natural distribution of the BCA
- Known areas where the BCA has been intentionally or accidentally introduced.

(B) Product information

2.4 Product information

For augmentative commercial release or classical biocontrol, briefly describe the intended use and potential benefits that may be derived.

- Function of the BCA (e.g. predator, parasitoid)
- Life stage(s) of the agent(s) to be released (e.g. pupae, adults)

For augmentative commercial releases, the following information should also be supplied:

- Trade name of the product
- Method of supply and formulation (e.g. single species, interim prey, mixed species)
- Label and container information
- Storage conditions (temperature, humidity, expiry date)
- Recommended method of use (e.g. frequency and dosage of release).

2.5 Product composition

Provide evidence that for inundative releases, the product is free from unwanted contaminants, i.e. entomopathogens and hyperparasitoids, including:

- Co-formulants: give a description of co-formulants/organic contaminants included with the BCA (e.g. plant material, live prey or other food materials, carrier material)
- Contaminants: give an assessment of the extent to which these should be of concern; frequency and percentage of hosts used in culture that might be present in the marketed product
- Any combined or contaminant organism should be separately authorised before import and/or release.

In the case of a renewal of a previously successful application (Section 1.3), or if the species or population is indigenous to the country or ecoregion, and/or imported for research or rearing only, and/or mentioned on the list of species considered safe for use in the intended area of release, no further information is required and only the submission details in Part 4(A) and (B) and Appendices (Part 5) need to be completed. For other applications, such as the release of a non-indigenous species, the information requirements in Part 3 must be supplied.

Part 3. Information requirements for intentional release of a non-indigenous BCA

(A) Biology and ecology

3.1 Information on the biology and ecology (in current area of distribution)

Information provided below will be the main basis for the risk assessment, including environmental risks. Give a description of the biology and ecology of the BCA, including:

- Life cycle and number of generations per year
- Information on developmental and reproductive biology (e.g. sexual/asexual reproduction, feeding and parasitisation habits, developmental period, reproductive potential, longevity)
- Known mechanisms of survival of extreme conditions (e.g. diapause, quiescence, migration)
- Known mechanisms of dispersal (e.g. flight capability, migratory behaviour)
- Describe the climatic conditions of areas where the BCA is known to be native and/or where it has established following intentional or accidental introductions
- Give information on the habitat range, including the habitat(s) where the BCA is known to be native and/or; where the BCA is known to have established following intentional or accidental introductions (e.g. pasture, forest, scrub, etc.) and known factors determining habitat selection (e.g. oviposition behaviour)
- Give details of natural enemies, including pathogens known to attack the BCA.

(B) Assessment of risks and benefits

Information presented in this section forms the basis for the assessment of risks on possible impacts on the environment, such as impacts on non-target invertebrates. This risk assessment should address the whole country within which releases will be made, with reference to regional variation that may affect risk where appropriate. Information required in this section is considered essential to such environmental risk assessment, and can be acquired from published literature, company reports and/or experimentation. Include details of previous risk assessments for the same species (strain/biotype) with outcomes and other relevant information, including the country of application. The submission of available and/or generated data and subsequent assessment of environmental risks follows a tiered approach: information should be acquired and risks assessed according to the hierarchical system proposed by Van Lenteren *et al.* (2003) and Van Lenteren *et al.* (2006), and further updated in REBECA.

When the target pest against which the BCA is planned is a plant (invasive alien plant or weed) or when the BCA has the potential to indirectly affect plants through effects on other organisms (See ISPM No. 11, Annex 1), EPPO Standard PM 5/3 (5) *Guidelines on Pest-Risk Analysis* provides detailed instructions for PRA.

When establishment of the BCA is very unlikely and is predicted to die out rapidly (as indicated by the data provided), the subsequent fields need not be filled in, and no further risk assessments are necessary; when establishment of the BCA is likely or necessary (e.g. in classical control), host range information is a crucial requirement for risk assessment; dispersal test results are needed when BCAs are released in open fields and establishment is very unlikely; a summary of known direct and indirect non-target effects should always be given.

3.2 Safety and health effects

Summarize available information on hazards to human, animal and plant health (for example, allergy, skin irritation, disease

vectoring etc.) by the BCA, product or any co-formulants and measures taken to limit operator exposure, where necessary.

3.3 Information on environmental risk assessment

All fields should normally be completed (but see exemptions listed below), but may be weighted differently in the evaluation of risks. Summarize the history of previous releases or introductions and the outcome of previous risk assessments, with known consequences, including non-target effects.

3.3.1 Potential for establishment. Indicate any evidence of establishment as a result of previous releases or accidental introductions. Describe conditions (including extremes) affecting the BCA's survival and reproduction in its current distribution.

Information on physical constraints, such as:

- Climatic similarities/differences between area of current distribution and area of intended release (e.g. temperature, altitude, humidity, day length etc.)
- Probability of temporary survival
- Ability to survive and reproduce at temperatures and humidities outside the normal range (e.g. cold tolerance, overwintering ability); lower and upper temperature thresholds for development and survival; ability to enter diapause and/or overwinter (include test results)
- Other physiological and behavioural mechanisms for surviving extreme conditions
- Dispersal potential (where known).

Information on resource constraints, such as:

- Availability and utilization of suitable hosts (target and non-target organisms) for short-term or long-term survival
- Availability of suitable habitat, vegetation and plant food resources.

Indicate any evidence of establishment as a result of previous releases and/or accidental introductions outside the EPPO region.

When outdoor establishment of the BCA is very unlikely and the organisms released are predicted to die out rapidly, the subsequent fields need not be completed, and no further risk assessments will be necessary; when outdoor establishment of the BCA is likely or necessary, host range information must be supplied.

3.3.2 Host range assessment. When establishment is likely and/or required, provide available information on recorded effects on non-target organisms, including:

- A list of known hosts other than the target pest(s) and potential of the BCA to utilize non-target host organisms living on wild or cultivated plants;
- A list of non-target organisms that have previously been tested, including unrelated non-target hosts, including pollinators, and threatened and endangered species; indicate hosts that were not accepted in such tests;
- Procedures used to determine host range (e.g. phylogenetic relatedness, experimentation) and methods used for host-range testing (e.g. experimental design, test conditions, rearing methods for non-target species, life-stages tested etc.);
- Possible direct effects on plants: describe possible direct effects of the BCA on the host plant(s) of the target pest and on plant hosts of non-target species.

3.3.3. Dispersal.

- Indicate potential direct (inundative) effects of mass-releases into open fields to neighbouring non-target hosts and habitats;

Direct effects of dispersal are considered for BCAs where relevant to the direct environment of release. Dispersal test results are not required for releases in protected structures which restrict escape (e.g. glasshouses), but should be provided when BCAs are released in open fields or structures that do not restrain escape (e.g. polytunnels). Augmentive releases in fields and polytunnels can involve large numbers of organisms with the potential to disperse into the wider environment before populations decline and die out. Hence, information on dispersal is required for such releases.

3.3.4. Additional information on direct and indirect non-target effects. Describe the history of previous releases or accidental introductions, with known consequences, including non-target effects. Indicate any other possible specific non-target effects, such as:

- Competition with, or displacement of, indigenous natural enemies in the area of intended release
- Other constraints on the presence of natural enemies, including transfer of pathogens, of the released BCA
- Presence of natural enemies, including pathogens, that may affect establishment of the BCA.

A summary of known direct and indirect non-target effects should always be given, irrespective of whether host range and/or dispersal have been assessed. This section should also include conclusions on the risks associated with the intended release.

3.4. Efficacy and benefits of the BCA and proposed release

Provide relevant information on:

- Anticipated contribution to the control of the target pest(s) and weeds
- Estimated economic benefits (crop specific) of the BCA
- Possible environmental benefits, e.g. beneficial effects of release of the BCA compared with current control methods
- Method(s) to determine efficacy and, when required by the National Authority, results of efficacy trials.

Part 4. Submission of forms and signature

(A) Submission details

4.1 Appendices

Check the application for completeness in the following areas:

- Information requirements (dossier)
- References, other literature and overview of information used in preparation of the dossier; include copies of relevant articles, chapters or reports in an appendix to the application documents

- Identification of applicant: ID-card or passport
- Chamber of Commerce copy
- Authorization for payment of fees
- Letter from a scientific expert, recognized by the National Authority, confirming identity of the organism
- Evidence of deposition of reference (voucher) specimens, with identity confirmed, in a recognized collection facility (these depositions must be made before the agent is released); include the name and location of institution(s) where reference (voucher) specimens are deposited
- In case of import for research and/or rearing, include a map of the facilities
- Any other information that is relevant to the application.

4.2. Where to submit the application

Address details of the National Authority

4.3. General safeguards

The applicant or authorized user undertaking the release proceeds under the conditions of the authorization for release, taking into account the following requirements:

- All appropriate safety procedures should be put in place
- Any relevant information on adverse effects which might relate to the released BCA should be reported immediately to the National Authority
- Information on end-users/sites and dates of supply or release of the BCA should be made available to the National Authority if requested
- Information requirements have been supplied according to the most recent knowledge, and that the conditions made by the National Authority will be respected.

4.4. Signature details

- Date
- Applicant's name
- Signature

All information and documents submitted for a licence application (dossier) will be regarded as 'commercial in confidence' by the National Authority. The Environmental Risk Assessment and decision will be based on data and documents submitted for that specific licence application only.