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Review Article

Guidelines on information requirements for import and release of invertebrate biological control agents in European countries[1]

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Abstract

Several international documents have been published in recent years with the objective of providing guidance to industry, biocontrol practitioners and competent national regulatory authorities on the regulatory framework for the import and release of invertebrate biological control agents (IBCAs). As the scope and the level of detail given in these documents were diverse in many respects, it has been difficult for all stakeholders to apply such guidelines, and to integrate them in a harmonized way into national regulatory documents. At the request of several stakeholders, the International Organization for Biological Control of Noxious Animals and Plants/West Palaearctic Regional Section (IOBC/WPRS) organized an initiative with the objective of merging all relevant international documents into one document, to provide more specific guidance, and to harmonize the regulation of IBCAs in European countries and in other countries of the IOBC/WPRS. This document consists of five sections which together form comprehensive guidelines specifying the information required for regulating import and release of IBCAs.

1. Introduction

Regulation of the introduction and release of invertebrate biological control agents (IBCAs) differs between European countries, and some have yet to establish guidelines and procedures. Requirements of international laws and agreements, and an increasing interest in the import and release of non-native biological control agents (i.e. those not naturally occurring in the country where the applicant submits the dossier) require a more harmonized and effective regulatory system between countries. In many cases, introductions of IBCAs are administered under regulations which were established for other purposes, such as plant quarantine, wildlife

[1] These guidelines are the result of an activity coordinated by the Commission on 'Harmonized Regulation of Invertebrate Biological Control Agents' of the International Organization for Biological Control of Noxious Animals and Plants/West Palaearctic Regional Section (IOBC/WPRS).

conservation and genetically modified plants. The application of appropriate regulatory procedures is important in order to maintain public confidence in biological control and to facilitate introductions and the use of exotic biological control organisms.

A number of regulatory documents for the import and release of IBCAs have been produced by international organizations, for example, the Food and Agricultural Organization of the United Nations (FAO) [1–2], the European and Mediterranean Plant Protection Organization (EPPO) [3–5] and the Organisation for Economic Co-operation and Development (OECD) [6]. More recently, guidance on procedures and methods for environmental risk assessment of non-native IBCAs has been developed and proposed [7–9]. The European biological control industry was concerned when the OECD guidance document was first published in 2003, as the information requirements were considered to be too stringent, and manufacturers feared that each competent National Authority[2] in Europe would establish its own regulatory system. As a consequence, the International Biocontrol Manufacturers Association (IBMA) proposed that the International Organization for Biological Control of Noxious Animals and Plants/West Palaearctic Regional Section (IOBC/WPRS) should coordinate the harmonization of the various regulatory documents among the European regulatory authorities. A Commission of the IOBC/WPRS was established in 2003. The first meeting was held in Zürich, Switzerland in 2004, with biocontrol scientists, regulators and industry representatives from 15 European countries. The results of this meeting are summarized in the guidelines presented here.

The purpose of these guidelines is to provide specific advice to applicants and competent National Authorities on the information required to perform risk assessments with respect to the import and release of an IBCA that is intended for use as a plant protection agent in classical or inundative/inoculative biological control in European and other countries within the IOBC/WPRS. In this context, IBCAs comprise insects, mites and nematodes, and the term may refer to one species or to a specified strain or biotype, where applicable. For convenience, the term 'host' is considered synonymous with 'prey'. Much of the information specified in the guidelines is also directly relevant to the regulation of weed biological control agents, but these are specifically excluded from this document.

The process of preparing a dossier and assessing the risks of an IBCA should be interactive between the applicant and the competent National Authority, in order to ensure that the applicant provides a complete dossier containing the relevant information so the risk assessment can be performed. As the information required is often case-specific, depending on the characteristics of the individual IBCA, early discussions are advised, to highlight particular issues which may need to be addressed in order to assess fully the possible impact of the proposed import or release.

There may be key pieces of information that demonstrate that an IBCA is inherently safe which preclude the need for detailed information in other sections, e.g. conclusive evidence that overwintering is not possible; hence, not all information is necessary in all cases.

The competent National Authority should examine the dossier, evaluate its content and analyse the risks and benefits for human health and the environment related to the import and release of the IBCA. The competent National Authority may request more information or clarification of specific issues in the submitted dossier. All relevant national and international regulations, standards and conventions (e.g. to safeguard biodiversity, plant health, intellectual property, etc.) should be respected. The competent National Authority may approve import and release of the IBCA, propose containment conditions and risk management/mitigation strategies, or it may refuse approval of the IBCA. On receipt of the dossier, the competent National Authority should inform the applicant of the likely time-scale within which a decision will be notified.

Competent National Authorities are advised to regulate import and release of non-native IBCAs in a two-step procedure. The first step should be to authorize import of a candidate IBCA for research purposes. It is assumed that, at the time of the first import, the candidate IBCA may not be well known, i.e. many biological characteristics of the IBCA may be unclear, such as climatic requirements and host range, or the proposed use of the IBCA for biological control may not be explicitly stated. The purpose of such imports under a 'research only licence' would be to perform research under containment to provide answers to these questions. As a result, environmental risks cannot be adequately assessed at this stage and careful handling is imperative. The consideration of the import may be different if the candidate IBCA is well known and has been previously released in other European or other IOBC/WPRS countries for biological control. In such cases, the importing organization may wish to study the IBCA from the perspective of its rearing, packaging or other experimental approaches, without the immediate intent to release the organism or to place it on the market. In these instances, most of the data and information for environmental risk assessment may be available and risks can be evaluated more accurately. If release on an experimental scale is intended, risk assessment should be as stringent as for release for inundative/inoculative or classical biological control (see section 3), because undesirable consequences in the environment may be irreversible, independent of the scale of release.

[2] The Government Authority that is responsible for regulating import and release of IBCAs in a country.

The second step should be to authorize release of the IBCA for classical biological control or to allow the IBCA to be placed on the market for inundative/inoculative release. The requirements for release of the IBCA, whether for classical biological control or for inundative/inoculative release, are necessarily more stringent than for import for research under containment. The applicant should provide all necessary information to enable the competent National Authority to perform an adequate risk assessment.

This document consists of five sections. The introductory section provides information on the historical background of the regulation of IBCAs, the purpose of the guidelines, the process of preparing a dossier, and the two-step procedure that the competent National Authorities are advised to follow. The second section sets out the information needed for the regulation of non-native IBCAs being imported for research purposes which will not necessarily lead to a request for release. The level of containment under which research will be performed depends on the risks identified for the IBCA in question. Section three addresses the information requirements relating to the release of non-native IBCAs. This section is divided into two parts; the first details the information required for IBCAs that have not been previously released in any European or other IOBC/WPRS country, and the second refers to IBCAs that *have* been previously released in other European and IOBC/WPRS countries. Section four is devoted to the specific information requirements for release of native IBCAs. Section five proposes information requirements and a matrix for non-native and native IBCAs that are widely used in European countries. These five sections together form comprehensive guidelines specifying the information requirements for regulating import and release of IBCAs.

2. Information requirements for the importation of non-native candidate IBCAs for research

This section sets out the information needed for a non-native IBCA to be considered for import into a European or other IOBC/WPRS country for research purposes only, and which will not necessarily lead to a subsequent request for release. This information is in the context of wider requirements that may need to be addressed under national procedures and in line with international guidelines, e.g. EPPO Standard PM6/1(1) [3].

The level of containment needs to be appropriate to the level of risk; it can vary from no containment to containment in a licensed quarantine facility. European Council Directive 77/93/EEC and European Commission Directives 95/44/EC and 97/46/EC may be relevant to defining containment levels, and how pest hosts of IBCAs should be handled. Where critical knowledge is inadequate, the level of containment will need to be higher than where biological and ecological characteristics of the IBCA are known (in line with the precautionary principle).

If at any point the applicant intends to alter the procedures/conditions from those specified in an earlier approved application (e.g. source of material, nature of the facility), a variation will need to be applied for and obtained before any import. Licences will normally be issued for a limited period, e.g. one or two years.

2.1. Information to be submitted by the importer/applicant

The dossier to be submitted to the competent National Authority must include the information specified below.

2.1.1. The applicant

Give the name and address of the organization concerned, and the names of the responsible persons, such as the research manager and the quarantine officer.

2.1.2. Purpose of importation

Give a brief description of the intended research activity and potential benefits that may derive from it.

2.1.3. Taxonomy and characterization

(a) Provide an accurate identification of the IBCA, including the name of the identifier or, where necessary, sufficient characterization of the agent to allow its unambiguous recognition. Supply evidence of the deposition of voucher specimens in a recognized collection facility (these depositions must be made before the agent is released). Give the order, family, genus, species (including scientific authority) of the IBCA, and where appropriate subspecies, strain or type together with relevant supporting taxonomic information, such as:

- A letter from a recognized scientific authority stating the identity of the organism;
- General diagnostic descriptions of all life stages of the IBCA, including details of any taxonomic difficulties with the group (e.g. species complexes, cryptic species);
- Known molecular information (e.g. unique microsatellite markers, etc.) used for diagnosis, especially for species complexes or cryptic species.

(b) Give the locality of the original or planned site(s) of collection of the IBCA from the wild.

(c) Provide details of the source laboratory if the IBCA is from culture.

(d) Where relevant, provide available information on biology, distribution, natural enemies (e.g. hyperparasitoids), commensals, contaminants (including from laboratory cultures). For contaminants give an assessment of the extent to which these should be of concern.

2.1.4. Assessment of risks to human/animal/plant health

Provide available information on hazards to human, animal and plant health (for example, allergy, skin irritation, disease vectoring).

2.1.5. Potential risks to the environment in the event of escape

Based on available information, identify possible risks to the environment, if the imported IBCA were to escape into the wild. Depending upon the level of containment envisaged, provide relevant information on:

- Host range and potential nontarget organisms in the area of study;
- Previous/current use in research and biological control, including observed environmental effects;
- The potential for establishment and spread.

2.1.6. Facilities and procedures

Describe how the identified risks, and the extent or probability of escape into the wild, will be managed. Include the following:

- A description of the facilities and standard operating procedures;
- 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;
- Where feasible, a contingency plan to prevent undesired environmental effects;
- Any other procedures specific to this importation (i.e. not part of standard procedures).

2.1.7. Risk assessment and conclusion

Review the risks identified and justify why the levels of containment proposed for both transport and research are appropriate.

3. Information requirements for the deliberate release of non-native IBCAs

The purpose of this section of the guidelines is to set out detailed information on the data which will be required by the competent National Authority that will evaluate the risks and benefits in order to decide whether to approve, conditionally approve or reject a request for the release of a non-native IBCA. Information requirements contained within this section were addressed under the EPPO guideline, Safe use of biological control, EPPO Standard PM6/2(1) [4], and the OECD guidance document [6].

At this stage it is assumed that the IBCA has previously been approved by the competent National Authority for import for research purposes into the country of release, or that the IBCA will be imported for direct release. In the first case, the notification procedures according to section two of these guidelines have been followed. If import is intended for direct release, this section of the guidelines applies.

This section of the guidelines is divided into parts A and B. Part A specifies information requirements for those IBCAs that have not been previously released in a European or other IOBC/WPRS country, whereas part B specifies information requirements for those IBCAs that *have* been previously released in another European or IOBC/WPRS country. Applicants may use parts A and B as a check list when preparing the dossier for the competent National Authority.

- Subsections 3.1.1 – 3.1.4 (part A) identify the applicant, the organism proposed for release, the nature and origins of the IBCA, and the purpose of the release;
- Subsections 3.1.5 – 3.1.8 (part A) describe the biology and ecology of the IBCA, in so far as these are known, and provide the basis for the risk/benefit analysis required under subsection 3.1.10;
- Subsection 3.1.9 (part A) provides information for assessment of safety and effects on human, animal and plant health;
- Subsections 3.1.10 and 3.1.11 (part A) are intended to take the information in the preceding subsections and combine this into an evidence-based risk/benefit analysis that can be assessed by the competent National Authority.

If more than one species, strain or biotype is contained in an IBCA product, the information has to be given separately for each of them.

3.1. Part A. Application for authorization to release non-native IBCAs not previously released in other European countries

The dossier to be submitted to the competent National Authority must include the information specified below.

3.1.1. The applicant

Give the name and address of the applicant, including the name of the responsible contact person.

3.1.2. Description and purpose of use

Provide a description of the IBCA and the purpose of use, including as appropriate:

- Trade name;
- Scientific name(s) of the species to be released (all species names for mixed agents);
- Method of supply and formulation (e.g. single species, interim prey, mixed species);
- Function of the IBCA (e.g. predator, parasitoid);
- Name(s) of pest(s) to be controlled (including scientific names), and crops on which releases will be made;
- Intended sites of release (e.g. protected, semi-protected glasshouse, open field);

- Any specific characteristics of the strain(s) involved (e.g. resistance to pesticides, diapause, searching capacity);
- Life stage(s) of the agent(s) to be released (e.g. pupae, adults);
- Recommended method of use (e.g. frequency and numbers to be released), storage;
- Permanent establishment intended/not intended.

3.1.3. Taxonomy and characterization

3.1.3.1. Identification.

(a) Give an accurate identification of the IBCA or, where necessary, sufficient characterization to allow its unambiguous recognition, such as:

- Order, family, genus, species (including scientific authority), and, where appropriate, subspecies, strain, biotype (see also subsection 3.1.7). Also, common names and synonyms;
- A letter from a scientific expert, recognized by the competent National Authority, stating the identity of the organism;
- General diagnostic descriptions of all life stages of the IBCA that are relevant for its use in biological control, highlighting details of any taxonomic difficulties with the group (e.g. species complexes, cryptic species, poorly studied group);
- When appropriate, molecular information (e.g. unique microsatellite markers) used for diagnosis, especially for species complexes or cryptic species.

(b) Supply evidence of deposition of 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 voucher specimens are deposited.

Where cultures are refreshed, confirmation of identity should be sought at regular intervals and additional vouchers should be deposited accordingly.

3.1.3.2. Origin.

Give details of the origin of the IBCA (species or lower taxonomic level) as follows:

(a) If field collected for immediate release, provide information on collection sites and dates, including:

- Geographic area (approximate latitude, longitude and altitude of site);
- A description of the original habitat(s) and host(s) from which the collection was made;
- The time of year when the collection was made.

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

- The numbers of individuals in the founder population;
- The length of time/number of generations in culture;
- The frequency and origin of additional wild stock used to refresh laboratory cultures.

(c) Provide 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.

(d) Name any other source from which the culture has been collected or supplied.

3.1.4. Current distribution

Supply distribution information, including:

- Known areas of original natural distribution of the IBCA;
- Known areas where the IBCA has been intentionally or accidentally introduced (detailed history of previous releases to be indicated under subsection 3.1.6).

3.1.5. Biology and ecology (in current area of distribution)

Information provided as outlined below will be the main basis for the environmental risk assessment (see subsection 3.1.10).

3.1.5.1. Biology.

Give a description of the biology of the IBCA, including:

- The life cycle and number of generations per year;
- Information on developmental and reproductive biology (e.g. sexual/asexual reproduction, feeding and parasitization habits, developmental period, reproductive potential, longevity).

3.1.5.2. Mechanisms of survival.

Describe known mechanisms of survival of extreme conditions (e.g. diapause, quiescence, migration).

3.1.5.3. Mechanisms of dispersal.

Describe known mechanisms of dispersal (e.g. flight capability, migratory behaviour).

3.1.5.4. Climatic range.

Describe the climatic conditions:

- Where the IBCA is known to be native;
- Where the IBCA has established following intentional or accidental introductions.

3.1.5.5. Habitat range.

Give information on the habitat range, including:

- A description of habitat(s) where the IBCA is known to be native;
- A description of habitat(s) where the IBCA is known to have established following intentional or accidental introductions;
- Available information on specific habitat requirements (e.g. pasture, forest, scrub, etc.) and known factors determining habitat selection (e.g. oviposition behaviour).

3.1.5.6. Host range.
Provide information on recorded effects on nontarget organisms, including:

- A list of known hosts other than the target pest(s);
- A list of nontarget organisms that have previously been tested, including hosts that were not accepted in such tests;
- Procedures used to determine host range (e.g. phylogenetic relatedness, experimentation);
- Methods used for host-range testing (e.g. experimental design, test conditions, rearing methods for nontarget species, life-stages tested, etc.).

3.1.5.7. Natural enemies/pathogens.
Give details of natural enemies, including pathogens known to attack the IBCA.

3.1.6. Previous introductions
Describe the history of previous releases or accidental introductions, with known consequences, including nontarget effects.

3.1.7. Further information
Describe special characteristics of the IBCA (if applicable), such as:

- Strain with cold-hardiness;
- Strain with pesticide resistance (if yes: what resistance);
- Strain with characterized searching ability;
- Any known mutants, including information on their difference from the parent wild strain;
- Any desirable or undesirable selection or breeding;
- Genetically modified species/strain.

3.1.8. Contaminants
Provide evidence that the IBCA is free from unwanted contaminants, i.e. entomopathogens and hyperparasitoids, including:

- A description of the measures to ensure purity (species/strain) of the IBCA;
- A statement that the IBCA is free from unwanted contaminants such as pathogens or hyperparasitoids;
- A description of co-formulants present with the IBCA (e.g. plant material, live prey or other food materials, carrier material);
- A description of any other organic contaminants which might be present.

3.1.9. Assessment of safety and effects on human health
Provide an assessment of the safety of the IBCA and effects on human health, including:

- A notification of any co-formulants; include a statement on known or potential risk to human and animal health;
- Available information on relevant hazards that may be posed to human health during and following introduction of the organism (e.g. allergy, skin irritation, disease vectoring);
- An assessment of safety for human health including methods to limit operator exposure, where necessary.

3.1.10. Assessment of environmental risks
The information presented in previous subsections, in particular in subsection 3.1.5, forms the basis for the environmental risk assessment. The environmental risk assessment should address the whole country within which releases will be made, but should address regional variation that may affect risk, where appropriate. Information required in subsections 3.1.10.1 – 3.1.10.3 is considered essential to an environmental risk assessment, and can be provided from published literature, company reports or experimentation.

3.1.10.1. Potential for establishment.
Describe conditions (including extremes) affecting the IBCA's survival and reproduction in its current range of distribution.

Physical constraints:

- Climatic similarities/differences between area of current distribution and area of intended release (e.g. temperature, altitude, humidity, day length, etc.), based on information provided under subsection 3.1.5.4;
- Dispersal potential, based on information provided under subsection 3.1.5.3;
- Ability to survive and reproduce at temperatures outside the normal range (e.g. cold tolerance, overwintering ability); lower and upper temperature thresholds for development and survival;
- Ability to survive and reproduce at humidities outside the normal range;
- Ability to enter diapause or quiescent states;
- Other physiological and behavioural mechanisms for surviving extreme conditions;
- Probability of temporary survival.

Resource constraints:

- Availability and utilization of suitable hosts (target and nontarget 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 or accidental introductions outside Europe or other IOBC/WPRS countries.

3.1.10.2. Host-range assessment.
Provide information on the IBCA's potential effects on nontarget hosts, including:

- Its potential to utilize nontarget hosts living on wild or cultivated plants;

- Its possible direct effects on nontarget hosts, phylogenetically or ecologically related to the target host(s);
- Its possible direct effects on non-related nontarget hosts, including pollinators, and threatened and endangered species.

3.1.10.3. Possible direct effects on plants.
Describe possible direct effects of the IBCA on the host plant(s) of the target pest and on nontarget plants.

3.1.10.4. Additional information on direct and indirect nontarget effects.
Indicate any other possible nontarget effects, such as:

- Competition with, or displacement of, indigenous natural enemies in the area of intended release;
- Potential for interbreeding with natural enemy strains or biotypes that are indigenous in the area of intended release;
- Other constraints on the presence of natural enemies, including pathogens, of the released IBCA;
- Presence of natural enemies, including pathogens, that may affect establishment of the IBCA;
- Previous risk assessments, for the same species (strain/biotype) with outcomes and other relevant information, including the country of application;
- Possible environmental benefits, e.g. beneficial effects of release of the IBCA compared to current control methods.

3.1.10.5. Summary and conclusions.
Summarize available information to indicate potential risks and benefits to the environment.

3.1.11. Assessment of efficacy and economic benefits
Provide relevant information on:

- Anticipated contribution to the control of the target pest(s);
- Estimated economic benefits (crop specific) of the IBCA.

3.1.12. General safeguards
The applicant or authorized user undertaking the release proceeds under the conditions of the authorization for release, taking account of the following:

(a) All appropriate safety procedures should be put in place.

(b) Any relevant information on adverse effects, which might relate to the released IBCA, should be reported to the competent National Authority.

(c) Information on sites and dates of supply or release of the IBCA should be made available to the competent National Authority, if requested.

3.2. Part B. Application for authorization to release non-native IBCAs previously authorized for release in one or more other European countries

The purpose of Part B of the guidelines is to specify information requirements for a non-native IBCA that has been previously authorized for release in one or more other European or IOBC/WPRC countries. IBCA may refer to one species or to a specified strain or biotype, where appropriate.

3.2.1. Application for renewal of an authorization by the same applicant for release in the same country
It is expected that when an IBCA has been released with no reported adverse effects, the authorization will be renewed. Further post-release monitoring may be requested.

3.2.2. Application for authorization by a second applicant for release of a previously released IBCA into the same country
On the grounds of intellectual property rights and commercial confidentiality it is expected that a full dossier will be submitted by the second and any subsequent applicant.

3.2.3. Application for authorization to release a previously released IBCA into a second European country by the same applicant
The original dossier can be submitted, with modifications where appropriate, clearly highlighting any factors likely to affect the original environmental risk assessment when applied to the second or subsequent release country.

3.2.4. Application for authorization to release a previously released IBCA into a second European country by a different applicant
On the grounds of intellectual property rights and commercial confidentiality it is expected that a full dossier will be submitted by the second and any subsequent applicant.

4. Information requirements for the release of native IBCAs

This section of the guidelines addresses the information needed in relation to the regulation of native IBCAs (i.e. those naturally occurring in the country where the applicant submits the dossier) intended for use in inundative/inoculative releases.

4.1. Information to be submitted by the applicant

The dossier to be submitted to the competent National Authority must include the information specified below.

4.1.1. The applicant
Give the name and address of the applicant, including the name of the responsible contact person.

4.1.2. Purpose of use
Briefly describe the intended use and potential benefits that may derive from it.

4.1.3. Taxonomy and characterization

(a) Provide an accurate identification, including the name of the identifier or, where necessary, sufficient characterization of the IBCA to allow its unambiguous recognition. Give evidence of deposition of voucher specimens in a recognized collection facility (these depositions must be made before the agent is released). Also give the order, family, genus, species (including scientific authority), and where appropriate subspecies, strain or type together with relevant, supporting taxonomic information, such as:

- A letter from a recognized scientific authority stating the identity of the organism;
- General diagnostic descriptions of all life stages of the IBCA, including details of any taxonomic difficulties with the group (e.g. species complexes, cryptic species);
- Known molecular information (e.g. unique microsatellite markers, etc.) used for diagnosis, especially for species complexes or cryptic species.

(b) Give the locality of the original or planned collection point(s) from the wild.

(c) Give details of the source laboratory if the IBCA is from culture.

(d) Where relevant, provide available information on biology, distribution, natural enemies, commensals, contaminants (including from laboratory cultures). For contaminants, give an assessment of the extent to which these should be of concern.

4.1.4. IBCAs on the list of species considered safe for use in the intended area of release

If the species is mentioned on the EPPO list of species considered safe [5] for use in the intended area of release (see section five of these guidelines), no further questions need to be answered. If not, the information requirements of subsequent subsections in this section need to be met.

4.1.5. Geographical distribution of the IBCA

Provide available information on the geographical distribution of the IBCA.

4.1.6. Assessment of risks to human/animal/plant health

Provide available information on hazards to human, animal and plant health (for example, allergy, skin irritation, disease vectoring).

Any relevant information on undesirable side effects should be reported to the competent National Authority.

4.1.7. Potential risks to the environment: assessment and management of risks

Based on available information, identify possible risks to the environment (including possible non-target effects) of releases of large numbers of the native IBCA. Describe measures designed to manage the identified risks.

4.1.8. Efficacy of the IBCA

Provide information on the efficacy of the IBCA, such as the anticipated contribution to the control of the target pest(s), and the economic benefits of the release (e.g. reduction in the number of pest organisms, of direct and indirect crop damage, or of yield loss). Any published information or the applicant's own data can be used.

5. Widely used non-native and native agents

The idea of listing IBCAs which are or have been widely used without any reports of adverse effects (a 'positive list') has been addressed by EPPO. The first positive list for the EPPO region was published in 2002 [5]. The IBCAs are listed according to expert judgement of available information, and are related to certain criteria, such as: (a) IBCAs are native or non-native, but established or widespread in the EPPO region, and successfully used in classical or inundative/inoculative biological control; (b) IBCAs have been used for at least five years in at least five EPPO countries.

The EPPO positive list should be considered as an advisory tool for the competent National Authority. This list should provide baseline data about the distribution and safe use of IBCAs in EPPO member countries. The list provides a standard to facilitate decisions on import and release of IBCAs within EPPO countries. Nonetheless, it is recommended that the inclusion of an IBCA on the EPPO positive list should not lead to the automatic granting of permission to release the IBCA on a wide scale.

In general, it is strongly recommended that an expert group should be established with the aim of revising and updating the list on an annual basis. The current list should be revised as a matter of urgency and improved by such an expert group. It is important that the revision process is transparent, and that the list is accessible to the public via the Internet.

The IOBC/WPRS Commission suggests the addition of the following information to the current EPPO positive list:

- EPPO countries where the list is approved;
- EPPO countries where the list is not used as part of the regulatory process;
- More precise information about the IBCA's original distribution and distribution in the EPPO region;
- Summary evaluation of host range assessment, dispersal, establishment and direct and indirect effects.

It is recognized that the EPPO positive list has a role in the risk assessment and regulatory process of IBCAs. If the list were made more comprehensive in terms of the information suggested above, it could become a valuable tool in the decision-making process and authorization of IBCAs in the future.

The IOBC/WPRS Commission concludes that the concept of eco-regions cannot be applied to the positive list as competent National Authorities make the

Table 1. Matrix to assign IBCAs to categories according to their origin and establishment, thereby defining the level of regulation required in European and other IOBC/WPRS countries.

Category	Description	Regulation Level
1	Native to the country of release and adjacent countries	Low
2	Not native to the country of release and adjacent countries, but (a) native to Europe[1] or (b) established in Europe	Medium
3	Not native or established in Europe	High

[1]'Europe' in this context includes Russia as far east as the Ural Mountains, and south to the Caucasus Mountains (but including neither mountain range), plus the Mediterranean islands, but does not include the Atlantic or other off-shore islands, North Africa and the Near East.

final decisions on import and release of IBCAs. Generally, national borders are more important in decision-making than eco-regions for the competent National Authorities. During the discussion of eco-regions and its application to the EPPO positive list, several suggestions, relating to the origin of the IBCA ('nativeness' and 'non-nativeness'), have been made (Table 1). A defined level of regulation (low, medium and high) would be required and should be applied for authorizing IBCAs according to the category (1, 2 and 3) to which the IBCA is assigned. As this concept is a first proposal for improving the usefulness of the positive list, further amendments will be needed in due course.

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