

Application for licence to release a non-native species for biological control purposes in England, under Sections 14 and 16 of the Wildlife and Countryside Act 1981

Guidelines for the completion of an application to release an invertebrate biological control agent in England^{1,2}

All required parts of the form must be completed.

- Part 1. Information on the applicant (A) and purpose of the application and use (B)
- Part 2. Information on the invertebrate biological control agent: identity, specific characteristics, origin and distribution (A), and product information (B)
- Part 3. Information relating to intentional release of a non-indigenous IBCA: biology and ecology of the IBCA (A) and an assessment of risks and benefits of the release (B)
- Part 4. Information on where to send the application (A) and conditions (B)
- Part 5. Appendices

Where application for renewal of a previously issued licence is sought, applicants must state whether release under the previous licence led to any new information becoming known, and whether any new information has been published about the organism since the previous application. If any new information affects the previous risk assessment this must be discussed in section 3.3 and a revised risk assessment provided. Additional relevant data and/or information should be provided as appendices.

Submitting an application and further information:

All applications and queries should be directed to:

Sarah Hugo

Food and Environment Research Agency

Sand Hutton

York YO41 1LZ, UK

Tel: + 44 (0) 1904 462223

Fax: + 44 (0) 1904 462250

Email: sarah.hugo@fera.gsi.gov.uk or bio-control.licensing@defra.gsi.gov.uk

Further information is available at: <http://www.defra.gov.uk/fera/nonnativebiocontrol>

¹These guidelines are largely based on Bigler, F., Bale, J.S., Cock, M.J.W., Dreyer, H., Greatrex, R., Kuhlmann, U., Loomans, A.J.M. and van Lenteren, J.C., 2005. Guidelines on information requirements for import and release of invertebrate biological control agents in European countries. *Biocontrol News and Information*, **26**: 115N-123N and redrafted during REBECA workshop discussions in 2005-2007.

² This application form and guidance was developed by the EU-funded 'REBECA' project (work package on microbial biological control agents). Key authors: A.J.M. Loomans, F. Bigler, G. Sterk and J.S. Bale. For all correspondence contact: a.j.m.loomans@minlnv.nl.

Information to be submitted by the applicant

Part 1. Application information

1A: Information on the applicant

Provide information (including contact details) on:

1.1 Who will apply for the licence: details of the person / company's seeking the licence.

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

1B: Purpose of application and use

1.3 Information on the application

- Indicate whether this is a first application or a renewal of a previous application. In the case of a renewal, include a dossier reference number and expiry date and highlight any changes introduced since the first application.
- Is the organism on the EPPO 'Positive List of IBCAs'³?
- Has an application for this organism been submitted elsewhere in Europe, or has the organism or a product containing the organism been registered elsewhere in Europe? Specify in what country and contact details, when the application was submitted and the outcome.
- Is there a relation with other applications currently submitted or previously licensed with other IBCAs or beneficial organism(s) in the same product?
- For what period is the licence requested?

1.4 Purpose of use

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

- Indicate whether the application is made for (i) import for research and/or (mass) rearing or (ii) direct release⁴. Indicate whether a release is intended in the country of application or not;
- When releases are intended, indicate whether the applications are for trial purposes or for full field releases, in commercial and/or classical programmes;
- Type of biological control programme⁵: classical biological control (CBC), augmentative (inundative) biological control (IBC), weed biocontrol;
- For direct release in field trials or for commercial release, indicate whether permanent establishment is intended (classical release) or not (augmentative release);
- Provide details of the receiving environment into which the organism will be release, e.g. protected, semi-protected glasshouse, open field, natural environment.
- State the likely numbers and locations of proposed release sites in England. If a defined area is not specified but release is likely to be widespread (e.g. where commercial glasshouses are located) please state this.
- The presence of any National Parks, Sites of Special Scientific Interest (SSSIs), actual or proposed Special Protection Areas, Ramsar sites, Special Areas of Conservation or Areas of Outstanding Natural Beauty in England which are either close to the proposed release sites(s) or are likely to be affected by the release should be stated clearly. Advice on the locations of these designated sites and for details of Red Data Book species may be obtained from the appropriate statutory nature conservation bodies.

3 EPPO (2002). List of biological control agents widely used in the EPPO region. EPPO Standard PM6/3(2). EPPO Bulletin 32: 447–461. See full REBECA WP 5 report.

4 Release: intentional liberation of an IBCA into an ecosystem [see ISPM No. 3, 1996].

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

1.5 Facilities and procedures

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

- Address (physical), postal code, location (city);
- For imported material, provide details of labelling, packaging and storage during transit;
- Facility: describe the types of facilities used (greenhouses, laboratories, climate rooms or cabinets);
- Levels of containment: do you have a permit to work with quarantine organisms under the provisions of Directive EC/95/44⁶? If not, justify why the levels of containment proposed for transport, rearing or research are appropriate to avoid escape and spread; where feasible, a contingency plan to prevent undesired environmental effects should be provided.
- Quality control management system: give a description of the measures, methods and intervals to ensure quality and purity of the IBCA (species/strain), and methods for periodic control of purity and identity of mass-rearing, including Standard Operating Procedures for:
 - Life stage and numbers (amount) to be imported;
 - Methods and materials to be used for shipping (e.g. sealed container, host mummies, prey to be included, plant material included, etc.);
 - Procedures to eliminate any contaminants of the imported agent that are of concern;
 - Procedures to dispose of used research materials, including shipping materials;
 - A plan for detecting escape and undesired environmental effects;
 - Any other procedures specific to this importation (i.e. not part of standard procedures).
- All releases must take place using disease free stock because pathogens which are carried by the non-native organisms may also infect or adapt to infect native species. The precautions taken to prevent or control outbreaks, such as quarantine procedures, must be described. Reference to any appropriate documentation from relevant authorities with respect to quarantine or pathogen testing and clearance procedures would be useful. Any disease outbreaks within the rearing facilities must be reported.
- Accreditation: is your organisation certified and/or accredited for processes and/or activities (ISOs) as developed by the International Organization for Standardization⁷. Relevant standards include ISO 9001 for 'Quality management' (general procedures) and ISO/IEC 17025 for 'General requirements for competence of test and calibration laboratories'. Provide details of the ISO standard(s) and activities for which you have certification and/or accreditation.

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

- Name(s) of pest(s) to be controlled (order, family, genus, species and author), including weeds;
- Origin of the pest(s)/weeds and the natural occurrence in the area of release;
- Biology of pests: life cycle(s) of pests/weeds released against;
- Crops: damage inflicted on target crops or vegetation; crops or vegetation on which releases will be made.

Part 2. Information about the invertebrate biological control agent

2A Taxonomy and origin

2.1 Identity and ID confirmation

⁶ Commission Directive 95/44/EC of 26 July 1995 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections: see <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0044:EN:HTML>

⁷ For details, see <http://www.iso.org/iso/home.htm>

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

- Order, family, genus, species and author, and, where appropriate, sub-species, strain, or biotype; include common names and synonyms;
- Include the name of micro-organisms directly associated with the IBCA, e.g. identity of the symbiotic bacteria in entomopathogenic nematodes.

2.1.1 ID confirmation: means, methods of ID confirmation and vouchers

- Authority: by which expert or institute has the organism been identified?
- By what method (morphological, molecular): if available, include a letter from a scientific expert stating the identity of the organism;
- Voucher specimens, with identity confirmed, must be placed in a recognized collection facility before the agent is released: include the name and location of institution(s) where voucher specimens will be deposited.
- Where cultures are refreshed, confirmation of identity should be sought at regular intervals and additional vouchers should be deposited accordingly;
- Include the accurate identity of the symbiotic bacteria associated with entomopathogenic nematodes used as an IBCA.

2.2 Characterization of IBCA

Specify life-stages, strains or taxonomic constraints:

- General diagnostic descriptions of all life stages of the IBCA that are relevant for its use in biological control, highlighting details of any taxonomic characteristics and difficulties with the group (e.g. species complexes, cryptic species, poorly studied group);
- Describe specific characteristics of the species/strain(s) (where relevant), such as:
 - o cold-hardiness (winter survival, diapausing abilities);
 - o known pesticide resistance (if yes: what resistance);
 - o information on differences from the parent wild strain.
- Where appropriate, molecular information (e.g. unique micro-satellite markers) used for diagnosis, especially for population identification, species complexes or cryptic species.

2.3 Origin and distribution

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

a) Confirm that it is non-indigenous to Great Britain

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

- geographic area (approximate latitude, longitude and altitude of site);
- description of the original habitat(s) and host(s) from which the collection was made.

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

- the immediate source of the organism (i.e. where it is produced), giving the name and address of the manufacturer, including the location of the production facility;
- any other source from which the culture has been collected or supplied;
- frequency and origin of additional wild stock used to refresh laboratory cultures.

d) Current distribution, including:

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

2B Product Information

2.4 Product information

Briefly describe the intended use and potential benefits that may be derived.

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

For augmentative (inundative) commercial releases, the following information should be supplied:

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

2.5 Product composition

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

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

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

3A Biology and ecology

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

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

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

3B Assessment of risks and benefits

Information presented in this section forms the basis for the ERA. The ERA should address the whole country within which releases will be made, with reference to regional variation that may affect risk where appropriate. Information required in this section is considered essential to an ERA, and can be acquired from published literature, company reports and/or experimentation. Include details of previous risk assessments for the same species (strain/biotype) with outcomes and other relevant information, including the country of application. The submission of available and/or generated data and subsequent assessment of environmental risks follows a tiered approach: information should be acquired and risks assessed according to the hierarchical system proposed by Van Lenteren *et al.*, (2003)⁸ and Van Lenteren *et al.*, (2006)⁹, and further updated in REBECA Work Package 5. When establishment of the IBCA is very unlikely and the organisms released are predicted to die out, the subsequent fields need not be filled in, and no further risk assessments are necessary; when establishment of the IBCA is likely or necessary (e.g. in classical control), host range information is a crucial requirement for risk assessment; dispersal test results are needed when IBCAs are released in open fields and establishment is very unlikely; a summary of known direct and indirect non-target effects should always be given.

3.2 Safety and health effects

Summarize available information on hazards to human, animal and plant health (for example, allergy, skin irritation, disease vectoring etc) by the IBCA, product or any co-formulants and measures taken to limit operator exposure, where necessary.

3.3 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. Summarize the history of previous releases or introductions and the outcome of previous risk assessments, with known consequences, including non-target effects. Where application for renewal of a previously issued licence is sought, applicants must state whether release under the previous licence led to any new information becoming known, and whether any new information has been published about the organism since the previous application. If any new information affects the previous risk assessment this must be discussed and a revised risk assessment must be provided.

3.3.1 Potential for establishment

Indicate any evidence of establishment as a result of previous releases or accidental introductions outside Europe or other IOBC/WPRS countries. Describe conditions (including extremes) affecting the IBCA's survival and reproduction in its current distribution.

Information on physical constraints, such as:

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

⁸van Lenteren, J.C., Babendreier, D., Bigler, F., Burgio, G., Hokkanen, H.M.T., Kuske, S., Loomans, A.J.M., Menzler-Hokkanen, I., van Rijn, P.C.J., Thomas, M.B., Tommasini, M.G. & Zeng, Q.Q. (2003) Environmental risk assessment of exotic natural enemies used in inundative biological control. *BioControl* **48**: 3–38.

⁹van Lenteren, J.C., Bale, J., Bigler, F., Hokkanen, H.M.T. & Loomans, A.J.M. (2006) Assessing risks of releasing exotic biological control agents of arthropod pests. *Annual Review of Entomology* **51**: 609–634.

Information on resource constraints, such as:

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

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

When 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 will be necessary; when outdoor establishment of the IBCA is likely or necessary, host range information must be supplied.

3.3.2 Host range assessment

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

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

3.3.3 Dispersal

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

Direct effects of dispersal are considered for both indigenous and non-indigenous IBCAs where relevant to the direct environment of release. Dispersal 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 is very unlikely.

3.3.4 Additional information on direct and indirect non-target effects

Describe the history of previous releases or accidental introductions, with known consequences, including non-target effects. Indicate any other possible specific non-target effects, such as:

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

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

3.3.5 Summary assessment of the risks of release of the IBA to the environment

Summarise the information presented in all parts of section 3.3 and provide your overall assessment of risks to the environment of the release, based on the evidence you have presented. This should pay particular attention to the specific environment into which it is intended to release the organism, as well as the wider receiving environment.

3.4 Efficacy and benefits of the IBCA and proposed release

Provide relevant information on:

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

Part 4. Post release monitoring and contingency plan

4A: Post release monitoring

4.1 Information on monitoring and control

- State whether it is intended to carry out post-release monitoring – delete yes/no as appropriate.
- If you do not intend to carry out post-release monitoring, explain why this is not considered necessary – provide your rationale for not monitoring, referring to relevant evidence to support your arguments.
- Describe the duration and frequency of post release monitoring that will be undertaken. Where releases are intended to be temporary, explain how long after the release is terminated monitoring will be carried out to assess whether or not the non-native organism has become established in the wider environment to assess the consequences arising, if successful establishment occurs/
- Describe the methods that will be used for tracing the organism and for monitoring its effects: describe the specificity, sensitivity and reliability of the monitoring techniques to identify the organism and to distinguish it from related native species.
- Describe the methods and procedures that will be used to prevent or minimise spread of the organism beyond the site of release: if it is intended to confine the non-native organism in a particular area, for example in glasshouses, describe the methods which will be used to prevent spread, with justification for their efficacy.

4.2 Emergency control measures

Should unexpected dispersal and establishment be detected and there is a risk of damage to the environment occurring, control measures of known efficacy should be implemented immediately. These must be described as requested below:

- Describe emergency control measures in place should unexpected dispersal and establishment be detected
- How effective are the emergency control measures likely to be?
- If the use of pesticides is proposed, please confirm that the pesticide product proposed has approval for this purpose

Part 5. Submission of forms and Signature

5A Submission details

5.1 Check your application for completeness in the following areas:

- Information requirements (dossier)
- References, other literature and overview of information used in preparation of the dossier: include copies of relevant articles, chapters or reports in an appendix to the application documents;
- Identification of applicant;
- Letter from a scientific expert confirming identity of the organism (optional);

- Any additional relevant data or information should be provided in clearly numbered appendices.

5.2 All applications should be directed to:

Sarah Hugo

Food and Environment Research Agency, Sand Hutton, York YO41 1LZ, UK

Tel: + 44 (0) 1904 462223; Fax: + 44 (0) 1904 462250

Email: sarah.hugo@fera.gsi.gov.uk or bio-control.licensing@defra.gsi.gov.uk

5B Agreement

5.3 General safeguards

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

- All appropriate safety procedures should be put in place.
- Any relevant information on adverse effects which might relate to the released IBCA should be reported immediately to the National Competent Authority (The Department for Environment Food and Rural Affairs, Defra).
- Information on sites and dates of supply or release of the IBCA should be made available to Defra if requested.
- Information requirements have been supplied according to the most recent knowledge.
- The conditions made by Defra will be respected.

5.4 Signature details

- Date
- Applicant's name
- Signature

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