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Number 21**

**Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents  
(IBCA)**

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OECD Environment, Health and Safety Publications

Series on Pesticides

No. 21

**Guidance for Information Requirements for  
Regulation of Invertebrates as Biological Control Agents (IBCA)**

**Environment Directorate  
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT  
Paris 2003**

### **Also published in the Series on Pesticides**

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The Pesticide Programme was created in 1992 within the OECD's Environmental Health and Safety Division to help OECD countries:

- harmonise their pesticide review procedures,
- share the work of evaluating pesticides, and
- reduce risks associated with pesticide use.

The Pesticide Programme is directed by the Working Group on Pesticides, composed primarily of delegates from OECD Member countries, but also including representatives from the European Commission and other international organisations (*e.g.* United Nations Food and Agriculture Organization, United Nations Environment Programme, World Health Organization, Council of Europe), and observers from the pesticide industry and public interest organisations (NGOs).

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The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. UNITAR joined the IOMC in 1997 to become the seventh Participating Organization. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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## **1. Introduction**

This document was developed to serve as guidance for information requirements for the regulation of Invertebrates as Biological Control Agents (IBCA) within OECD countries. It incorporates information requirements from a number of OECD countries for the regulation of IBCAs, including insects, mites and nematodes. In developing this regulatory approach for IBCAs, the inherent differences between these products and chemical plant protection products were taken into consideration. IBCAs are usually more target pest specific than chemical plant protection products, and generally pose lower risks to human health and the environment. IBCAs have been used successfully for many years in many OECD countries without significant harm to plants or native arthropod species.

To facilitate the use of biological control agents in some of these countries, documentation on lists of IBCAs that have been used for many years (5 or more) without undesirable side-effects have been prepared and updated by government agencies (see Appendix 2).

A growing number of IBCAs, including insects, mites, and nematodes, are being tested and used in various countries, and interest has increased for the commercialisation of IBCA products. The importation and use of exotic, non-established species have raised particular concerns with regard to the need for appropriate regulatory oversight. The development of guidance for information requirements for regulation of IBCAs may facilitate access to new, reduced risk, Integrated Pest Management (IPM) compatible pest management tools by making it possible for companies to submit the same regulation applications to many countries, and for different regulatory agencies to benefit from each other's reviews. At the same time, this will ensure appropriate and consistent regulatory oversight. The main reasons for considering the development of a guidance document may be summarised as follows:

1. To ensure appropriate consideration of environmental risks posed by IBCAs, including those posed by their establishment, and impact on biodiversity and non-target species.
2. To promote and support the use of biological control by providing lists of IBCAs that have been used successfully for 5 or more years without environmental or other problems, and harmonizing information requirements for the release of IBCAs within OECD countries.
3. To ensure efficacy of IBCA products.

This document proposes guidance for OECD countries on information requirements for regulation of invertebrate biological control agents. This guidance is provided in Appendix 1. However, it is up to the individual countries to decide whether and how these types of organisms should be regulated. Also, please note that this is a general guidance document only, and that countries may require additional information to meet national or international requirements. Particularly for weed IBCAs and nematodes, additional or different information requirements may be necessary. Moreover, with native or established IBCAs and with IBCAs long in use in a country, substantially reduced information requirements may be appropriate for that country. With respect to confidentiality, country laws dictate which aspects of submitted information should remain confidential. It is expected that producers will be responsible for providing relevant information for each of their IBCAs. With regard to requirements for IBCA importation and research, it is suggested that national authorities be contacted (for example, see [www.eppo.org](http://www.eppo.org), document PM 6/1(1)).

## **2. Background**

This project is the result of an action item discussed at an informal meeting of OECD countries organised by Canada and held in Ottawa in February 1999. It included the Netherlands, Italy, UK, Finland, Norway, Sweden, and Switzerland. The purpose of the meeting was to determine whether countries were interested in working together on a harmonised approach for regulation of IBCAs. Participants agreed that it would be beneficial to take a harmonised approach, and that a "light" form of

regulation would be appropriate. A number of key issues in the risk assessment of IBCAs were also identified and discussed. A report on the meeting was presented to the June 1999 meeting of the OECD Working Group on Pesticides (WGP).

On 15-16 October 1999 a group of experts met in Montpellier, France, and included representatives from Australia, New Zealand, and NAPPO (North American Plant Protection Organisation). A review of existing or proposed approaches of EPPO (European Plant Protection Organization), NAPPO, International Plant Protection Convention (IPPC), Switzerland, Sweden, Japan, Norway, Australia, New Zealand, the Czech Republic and the European Commission was carried out.

A report of the meeting and a draft work plan were presented to the WGP in February 2000 and the WGP agreed to initiate work on guidance for information requirements for IBCAs at the OECD level. The WGP asked the interested countries to develop a work plan for presentation and discussion at the November 2000 WGP meeting. Another meeting was held in May 2000 in Wageningen, hosted by the Netherlands, to discuss with industry representatives their views of this approach to regulating IBCAs. Industry was represented at all meetings that followed. Subsequent meetings were held to discuss information requirements and to refine the guidance document. A draft guidance document was sent out for review in 2002, with comments incorporated into this final document.

### 3. Definitions

*Antagonist*: An organism (usually pathogen) which does no significant damage to the host but its colonisation of the host protects the host from significant subsequent damage by a pest.

*Augmentative releases*: Either inundative or seasonal inoculative releases, *i.e.* those forms of biological control where mass-produced, biological control agents are released to reduce a pest population without necessarily leading to continuing impact or establishment of the IBCAs.

*Biological control (biocontrol)*: Pest management strategy making use of living natural enemies, antagonists or competitors and other self-replicating biotic entities.

*Biological control agent*: A natural enemy, antagonist or competitor, and other self-replicating biotic entity used for pest management.

*Biological pesticide (biopesticide)*: A generic term, not specifically definable, but generally applied to a microbial control agent, usually a pathogen, formulated and applied in a manner similar to a chemical pesticide, and normally used for the rapid reduction of a pest population for short-term pest management.

*Classical biological control*: The intentional introduction and permanent establishment of an exotic biological agent for long-term pest management.

*Clearance (of a consignment)*: Verification of compliance with phytosanitary regulations.

*Competitor*: An organism which competes with pests for essential resources (*e.g.* food, shelter) in the environment.

*Consignment*: A quantity of plants, plant products and/or other regulated articles being moved from one country to another and covered by a single phytosanitary certificate.

*Direct effect (from the introduction of an exotic biocontrol agent):* This involves physical interaction between the biocontrol agent and target or non-target organisms (effects can be positive, negative or neutral).

*Ecoarea:* An area with similar fauna, flora and climate and hence similar concerns about the introduction of biological control agents.

*Ecosystem:* A complex of organisms and their environment, interacting as a defined ecological unit (natural or modified by human activity, *e.g.* agroecosystem), irrespective of political boundaries.

*Efficacy (of a biological control agent):* The ability to cause a statistically significant reduction with regard to the number of pest organisms, direct and indirect crop damage, or yield loss.

*Eradication:* Application of phytosanitary measures to eliminate a pest from an area.

*Established species:* Successful long-term survival and reproduction of a species after introduction into a new area.

*Establishment (of a biological control agent):* The perpetuation, for the foreseeable future, of a biological control agent within an area after entry.

*Exotic:* Not native to a particular country, ecosystem or ecoarea.

*Generalist:* See 'host specificity' below.

*Hazard of adverse effects (from the release of biocontrol agents):* Any imaginable adverse effect which can be named and measured (*e.g.* in biological control: direct and indirect adverse effects on non-target organisms and ecosystem).

*Host specificity:* A measure of the host range of a biological control agent on a scale ranging from 'extreme specialist' where the IBCA is only able to complete development on a single species or strain of its host (monophagous), to 'generalist', where many hosts ranging over several groups of organisms (polyphagous) can be used.

*Import permit (for a biological control agent):* An official document authorising importation (of a biological control agent) in accordance with specified requirements.

*Indirect effect (from the introduction of an exotic biocontrol agent):* The effect that the introduction of exotic IBCAs has on other organisms not involving physical interaction with the biocontrol agent (effects can be positive, negative or neutral).

*Inoculative release:* The introduction of a biological control agent with the aim of obtaining its establishment for long-term pest management, *e.g.* classical biological control.

*Integrated Pest Management (IPM):* A pest population management system that utilises all suitable techniques in a compatible manner to reduce pest populations and maintains them at levels below those causing economic injury (Smith and Reynolds, 1966) (definition adopted by FAO).

*Intraguild predation:* The killing and eating of species that otherwise use similar resources.

*Introduction (of a biological control agent):* The release of a biological control agent into an ecosystem where it did not exist previously.

*Inundative release:* The release of very large numbers of a mass-produced biological control agent with the expectation of achieving a rapid reduction of a pest population without necessarily achieving continuing impact or establishment of the IBCA.

*Invertebrate Biological Control Agent (IBCA):* An invertebrate natural enemy used for pest management.

*Legislation:* Any act, law, regulation, or other administrative order promulgated by a government.

*Management or control of a pest:* Suppression, containment or eradication of a pest population.

*Microbial control:* The use of micro-organisms (including viruses) as biological control agents.

*Micro-organism:* A protozoan, fungus, bacterium, virus or other microscopic self-replicating biotic entity.

*Monophagous:* An organism that attacks only one host species and is species specific.

*Native:* Naturally occurring at area of proposed IBCA releases.

*Natural enemy:* An organism which lives at the expense of another organism and which may help to limit the population of this other organism. The term 'natural enemy' in this context includes parasitoids, parasites, predators and pathogens.

*Naturally occurring:* Refers to a component of an ecosystem or a selection from a wild population, not altered by artificial means.

*Non-target organism :* All organisms except the target organism.

*Oligophagous:* An organism that attacks a limited group of related hosts (*e.g.* up to 20 species in the same genus or subfamily).

*Organism:* Biotic entity capable of reproduction or replication, includes vertebrate and invertebrate animals, plants and micro-organisms.

*Parasite:* An organism which lives on or in a larger organism, feeding upon it.

*Parasitoid:* An insect parasitic only in its immature stages, killing its host in the process of its development, and free living as an adult.

*Pathogen:* Micro-organism causing disease.

*Pest:* Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.

*Polyphagous:* An organism that attacks a wide range of hosts from different subfamilies.

*Predator:* A natural enemy that preys and feeds on other animal organisms, more than one of which are killed during its lifetime.

*Probability of adverse effects (from the release of biocontrol agents):* The likelihood that an adverse effect will occur (e.g. reduction in the number of a non-target organism); in biological control, the likelihood that an adverse effect will occur is often a matter of space (dispersal) and time (survival and establishment).

*Quarantine (of a biological control agent):* Official confinement of biological control agents subject to phytosanitary regulations for observation and research, or for further inspection and/or testing.

*Release (into the environment):* Intentional liberation of an organism into the environment.

*Release (of a consignment):* Authorisation for entry after clearance.

*Risk of adverse effect (from the release of biocontrol agents):* Hazard times probability.

*Seasonal inoculative releases:* The release of mass-produced biological control agents with the expectation of achieving the reduction of a pest population during several generations without necessarily achieving continuing impact or establishment of the IBCA.

*Specialist:* See 'host specificity' above.

*Suppression:* The application of phytosanitary measures in an infested area to reduce pest populations.

#### **4. Information requirements**

The following provides a review of some of the information requirements (outlined in Appendix 1) that may be needed for introducing a biological control agent, *i.e.* for obtaining permits, handling the agent, or meeting regulation - as well as for achieving its release and for subsequent monitoring of the outcome. Information on the characterisation and identification of the control agent is typically required, as is information for assessing the agent's safety and effects on human health, the environmental risks it poses and its efficacy. Because the information and/or data needed tends to be very case specific to individual IBCAs, it is suggested that the applicant discusses requirements with the regulatory authority. This is particularly important for weed IBCAs and nematodes. With native or established IBCAs, and with IBCAs long in use, substantially reduced information requirements may be appropriate (see Appendix 2).

##### **4.1 Information for assessment of characterisation and identification**

###### **4.1.1 Identity**

- Exact identity of the organism. This should be the full scientific name (with a citation of the source of the formal description of the organism). If this is not possible, information should be provided which will give an exact and unambiguous description - morphological description, biochemical or molecular characterisation, as appropriate - and if possible, an accession number to a voucher specimen or culture deposited in a museum or culture collection.
- Means of accurate identification. This should comprise the information required for identification of the organism (e.g. keys, distinguishing characteristics of the organism and close relatives) by specialists. Also included should be any unique characteristics which can be used by those handling the organism in the laboratory or the field for recognition of the organism, or if this is not possible, indicators of its presence (e.g. any observable changes in the infected host). Fully

labelled voucher specimens should be deposited in museums, appropriate scientific institutions and reference collections.

- Source and characterisation of the culture to be imported. The geographical origin and original host(s) of the organism should be described. In cases where special claims are made, information which will enable the culture to be distinguished from others should be given. Any inseparable organisms associated with the agent should be noted.
- Information on whether the IBCA has been genetically manipulated other than by traditional breeding methods.

#### **4.1.2 Biology and ecology of the agent**

##### ***Description of the life history of the candidate agent***

This should include any available data on the biology, size, mode of reproduction, limiting factors (*e.g.* temperature, day length), *etc.* of the agent which may affect its distribution and performance upon release. For instance, the following type of information would be useful:

- taxonomic classification of the organism (*e.g.* phylum, class, order, family, genus, species, *etc.*), including reference to common names and history of any recorded name change;
- general information on attributes and characteristics of the family and genus the organism belongs to;
- information on the biology and lifecycle of the organism including, for example:
  - physical characteristics: morphology, appearance, sexual dimorphism, height, length, weight and size, winged/wingless
  - behavioural characteristics
  - predator/prey characteristics
  - life history and life cycle information; for example, mode of reproduction, and seasonal pattern of reproduction; reproductive potential (number of eggs, young, generations), and longevity; and
- special characteristics, *e.g.* toxicity, venomous nature, ability to induce allergic reaction, feeding habits, defensive and aggressive behaviour, offensive odour, damaging effects on plants, *etc.* If there is a known problem, it should be reported. If the organism is known to cause an adverse effect, instructions should be given on how to mitigate this effect.

##### ***Culture methods of the candidate agent***

##### ***Host plant and host organism for rearing of the agent***

##### ***Distribution of the candidate agent***

Native range and world distribution of the agent, and information on any known variability over its range, including countries where the agent has been used for biological control:

- natural distribution of the organism, *e.g.* tropical, sub-tropical, cool temperate, warm temperate, *etc.*; and
- factors that might limit the organism's distribution, *e.g.* altitude, temperature, humidity, wind dispersal, rainfall, food supply, soil type, water quality, *etc.*

##### ***Ecology of the candidate agent***

Available information from the literature, field observations and the natural range of distribution of the

agent should be summarised to provide as fully as possible a description of its climatic tolerance, habitat preferences, phenology, natural enemies, voltinism (number of generations per year), dispersal mechanism, means of overcoming unfavourable periods (*e.g.* diapause, resting stage, migration), *etc.* This would include information on:

- habitat requirements of the agent, such as specific habitat requirements, for example, terrestrial, aquatic, pasture, forest, scrub, mountain, arable land, waste land, *etc.*;
- affinities of the agent with other biota in terms of its potential to interact and form associations with organisms already present in the new environment and the agent's ability to produce hybrids; and
- competitors and natural enemies in managed and natural environments.

Please note that much of the information indicated in this Section is also relevant for Section 4.3.

#### **4.2 Information for assessment of safety and effects on human health**

Generally speaking, there is little evidence that IBCAs present a health risk to users and no evidence that they present a health risk to consumers. However, health problems are known for people involved in mass-rearing of some IBCAs. Workers may suffer from attacks of asthma and rhinitis after long-term exposure to large quantities of IBCAs. Typically, users have a lower level of exposure to IBCAs than those who work in facilities where mass-rearing occurs. If there are health problems caused by IBCAs, they are most likely skin irritation and sensitisation due to the ability of a biological control agent to evoke an immune response in humans. (Please note that there are no OECD Test Guidelines for testing skin irritation or sensitisation specifically caused by living IBCAs.)

If there is a known problem, it should be reported. If the organism is known to cause an adverse effect, instructions should be given on how to mitigate this effect.

#### **4.3 Information for assessment of environmental risks**

Any environmental risk assessment should be tailored to a specific country, climate or ecoarea. (Please note recent references regarding the assessment of risks, for example in Van Lenteren *et al.*, 2003).

##### **4.3.1 Direct effects**

***Host range.*** Available information on host/prey range of IBCAs must be provided. Monophagous and oligophagous IBCAs are expected to pose no or very limited potential risks to non-targets, whereas polyphagous IBCAs may cause direct and indirect effects on non-targets.

***Intraguild predation.*** Provide available information on negative intraguild predation effects for specific or related natural enemy species, or determine from the biology of the natural enemy whether negative effects are likely. Conclusions concerning risk should also be provided.

***Competition and displacement.*** Check literature to see if competition and displacement effects are indicated for specific or related natural enemy species, or determine from the biology of the natural enemy whether negative effects are likely.

***Potential for hybridisation with indigenous strains or biotypes.*** Provide available information on hybridisation of the natural enemy with indigenous strains or biotypes of same or very closely related natural enemy species.

***Effects on plants.*** Effects of natural enemy on plants should be provided if the biological control agent

is potentially a facultative herbivore and if there is a potential for phytotoxic effects. Check literature to see if negative effects on the target crop and non-target plants are indicated for specific or related natural enemy species, or determine from the biology of the natural enemy whether effects are likely.

#### **4.3.2 Available information on the potential for establishment and dispersal of the biological control agent**

***Potential for establishment.*** In case of movement of IBCAs from one ecoarea to another, it is important to know if the agent can establish. If the agent cannot establish, the information required may be less extensive.

Key factors that need to be considered include:

- abiotic factors: do the climates of the area of origin and area of release match?
- biotic factors: availability of non-target species suitable for reproduction, temporal and/or spatial matching of non-target organisms and biocontrol agent, diapause capabilities, winter survival; and
- combined biotic and abiotic factors: availability of other resources for survival and reproduction.

***Potential for dispersal.*** In order to answer the question ‘what is the probability of a temporal and spatial encounter between the biological control agent and non-target species?’ it is important to determine the potential for dispersal of the IBCA. This is based on the mechanism of dispersal and lifespan of the IBCA, and the local climate and habitat conditions in the area of release. Any information on the possibility for secondary dispersal, e.g. mechanical, or with crops, should be provided.

#### **4.3.3 Available information on possible indirect effects**

Report any known indirect effects or discuss potential indirect effects on individual species and/or ecosystem.

#### **4.3.4 Available information on environmental benefits (e.g. beneficial effects of release of IBCAs compared to current or alternative pest management methods)**

The applicant should provide information on the beneficial effects of release of IBCAs compared to current or alternative pest management methods.

#### **4.3.5 Summary of information for assessment of environmental risks**

The applicant should provide a summary of the information indicated in Section 4.3.

### **4.4 Information for assessment of efficacy, quality control and benefits of use**

#### **4.4.1 Efficacy**

The role of information on efficacy in the regulation process is to enable the regulatory authority to assess the effectiveness of the biological control agent and to prevent the introduction and release of ineffective IBCAs. A biological control agent is considered to be effective if it can cause a statistically significant reduction of at least 10% in the number of pest organisms, of direct and indirect crop damage, or of yield loss. Relevant information, so that a reviewer can judge the efficacy of an IBCA, should be provided. Summarise information on what crop, against what pest, and under what conditions the agent is shown to be effective, and what the role and strength of the agent would be in IPM programmes.

**4.4.2 Methods for evaluation of quality control**

Provide information on methods for evaluation of quality and purity, (for reference on some evaluation methods see for example: van Lenteren and Tommasini, 1999; van Lenteren, 2003).

**4.4.3 Benefits of use**

The benefits of use of the proposed biological control agent should be described (for example with respect to alternative control methods, resistance management, and level of control).

**Appendix 1****Guidance for information requirements for regulation of IBCAs**

<b>1. Information required for characterisation and identification</b>	
1.1	<p>(a) Accurate identification, including name of identifier or, where necessary, sufficient characterisation of the agent to allow its unambiguous recognition:</p> <ul style="list-style-type: none"> <li>▪ order, family, genus, species (including scientific authority) and, where appropriate, subspecies, strain, type (synonyms should be included);</li> <li>▪ letter from recognised (by receiving country) scientific authority stating the identity of the organism;</li> <li>▪ general diagnostic description of all life stages of the agent, including details on any taxonomic difficulties with the group (<i>e.g.</i> species complexes, cryptic species, poorly studied group); and</li> <li>▪ known molecular information (<i>e.g.</i> unique microsatellite markers) used for diagnosis, especially of species complexes or cryptic species.</li> </ul>
	<p>(b) Deposition of voucher specimens in an internationally recognised collection facility before the release of a new agent:</p> <ul style="list-style-type: none"> <li>▪ name and location of institution(s) where voucher specimens are to be deposited.</li> </ul>
1.2	<p>(a) Information on origin of organism (species or lower taxonomic level):</p> <ul style="list-style-type: none"> <li>▪ if field collected, see 1.2 (b) below; and</li> <li>▪ if from laboratory culture, information on the number of individuals in the founder population, and the number of generations in the culture.</li> </ul>
	<p>(b) Where the culture was originally collected:</p> <ul style="list-style-type: none"> <li>▪ latitude, longitude of field location;</li> <li>▪ description of original habitat and host(s) from which collection was made; and</li> <li>▪ description of time of year when collection was made.</li> </ul>
	<p>(c) Immediate source of organism (where it was produced):</p> <ul style="list-style-type: none"> <li>▪ name of organisation providing organism; and</li> <li>▪ country, city where production facility is located.</li> </ul>
1.3	<p>Available information on distribution, dispersal, biology, host range/specificity, host preference, natural enemies, physical requirements for establishment and distribution, requirements for survival and reproduction:</p> <ul style="list-style-type: none"> <li>▪ known geographical and ecological areas where agent naturally occurs;</li> <li>▪ known regions where agent has been introduced intentionally or accidentally;</li> <li>▪ potential for dispersal (<i>e.g.</i> good/poor flier, presence of alternate hosts in the wild, known migratory behaviour);</li> <li>▪ detailed description of biology, including description of all life stages, reproductive potential,</li> <li>▪ details on natural enemies known to attack the agent;</li> <li>▪ details on hosts, habitats and climatic conditions favourable for establishment and dispersal of the agent;</li> <li>▪ biological (including extreme) conditions in which there is potential for agent survival and reproduction;</li> <li>▪ list of known hosts other than the target;</li> <li>▪ list of non-target organisms that have been tested;</li> <li>▪ details on the methodology used to determine host range, including experimental design, experimental conditions of tests, rearing methods for non-target species, life stage(s) tested, statistical tests used, etc.; and</li> <li>▪ statement of potential host range, including limitations of testing methods.</li> </ul>

1.4	Natural enemies of candidate agent or contaminants of candidate agent or rearing hosts/prey, and procedures required for their elimination from lab colonies if necessary: <ul style="list-style-type: none"> <li>• details on the biology of predators, parasitoids (hyperparasitoids), pathogens or commensal species in the native habitat that might be carried on the candidate agent or rearing hosts/prey to the region of introduction; and</li> <li>• procedures used to ensure purity of the agent before shipment to the recipient (<i>e.g.</i> washing surface of cocoons/mummies with fungicide, removal of individuals with mites).</li> </ul>
1.5	Available information on specific characteristics of strain ( <i>e.g.</i> resistance to pesticides, mutants): <ul style="list-style-type: none"> <li>• description of special characteristics (<i>e.g.</i> pesticide resistance, cold hardiness, aggressive searching capacity of the source culture).</li> </ul>
<b>2. Information for assessment of safety and effects on human health</b>	
2.1	Provide available information on relevant hazards to human and animal health that may be posed by the use of IBCAs during and following introduction (for example, allergy, skin irritation, disease vectors).
2.2	Summary of information for assessment of safety and effects on human health.
<b>3. Information for assessment of environmental risks</b>	
3.1	Identify any potential hazards posed to the environment by IBCAs, including: <ol style="list-style-type: none"> <li>(a) available information on the role of the agent in original ecosystem, the type of natural enemy (parasitoid, predator, pathogen), type of organisms it attacks, effect of attack on target and non-targets, intraguild effects, higher up trophic level effects, and effects on ecosystem;</li> <li>(b) available information on existing natural enemies of the target organism in the area of release;</li> <li>(c) available information on non-target effects from previous use of IBCAs in biological control.</li> </ol>
3.2	Host range testing <ol style="list-style-type: none"> <li>(a) Available information and/or data on possible direct effects: <ul style="list-style-type: none"> <li>• on non-target host/prey related to target host (phylogenetically or ecologically related);</li> <li>• on non-related non-target hosts, such as threatened and endangered species;</li> <li>• concerning competition or displacement of organisms;</li> <li>• concerning potential for interbreeding with indigenous natural enemy strains or biotypes;</li> <li>• on plants (target crop and non-target plants).</li> </ul> </li> <li>(b) Available information and/or data on potential of establishment and dispersal of biological control agent.</li> <li>(c) Available information on and/or data on possible indirect effects.</li> <li>(d) Available information (from rearing facility or from the field) on the ability of the IBCA to carry viruses or micro-organisms that can negatively affect non-target organisms.</li> </ol>
3.3	Available information, and/or data on potential host/ prey range in areas of release and potential distribution of the IBCA.
3.4	Available information on environmental benefits ( <i>e.g.</i> beneficial effects of release of IBCAs compared to current or alternative control methods).
3.5	Summary of information for assessment of environmental risks.
<b>4. Information for assessment of efficacy</b>	
4.1	Information relevant for determining the efficacy of an IBCA should be provided.
4.2	Information on methods for the evaluation of quality and purity (quality control) of IBCAs.
4.3	Information on benefits of use of IBCAs.
4.4	Summary of information for assessment of efficacy.

*Footnote:* Recommend that companies which produce IBCAs report any adverse effects from IBCAs on non-targets to regulatory authorities.

## Appendix 2

### **Guidance for regulation of IBCAs already in use**

About 150 species of IBCAs have been in use for many years in various countries all over the world. This Guidance proposes that these species be exempted from a full environmental risk analysis, but should be evaluated with a quickscan method to estimate potential adverse environmental effects based on available information only. The results of such a quickscan could help to establish lists of species that can be used in certain, specified regions of the world, without having to undergo a full environmental risk analysis.

Available information on the following issues should be provided:

#### **1. Information on characterisation and identification of IBCAs**

- 1.1 Identity of IBCAs
- 1.2 Biology and ecology of IBCAs

#### **2. Available information on effects of IBCAs on human health and their safety**

#### **3. Available information on environmental risks of IBCAs**

- 3.1 Available information on host/prey range (direct effects) of IBCAs
- 3.2 Available information on potential of establishment and dispersal of IBCAs
- 3.3 Available information on indirect effects of IBCAs
- 3.4 Available information on environmental benefits of release of IBCAs (should include discussion of beneficial effects of release of IBCAs compared to currently used or alternative pest management methods).

#### **4. Information for assessment of efficacy of IBCAs**

The following documents could serve as a basis for establishing lists of exempted species:

European Plant Protection Organization: List of biological control agents widely used in the EPPO region: commercially available biological control agents (version 2002) [www.eppo.org](http://www.eppo.org).

European Plant Protection Organization: Candidates for the list of biocontrol agents widely used in the EPPO region: classical biocontrol agents (version 2002) [www.eppo.org](http://www.eppo.org).

European Plant Protection Organization: Candidates for the list of biocontrol agents widely used in the EPPO region: commercially available agents (version 2002) [www.eppo.org](http://www.eppo.org).

Agriculture Canada: Fast track list of organisms in draft guideline for introduction and release of invertebrate biological control agents (July, 1993; page 12 and 13).

APHIS-USDA: Exclusion list: entomophagous and entomopathogenic biological control agents not requiring a permit for interstate shipment in Continental USA (March, 1999; 8 pages).

### **Appendix 3**

#### **Selected publications**

##### ***Definitions***

Eilenberg, J., Hajek, A. and Lomer, C. (2001). "Suggestions for unifying the terminology in biological control" *BioControl* 46 (4): 387-400.

FAO (2001). *Glossary of phytosanitary terms, international standards for phytosanitary measures*. Secretariat of the International Plant Protection Convention, Food and Agriculture Organization of the United Nations, Rome, ISPM Pub. No. 5: 62 p.

Lenteren, J.C. van (2000). "Measures of Success in Biological Control Of Arthropods By Augmentation Of Natural Enemies". In: *Measures of Success in Biological Control*, S. Wratten and G. Gurr (eds.). Kluwer Academic Publishers, Dordrecht: 77-103. Version 4, J.C. van Lenteren, December 2001.

##### ***Efficacy and quality control***

EPPO (1989). "EPPO guidelines for Efficacy Evaluation of Plant Protection Products", *OEPP/EPPO Bulletin* 19, 184-264.

EPPO (1990). "EPPO Guideline No. 152", *OEPP/EPPO Bulletin* 20, 551-579.

FAO (1995). *Guidelines of Efficacy Data for the Registration of Pesticides for Plant Protection*, FAO, Rome, 1995.

Lenteren, J.C. van and M.G. Tommasini (1999). "Mass production, storage, shipment and quality control of natural enemies". In *Integrated Pest and Disease Management in Greenhouse Crops*, R. Albajes, M.L. Gullino, J.C. van Lenteren and Y. Elad (eds.). Kluwer Publishers, Dordrecht: 276-294.

Lenteren, J.C. van (ed.) (2003). *Quality and Production of Biological Control Agents: Theory and Testing Procedures*. CABI, Wallingford.

##### ***Host range testing***

Barratt, B.I.P., Ferguson, C.M., McNeill, M.R., and Goldson, S.L. (1999). "Parasitoid host specificity testing to predict host range". In *Host specificity testing in Australasia: towards improved assays for biological control* (eds. T.M. Withers, L. Barton Browne and J.N. Stanley), pp. 70-83. CRC for Tropical Pest Management, Brisbane, Australia.

Dijken, M.J. van, M. Kole, J.C. van Lenteren and A.M. Brand (1986). "Host-preference studies with *Trichogramma evanescens* Westwood (Hym., Trichogrammatidae) for *Mamestra brassicae*, *Pieris brassicae* and *Pieris rapae*". *Journal of Applied Entomology* 101: 64-85.

Follett, P.A., J. Duan, R.H. Messing and V.P. Jones (2000). "Parasitoid drift after biological control introductions: re-examining Pandora's box". *American Entomologist* 46: 82-94.

Sands, D.P.A. (1988). "Guidelines for testing host specificity of agents for biological control of arthropod pests". In *Proceedings of the 6<sup>th</sup> Australian Applied Entomological Conference* (eds. M.P. Zalucki, R.A.I. Drew and G.G. White), Brisbane: 556-560.

***Phylogenetic centrifugal method***

Londsdale, W.M., D.T. Briese and J.M. Cullen (2000). "Risk analysis and weed biological control". In *Evaluating Indirect Ecological Effects of Biological Control* (eds. E. Wajnberg, J.K. Scott and P.C. Quimby): 185-210.

Wapshere, A.J. (1974). "A strategy for testing the safety of organisms for biological weed control". *Annals of Applied Biology* 77: 201-211.

***Intraguild predation***

Rosenheim, J.J., H.K. Kaya, L.E. Ehler, J.J. Marois and B.A. Jaffee (1995). "Intraguild predation among biological-control agents: theory and evidence". *Biological Control* 5: 303-335.

***Competition and displacement***

Bellows, T.S. and M.P. Hassell (1999). "Theories and mechanisms of natural population regulation". In *Handbook of Biological Control* (eds. T.S. Bellows and T.W. Fisher), Academic Press, San Diego: 17-44.

***Risk analysis***

Hickson, R, A. Moeed and D. Hannah (2000). "HSNO, ERMA and risk management". *New Zealand Science Review*, 57: 72-77.

Lenteren, J.C. van (2001). "Harvesting safely from biodiversity: natural enemies as sustainable and environmentally friendly solutions for pest control". In *Balancing Nature: Assessing the Impact of Importing Non-Native Biological Control Agents* (eds. J.A. Lockwood, F.G. Howarth and M.F. Purcell). Thomas Say Publications in Entomology: Proceedings, Entomological Society of America, Lanham, Maryland: 15-30.

Lenteren, J.C. van, Babendreier, D., Bigler, F., Burgio, G., Hokkanen, H.M.T., Kuske, S., Loomans, A.J.M., Menzler-Hokkanen, I., Rijn, P.C.J. van, Thomas, M.B., Tomassini, M.C., Zeng, Q.Q. (2003). "Environmental risk assessment of exotic natural enemies used in inundative biological control". *Biocontrol*. *Biocontrol* 48: 3-38.

Lynch, L.D., H. M. T. Hokkanen, D. Babendreier, F. Bigler, G. Burgio, Z.-H. Gao, S. Kuske, A. Loomans, I. Menzler-Hokkanen, M. B. Thomas, G. Tommasini, J. Waage, J. C. van Lenteren, Q.-Q. Zeng (2000). "Indirect effects in the biological control of arthropods with arthropods". In *Evaluating Indirect Ecological Effects of Biological Control* (Eds. E. Wajnberg, J.C. Scott and P.C. Quimby). CABI Publishing, Wallingford: 99-125.

Zadoks, J.C. (1999). "Risk analysis of beneficial microorganisms – wild types and genetically modified". In *KEMI Proceedings: Microbiological plant protection products - Workshop on the scientific basis for risk assessment*, Stockholm, Sweden 26-28 October, 1998. Solna (Sweden), National Chemicals Inspectorate : 9-38.

***Guidances documents and approaches***

Australian Quarantine and Inspection Service (1998). "Code of Conduct for the Import and Release of Exotic Biological Control Agents" (Australia), <http://www.aqis.gov.au/docs/appolicy/part1a2.htm>, 9 December.

Bigler, F. (1997). "Use and Registration of Macroorganisms for Biological Crop Protection", *Bulletin OEPP/EPPO* Bulletin 27, 95-102.

European and Mediterranean Plant Protection Organization (1998). "Guidelines for the Safety and Efficacy of Biological Control: First Introduction of Exotic Biological Control Agents for Research Under Contained Conditions". EPPO.

Food and Agriculture Organization of the United Nations (1996). *International Standards for Phytosanitary*

*Measures: Code of Conduct for the Import and Release of Exotic Biological Control Agents.* FAO, February.  
Ministry of Agriculture, Forestry and Fisheries (MAAF), *Guidelines for Evaluating Environmental Effects of Macroorganisms* (Japan).

National Chemicals Inspectorate (1994). *A Guide to the Completion of the Application Form for Approval of a Biological Pesticide: Nematodes, Insects, and Arachnids.* (Sweden), 16 November.

North American Plant Protection Organization (1998). "NAPPO Standards for Phytosanitary Measures: Guidelines for Petition for Release of Non-native Phytophagous Agents for the Biological Control of Weeds", *NAPPO Document 978-017*, August.

Norwegian Agricultural Inspection Service (1999). *Proposal for Regulation of Beneficial Organisms (Macroorganisms) for Use in Biological Control* (Norway), 21 June.

State Phytosanitary Administration, *Regulation of the Biological Products Based on Macroorganisms in the Czech Republic.* (Czech Republic).

Federal Office of Agriculture (1996). *Examen et autorisation pour le commerce de macroorganismes (auxiliaires) considérés comme des produits pour le traitement des plantes.* (Switzerland), November.