

REBECA Work Package 5 – Macrobial (Invertebrate) Biological Control Agents

Report from the sub-group for the Development of Guidance and Administration Documents in support of an Application for the Import and Release of Macrobial (Invertebrate) Biological Control Agents

Application Form (Draft)

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Application form for the import, shipment, rearing and release of invertebrate biological control agents in European countries¹

Using this form

This form should be used for the submission of an application to a National Competent Authority (NCA) of the European Union (EU) for a permit to license the import, shipment, mass-rearing and/or release of an invertebrate natural enemy for the biological control of invertebrate and plant pests (Invertebrate Biological Control Agent or IBCA). Guidance on the completion of this form is provided in the accompanying Guidance Document¹. This form is valid for an application relating to a single biological control organism. An organism is characterised as any identifiable and recognisable taxon of the IBCA, either a species, or recognised sub-species, population, strain or biotype. The form can be used for biocontrol agents, and also for other beneficial organisms that are used in biological control programmes.

After the NCA has received your application (administrative forms and documentation/dossier), you will receive an acknowledgement of receipt within a specified period of time. The application will then be checked for completeness and subjected to a risk assessment in relation to the purpose of your application (e.g. for research under quarantine conditions, or a commercial release). The risk analysis will be conducted by the NCA or – upon its request – by a specified expert or group of experts. The NCA will assess the risk analysis in the light of the information provided, or any other sources they have available. The NCA may need to contact you to clarify parts of the application or to seek further information. At all times and in all communication, including that with external experts, your application will be regarded as confidential. After the risk assessment has been completed, the NCA will make a decision as to whether to grant a permit within a previously agreed period of time. The licence to permit an import and/or release will be valid for a fixed period of time, after which a renewal may be sought, or a request may be made to place the organism on the EPPO Positive List.

Information required to complete this form

This application form and related information requirements for the release of non-indigenous IBCAs contains 5 parts (numbered 1-5) and is structured in a step-wise 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. *Information on the purpose of the application and use*

- Part 2. IBCA information
 - A. *Taxonomy and characterisation of the organism*

Where an application is made for the import for research and rearing of a non-indigenous species and/or release of a native IBCA, the applicant should proceed to sections 4 and 5 of the form. Where the application is for the release of a non-indigenous IBCA, section 3 of this form must be completed.

- Part 3. Release information for a non-indigenous IBCA with reference to:
 - A. *Species and product information*
 - B. *Assessment of environmental risks and benefits*
 - a. Establishment,
 - b. Host specificity
 - c. Dispersal
 - d. Direct and indirect effects

- Part 4. Submission of forms and signature

- Part 5. Appendix (references and other literature)

For more information: Call... or refer to our website..... or consult the Guidance Document

¹ Guidance on the completion of this Application form is provided in a separate document – Form 2 .

Part I. Application Information

A Information on the Applicant		
1.1 Who will apply for the permit? * *only a legally authorized person is allowed to apply.	Name of organisation	
	Name of applicant	
	Affiliation of applicant	
	Address	
	Postal code	
	City	
	Phone	
	Fax	
	E-mail	
	Chamber of Commerce #	
1.2. Contact person? Contact person, research manager and/or quarantine officer. Include confirmation of the person's authorization and a copy of a valid identification card with the application.	Name of contact person	
	Affiliation of contact person	
	Visiting Address	
	Postal code	
	City	
	Phone	
	Fax	
	E-mail	
1.3. Production facility and procedures Describe how the risks, and the extent or probability of escape into the wild will be managed (waiver)	Address	
	Postal Code	
	Location	
	Facility	
	Level of containment	
	Standard Operating Procedures	
	Quality control management	
	Accreditation	

B Information on the Purpose of Application and Use		
1.4. Information on Application	First application	
	Renewal	
	Licence period requested	
	Application or registration elsewhere in Europe	
	Relation with previous/ other applications	
	Positive List organism	
1.5. Purpose of use	Type of biocontrol programme	
	Research	
	(Mass) rearing	
	Release	
1.6. Information on target organism(s) Give a description of the biology and ecology of the target pest(s)	Target host taxon	
	Names of pests	
	Original area of distribution of the pests	
	Biology of pests	
	Target crops	
	Area of release	

Part 2. IBCA Information

A Information on the IBCA – taxonomy and characterization		
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	Kingdom	
	Phylum	
	Class	
	Order	
	Family	
	Genus	
	Species	
	Sub-species	
	Common names	
	Alternative names	
	ID-Confirmation Indicate means, methods of ID-confirmation and vouchers.	Authority
Methodology		
Voucher deposits		
2.2. Origin and Distribution IBCA What is the immediate source of the organism. Include details of the origin and distribution of the IBCA (species or lower taxon)	Indigenous	
	Non-indigenous	
	Field collected	
	Laboratory culture	
	Producer/Company	
	Original area and distribution	
	Areas introduced before	
2.3. Characterization of IBCA Specify life-stages, strains or taxonomy.	Diagnostic descriptions	
	Specific characteristics	
	Taxonomic characteristics	
	Known non-target effects	

In the case of a renewal of a previously successful application (section 1.4), or if the species or population is indigenous to the country or ecoregion, and/or imported for research or rearing only and/or is 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 4A and Appendix of cited literature (Part 5) need to be completed. For other applications, such as the release of a non-native species, the information requirements in Part 3 must be supplied.

Part 3. Information requirements for the intentional release of a non-native IBCA

A Species and Product Information		
3.1. Species/Strain Information	Scientific species name	
	Specific strain used	
3.2. Product Information	Product/Trade name	
	Producer	
	Method of supply	
	Life stages released	
	Label information	
	Storage	
	Method of Use	
3.3. Product Composition	Co-formulants	
	Contaminants	
3.4. Information on Biology and Ecology <small>Give a description of the biology and ecology of the IBCA</small>	Life cycle – generations/year	
	Developmental biology	
	Mechanisms of survival	
	Mechanisms dispersal	
	Climatic conditions	
	Habitat range	
	Host range	
	Natural enemies	

B Assessment of Risks and Benefits

3.5. Safety and Health Effects Potential hazards of IBCA, product or any co-formulants, and measures taken to limit operator exposure	Human health	
	Animal health	
	Measures of prevention	
3.6. Information on Environmental Risk Assessment (ERA) 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	
3.6.1. Potential for establishment¹	Physical constraints	
	Resource constraints	
	Survival data and methods used	
	Evidence of establishment	
3.6.2. Host range assessment²	Wild hosts known	
	Organisms tested	
	Procedures used for host range testing	
	Target and non-target host plants	
3.6.3 Dispersal³	Ability to disperse	
3.6.4. Direct and/or indirect non-target effects⁴	Summary of available information	

¹When outdoor establishment of the IBCA 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 are necessary;

²when outdoor establishment of the IBCA is necessary or likely to occur, host range information is essential for the risk assessment;

³dispersal test results are not required for glasshouse releases, but should be provided when IBCAs are released in open fields or structures that do not prevent escape (e.g. polytunnels) and long term establishment very is unlikely;

⁴a summary of known direct and indirect non-target effects should always be given, irrespective of whether host range and/or dispersal have been assessed.

3.7. Efficacy and benefits of the IBCA and proposed release Assessment of efficacy, economic and environmental benefits	Method(s) to determine efficacy	
	Results 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	
	Identification of applicant	
	Chamber of Commerce	
	Authorization payment	
4.2. Where to submit the application	Name organisation	
	Bureau	
	Address	
	Postal code	
	City	
4.3. Disclaimer * * completed by a legally authorized person	Declaration	
	Conditions	
	Date	
	Applicant's name	
	Signature	

B Conditions

4.4 General safeguards

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

- All appropriate safety procedures should be put in place.
- Any relevant information on adverse effects which might relate to the released IBCA should be reported immediately to the NCA.
- Information on sites and dates of supply or release of the IBCA should be made available to the NCA, if requested.

Part 5. Appendix (cited references and other literature)

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.