

**Guidelines for the completion of an application to release a classical non-native microbial biological control agent (MBCA) in England**

All required parts of the form must be completed.

Part 1. Applicant and product information

Part 2. Initiation

Part 3. Risk assessment

Part 4. Post release monitoring and contingency plan

Part 5. Appendices

Throughout the form, references should be cited in the text and provided in full at the end of the application.

**Submitting an application and further information:**

**Matthew Everatt**

Non-native biological control agent regulation team

Department for Environment, Food and Rural Affairs

York Biotech Campus

Sand Hutton

York

YO41 1LZ
Email: non-nativebiocontrol.licensing@defra.gov.uk



**Information to be submitted by the applicant**

**Part 1. Application information**

First state whether an approval has been sought, or is intended to be sought, from Scotland, Wales or Northern Ireland.

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| **1A: Information on the applicant** |

Provide information on:

* **Who will apply** **for the approval**
	+ Name and affiliation of the person who is seeking the licence.
	+ Address and contact details.
* **Who is the contact person** (if different from the person applying for the licence)
	+ This may be the research manager and/or quarantine officer.

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| **1B: Purpose of the application and use of the MBCA in pest control** |

Provide information on:

* **The application**
* Application type - indicate whether this is a first application or a renewal of a previous application.
* Positive List organism - is the organism on the EPPO ‘Positive List of BCAs’? (<https://www.eppo.int/media/uploaded_images/RESOURCES/eppo_standards/pm6/pm6-03-2020-en.pdf>). If the organism is on the Positive List, state whether the organism is in Appendix 1 (commercially or officially used biological control agents) or Appendix 2 (Classical BCAs successfully established in the EPPO region).
* Relation to previous/other applications - state whether the application relates to another application currently submitted or previously licensed with other MBCAs or beneficial organisms in the same product.
* Applications or registrations in another countries - state whether an application for this organism has been submitted in another country, or if there is a product containing the organism registered in another country. Specify in what country, contact details of the applicant, when the application was submitted and the outcome.
* Existence of an earlier risk assessment - if there is an earlier risk assessment available, provide a link or add as an appendix, and assess the validity of the risk assessment.
* **The purpose of use**
	+ Target species - name the pest/weed species that the MBCA is aimed at.
	+ Receiving environment - provide details of the receiving environment into which the organism will be released e.g., protected, semi-protected glasshouse, open field, natural environment.
	+ Area of release - state the likely number and locations of proposed release sites in England. If a defined area is not known, but release is likely to be widespread (e.g., where commercial glasshouses are located), this should be mentioned.
* **Culturing/research facilities and procedures**

For the research/production facilities and procedures, describe how the risks, and the extent or probability of escape into the wild will be managed*.* This may not be relevant for phytophagous biological control agents, which may be covered by scientific authorisation (formerly licensing) processes if they meet Provisional Quarantine Pest criteria (as set out in Regulation (EU) 2016/2031). Guidance for the scientific authorisation process is here - [Moving specified plants, plant pests, pathogens and soil - GOV.UK (www.gov.uk)](https://www.gov.uk/guidance/moving-prohibited-plants-plant-pests-pathogens-and-soil).

* + Address and postal code - provide the address of the facilities.
	+ Labelling, packaging and storage - for imported material, provide details of labelling, packaging and storage during transit.
	+ Facility - describe the type of facilities used e.g., greenhouses, laboratories, climate rooms or cabinets.
	+ Levels of confinement - describe the levels of confinement proposed for transport, rearing or research to avoid escape and spread of the MBCA e.g., security, filters, drainage etc.
	+ Contingency plan - describe the plan for detecting escape and managing undesired environmental effects.
	+ Quality control management system - give a description of the measures used to ensure the quality and purity of the MBCA (species/strain/biotype etc.), and methods of periodic control of purity and identity of mass rearing, which may include Standard Operating Procedures for:
		- Life stage and amount to be imported
		- Methods and materials used for shipping (e.g., sealed container, hosts included, plant material included etc.)
		- Procedures to avoid, eliminate and/or control any contaminants of the imported agent or other material (e.g., packaging) that are of concern
		- Procedures to dispose of used research materials, including shipping materials
* Standard operating procedures can be included as an appendix, if appropriate
	+ Accreditation - provide details (if any) of the ISO standard(s) and activities for which you (and sub-contractors, if appropriate) have certification and/or accreditation. Relevant standards include ISO 9001 for ‘Quality management’ (<https://www.iso.org/iso-9001-quality-management.html>).
	+ Safety information – Measures in place to ensure the safety of staff e.g., for microbials that cause allergic reactions.

**Part 2. Initiation**

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| **2.1. Identity** |

Provide information on the:

* **Name of the MBCA**
	+ Provide the full scientific name, including its taxonomic position – kingdom, phylum, class, order, family, genus and species (where appropriate, also provide the sub-species, strain or other taxonomic description);
		- If a level below that of species is used, there should be evidence showing a difference in host range, low temperature tolerance etc. that is significant enough to affect its potential economic, environmental and/or social impact
		- Note that the highest taxonomic level that can be applied for is that of species
	+ Indicate the authority, any common names and synonyms.
	+ Highlight any taxonomic uncertainties (e.g., species complexes, cryptic species, whether it is a poorly studied group)
	+ Include the name of any microorganisms directly associated with the MBCA e.g. the identity of any symbiotic microorganisms.
* **ID confirmation**
	+ Provide the authority; the expert or institute that has identified the MBCA and microorganisms. Identification should be confirmed by a recent letter from the expert or institute.
	+ Describe the method (morphological, molecular) by which the MBCA and any other symbiotic microorganisms have been identified.
	+ Voucher specimens, with identity confirmed, must be placed in a recognised collection facility before the MBCA is released, and the name and location of institution(s) where voucher specimens have been/will be deposited should be stated. The date of the deposit should also be stated.
	+ Where cultures are refreshed, confirmation of identity should be sought at regular intervals and additional vouchers should be deposited accordingly. Confirmation of ID is also required at each renewal of a biological control licence.
* **Collection and culture**
	+ If field collected, provide information on the:
		- Location
		- Date collected
		- Geographic area (approximate latitude, longitude and altitude of site)
		- Orginal habitat(s) and host(s) from which the collection was made
		- Method of collection
		- How many different regions/populations make up the culture.
	+ If from a laboratory culture or production facility, provide information on:
		- The original source of the organism, 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
		- The frequency and origin of additional wild stock used to refresh laboratory cultures

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| **2.2. Distribution of the MBCA** |

Provide information on:

* Its current worldwide distribution, ideally in the form of a map, including the habitats (e.g. forest, pasture, glasshouse) and climatic conditions/zones where it is found.
* Its history of introduction (including use as a biological control agent and year of introduction) and spread.
* The countries where the MBCA is naturally found (in the table). For larger countries (e.g. China and the USA), it would be helpful to include the regions in which the MBCA has been recorded.

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| **2.3. Biology of the MBCA** |

Provide information on its:

* **Morphology**
	+ Provide a detailed description of each life stage of the MBCA (Photographs and/or diagrams would be helpful).
* **Life cycle**
	+ Provide a description of the MBCA’s lifecycle on its target hosts, which may include if relevant:
		- Mode of reproduction (e.g. asexual or sexual)
		- Development time for each life stage
		- Transmission
		- Longevity
		- Information on symptom development and expression
		- Overwintering behaviour/the location for each life stage e.g. whether it takes place within the host, on a plant or in the ground

**Part 3: Risk assessment**

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| **3.1. Establishment** |

Provide information on:

* **Geographic distribution of hosts in the UK**
	+ Describe the geographic and habitat distribution of target and non-target hosts in the UK. Depending on the hosts, a map may be appropriate.
	+ Describe the temporal availability of these hosts with respect to the lifecycle of the MBCA in the UK.
* **Alternate hosts and other essential species**
	+ Detail whether the MBCA requires more than one host or other species to complete its lifecycle.
	+ Describe whether all necessary hosts or species are present in the UK and if they are distributed sufficiently near to each other for the MBCA to complete its lifecycle (can link back to “Host distribution”, where appropriate).
* **Temperature tolerance**
	+ Match the climate of the UK with areas of the MBCA’s current distribution, which could include a comparison of mean min/max temperatures, Köppen-Geiger zones or CLIMEX (or other program) modelling.
	+ Detail the temperature biology of the MBCA, including its:
		- Development thresholds
		- Temperature optimums
		- Temperature survival thresholds
		- Sub-lethal effects of temperature (e.g., on reproduction, development etc.)
* **Other abiotic factors**
	+ Provide details of other abiotic factors that may affect the establishment of the MBCA, including those which may affect climate and habitat matching beyond temperature and host distribution, and provide information on physiological limits as for temperature tolerance.
	+ Other abiotic factors may include:
		- Humidity and rainfall
		- pH
		- Salinity
		- Topography
		- Soil characteristics
* **Competition and natural enemies**
	+ Provide details of other organisms that may outcompete, infect, or feed on the MBCA in the UK and this many limit establishment.
* **Other factors**
	+ Provide information on any other factors that may affect the establishment of the MBCA, including:
		- Current management practices (e.g., pesticide programmes)
		- Agronomic factors such as the systems used to grow the crops where the MBCA is intended for use
		- Reproductive strategy and adaptability (e.g., if asexual, there is a greater chance of establishment)
		- Preferred and less preferred habitats, including factors that determine habitat selection

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| **3.2. Host range**  |

Provide information on:

* **Target hosts**
	+ The hosts intended to be suppressed by the MBCA.
* **Host testing (own and others’ work)**
	+ Describe the procedures used to determine the host range (e.g., phylogenetic relatedness and experimentation).
	+ Provide a list of hosts tested, with information on their relatedness to the target host and if they are present in the UK.
	+ Describe the methods used for host-range testing, including:
		- Collection and culturing methods
		- Experimental design (including number of replicates) and test conditions
		- Life-stages tested and quantity of organism
	+ Describe the results from these tests, including the level of infection incurred by the MBCA.
* **Non-target hosts**
	+ This should include those where testing has been done and hosts that the MBCA has been recorded feeding on. Non-target hosts can be split into four categories:
		- Main host = a species that is regularly used as a host in its current habitat
		- Minor host = a species that is irregularly used as a host in its current habitat
		- Incidental host = a species that only becomes infected when in close proximity to other host species that are heavily infected
		- Experimental or potential host = a species that has only been demonstrated to be a host under experimental conditions or that is considered to be a potential host of the MBCA, especially those that may be of particular ecological significance.
* **Non-target host impacts**
	+ Provide information on any negative impact of the MBCA on non-target hosts, including the:
		- Economic impact, including any reduction in yield or quality of commercial goods, and any indirect impacts on trade, as a result of having the MBCA in the UK
		- Environmental impact, including any reduction in the population and quality of non-target hosts growing in the wider environment, and any subsequent impact on ecosystem services
		- Social impact, including the loss of culturally important species, the loss of aesthetic value of species as part of recreational activities, and the loss of jobs. For example, rose rosette virus was originally used as a biological control of the invasive weed *Rosa multiflora* in the USA, but was soon after found to affect several other rose species. Roses are culturally important species in England, and this would therefore fall under social impact.
* **Target crops and environments**
	+ The crops on which the target hosts occur and where the MBCA is intended to be released.

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| **3.3. Spread**  |

Provide information on:

* **Natural spread**
	+ Describe the mode of spread e.g., air borne, water borne etc.
	+ Provide some indication of the rate of spread e.g., in metres or km/year (distance per unit of time) or km2/year (area per unit time).
	+ Indicate if the MBCA could transfer to non-target hosts or habitats.
* **Artificial spread**
	+ Describe the mode of spread, including unintentional spread e.g., with machinery, baggage, packaging, clothing etc. and intentional spread through the release of the MBCA.
	+ Provide some indication of the rate of spread, as previously done for natural spread.
	+ Indicate if the MBCA could transfer to non-target hosts or habitats**.**

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| **3.4. Direct and/or indirect impacts**  |

Provide information on:

* **Hybridization**
	+ Describe any evidence of hybridization of the MBCA with other species, including any testing done (methods and results).
	+ If there is no evidence of hybridization, indicate whether there is any hybridization known from related species (e.g., in the same genus or family).
* **Trophic effects**
	+ Describe any known impact or potential impact of the MBCA on native species communities e.g., apparent competition, disruption of food webs, impact on pollination, conservation and other bioservices.
* **Human and vertebrate animal health effects**
	+ Describe any human and vertebrate animal health effects of the MBCA, product or any co-formulants, such as allergic reactions, biting or being a vector of disease.
* **Habitat modification**
	+ Describe any changes to the environment, including hydrology, nutrient cycling and succession, as a result of the MBCA.
* **Plant health effects and vector capacity**
	+ Describe any plant feeding or other damage. This information is not needed if the target host is a plant.
	+ Identify any plant pathogens that the MBCA can vector.
* **Other impacts**
	+ Describe any other relevant impacts caused by the MBCA that are not covered by the other points in this section.

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| **3.5. Benefits of the MBCA** |

Provide information on the:

* **Efficacy against target hosts**
	+ Describe how the MBCA infects the target (can link back to the lifecycle section).
	+ Describe how voracious the MBCA is e.g., number of targets killed or amount of plants killed in a set time frame.
	+ If any efficacy testing has been done, describe the methods used and results.
* **Economic benefits**
	+ Describe the negative economic effects caused by the target organisms, such as reduction of yield and quality of plants and plant products, and the cost of controlling them with pesticides and other means.
	+ Describe the positive effects the MBCA will have by reducing the population of the target organisms.
* **Environmental benefits**
	+ Describe the negative environmental effects caused by the target organisms, such as competition with and/or predation/parasitisation of pollinators, other beneficial organisms and rare or vulnerable species, or impacts on the physical environment.
	+ Describe the positive effects the MBCA will have by reducing the population of the target organisms, such as the expected reduction in pesticide/herbicide use and associated benefits (human health, effect on biodiversity, resistance to pesticides).
* **Social benefits**
	+ Describe the negative social effects caused by the target organisms, such as reduced cultural value of plants, the loss of aesthetic value of species as part of recreational activities, and the loss of jobs.
	+ Describe the positive effects the MBCA will have by reducing the population of the target organisms.

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| **3.6. Uncertainty** |

Provide information on:

* The degree of uncertainty with respect to:
	+ Establishment (e.g., lack of low temperature studies).
	+ Host range (e.g., untested hosts).
	+ Spread (e.g., little information on spore viability in the absence of a suitable host).
	+ Direct and/or indirect impacts (e.g., no studies on human and animal health effects).
	+ Benefits of the MBCA (e.g., how it will fare in the UK climate).

If the MBCA is not considered to establish, only uncertainties associated with establishment and benefits need to be given.

If the uncertainties are high, note what can be done to reduce the level of uncertainty.

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| **3.7. Conclusion** |

Provide a summary of:

* Establishment
* Host range
* Spread
* Direct and/or indirect impacts
* Benefits of the MBCA
* Provide an overall conclusion
	+ Including the risk of releasing the MBCA into the UK, based on the evidence provided in the application.
	+ Balance the risks against the benefits.

**Part 4: Post release monitoring and control measures**

First state whether post release monitoring and/or control measures are intended to be carried out. Post release monitoring will be most relevant for MBCAs that have not been released in the UK before, especially any species which have not been studied extensively. If post-release monitoring is not intended, explain why this is not considered necessary.

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| **4.1. Monitoring methodology** |

Provide information on:

* 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 and any subsequent effects.
* The methods that will be used for monitoring the organism and its effects.
	+ Describe the specificity, sensitivity and reliability of the monitoring techniques to identify the organism and to distinguish it from related native species.
* The methods that will be used to assess economic, environmental and/or social impacts.
* 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.

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| **4.2. Control measures** |

Should unexpected dispersal and establishment be detected and there is a risk of damage to the economy, environment or society occurring, control measures of known efficacy should be implemented immediately.

Provide information on:

* The emergency control measures in place should unexpected dispersal and establishment be detected.
* The efficacy of the proposed control measures.
* The approval of any pesticides intended for use.

**Reference**

van Lenteren, J.C., Bale, J., Bigler, E., Hokkanen, H. M. T. and Loomans, A. M. (2006) Assessing risks of releasing exotic biological control agents of arthropod pests. Annual Review of Entomology. 51, 609-634.