|  |  |
| --- | --- |
| Date | Reg. No. |
|  |  |

INFORMATION ON APPLICANT

|  |  |  |
| --- | --- | --- |
| Company name or operator name: | Business identity code: | Operator's first language or language used in company |
|  |  |  |
| Street address: | Post code and post office: | Municipality: |
|  |  |  |
| Telephone: | Mobile phone: | Email: |
|  |  |  |
| Name of contact person: | Language: |
|  |  |
| Street address: | Post code and post office: | Municipality: |
|  |  |  |
| Telephone: | Mobile phone: | Email: |
|  |  |  |

OPERATION THAT THE APPLICATION PERTAINS TO AND PURPOSE OF USE OF MACROORGANISM

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| --- |
| **1. Type of operation** |
| [ ]  Import | [ ]  Marketing | [ ]  Use | [ ]  Research |
| Macroorganism that the application pertains to: |
| [ ]  Pollinator | [ ]  Biological control agent |

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| **2. Purpose of use of macroorganism** |
| 2.1Purpose of use of control agent | Target pest, pests or weeds: |
|  |  |
|  | Target plant species: |
|  |  |
|  | Environment of use: |
|  | [ ]  Open field | [ ]  Greenhouse | [ ]  Plastic tunnel |
|  | Scientific name, taxonomy and auctor of target pest: |
|  |  |
|  | Common name of pest: |
|  |  |
|  | Original area of occurrence of pest: |
|  |  |
|  | Biology of target pest: |
|  |  |
|  | Damage inflicted by pest to plant: |
|  |  |

|  |  |
| --- | --- |
| 2.2Purpose of use of pollinator | Target plant species of pollinator: |
|  |
| Environment of use: |
| [ ]  Open field | [ ]  Greenhouse | [ ]  Plastic tunnel |

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| **3. Efficiency of macroorganism and benefits gained by its use**  |
|  |

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| **4. Other applications and registrations**  |
| The application is |
| [ ]  New application | [ ]  Extension of scope of use |
| Has the applicant previously applied for approval for the same organism or equivalent product? |
| [ ]  Yes  | [ ]  No |
| Has approval or registration been applied for elsewhere in the area of operations of the European and Mediterranean Plant Protection Organization? |
| [ ]  Yes | [ ]  No |

INFORMATION ON MACROORGANISM

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| **5. Macroorganism to which the application pertains** |
| Scientific name and taxonomy of macroorganism: |
|  |
| Common names and alternative names in Finnish and English: |
|  |
| Symbiotic bacteria in nematode: |
|  |
| **Species confirmation** |
| Confirmation made by: |  |
| Method used: |  |
| Reference specimen deposited in: |  |
| Is the control agent: | [ ]  predator | [ ]  parasite |

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| **6. Description of macroorganism** |
| Life-stages: |
|  |
| Characteristics of life-stages: |
|  |
| Special characteristics of species and strain: |
|  |

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| **7. Origin and distribution of macroorganism** |
| [ ]  Stock has been collected from the field  | [ ]  Stock has been cultured in laboratory |
| Collection sites: | Origin of parent individuals: |
|  |  |
| Production facility: |
|  |
| Contact information for producer: |
|  |
| Refreshing of laboratory culture with wild stock (frequency, origin of stock, and when was last refreshed): |
|  |
| Date: | Origin of wild stock: |
|  |  |
| Producer: | Supplier: |
|  |  |
| Original area: |
|  |
| Distribution: |
|  |
| Areas to which macroorganism has been introduced or has spread into previously: |
|  |

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| **8. Information on product** |
| Product/trade name: |
|  |
| Producer/supplier: |
|  |
| Life-stages: |
|  |
| Storage: |
|  |
| Method of use of product: |
|  |

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| **9. Product composition** |
| Associated organisms: |
|  |
| Possible contaminants: |
|  |

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| **10. Biology and ecology of macroorganism** |
| Life cycle – generations/year: |
|  |
| Reproduction: |
|  |
| Means of survival: |
|  |
| Means of dispersal: |
|  |
| Climate conditions: |
|  |
| Habitats: |
|  |
| Target organisms: |
|  |
| Natural enemies: |
|  |

|  |  |
| --- | --- |
| Time and place: | Signature and name in print: |
|  |  |

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| **11. Appendices** |
| Appendix1. Risk assessmentAppendix2. Description of operator's risk management regarding use of organism and productAppendix3. Information provided in labelling |

**Application to be submitted to the address: Finnish Food Authority, Plant Health Unit**

 **P.O. Box 200, FI-00027 FINNISH FOOD AUTHORITY, FINLAND**

**INSTRUCTIONS FOR FILLING IN THE FORM**

Pursuant to the Act on protecting plant health (702/2003, amendment 948/2012), a notification or approval application shall be submitted to Finnish Food Authority when macroorganisms are to be used for biological control or pollination; the notification or application shall be submitted before the import, use or marketing of the organism starts.

An approval application must be submitted, if

* the species contained in the product for which approval is applied is not included in [EPPO list of widely used biological control agents (standard PM 6/3)](http://archives.eppo.int/EPPOStandards/biocontrol_web/bio_list.htm) of the European and Mediterranean Plant Protection Organization, or
* the species is not indigenous to Finland

The application is organism-specific, if the control agent or pollinator has not been made into a commercial product, and product-specific, if the organism has been made into a product. With one application approval can only be sought for one macroorganism or product at a time.

The application shall be submitted to Finnish Food Authority no later than three months before the start of marketing, import or use. Finnish Food Authority maintains on its website a list of approved macroorganisms and products and their purposes of use. The approved organisms and products included in the list may be used in Finland commonly for the approved purpose of use. A new notification or approval application is needed for any other purposes of use, such as extending the use of the macroorganism to new crop plants. A new application for an extension of the purpose of use is not needed for new target pests, on the other hand. Changes in the environment of use e.g. from greenhouses to open field also require submittal of a new extension application.

A fee is charged for the submittal of applications, including applications for extension of the purpose of use.

Finnish Food Authority forwards the decision to environmental authorities for information and for any action needed under legislation of invasive alien species 1709/2015.

If it becomes evident or there is cause to suspect that the organism causes a risk to plant health that was not foreseen when the application was submitted, the marketing, use and import of the macroorganisms shall be discontinued and the operator shall inform Finnish Food Authority without delay about the matter. Finnish Food Authority can in this case forbid the marketing, use and import of the macroorganism.

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| **Information on applicant** |

Contact information for applicant

* The applicant can be a company, organisation or a natural person. The business identification code shall be indicated for companies and organisations.

Contact person

* The contact person refers to a natural person who can be contacted by Finnish Food Authority regarding any changes in the use of the macroorganisms or restrictions of use. The contact person shall be indicated, if the contact person is not the indicated applicant.

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| **1. Purpose of operation** |

The application shall indicate whether it pertains to the import, use or marketing of the product, and whether the macroorganism is to be used for biological control or pollination. Purpose of use refers to all other forms of use except research purposes. The purpose of use also includes the use of the organisms exclusively in the applicant's own farm.

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| 1. **Purpose of use of macroorganism**
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2.1. Purpose of use of control agent

The application shall indicate the target pest, pests or weeds that the agent is to be used to control.

The application shall indicate the target plant species on which the control agent is to be used. For crop plants, the scientific name as well as the common names in Finnish and English shall be filled in.

The environment of use shall be indicated, i.e. is the organism or product to be used in open fields, plastic tunnels and/or greenhouses.

For the target pest or pests, the scientific name and the taxonomy (class, order, family, genus, species and subspecies incl. alternative names, and the auctor), the common name (in Finnish and English) and the original areas shall be filled in.

‎

The biology of the target pest shall be described.

The damages that the pest inflicts to the crop plant or the crop are also described.

* 1. Purpose of use of pollinators

For macroorganisms used for pollination, the environment of use, i.e. open field or greenhouse, shall be indicated as well as the target plant or plants they are to be used to pollinate. The scientific name or names of the plant species shall be indicated.

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| **3. Benefits gained by use of macroorganism** |

The financial and environmental benefits gained by the use of the macroorganism shall be indicated.

The expected result achieved in the control of the pest or weed shall be described. For pollinators, the form shall indicate how well the pollinator pollinates the target plant.

The financial benefits (for each specific plant) and the positive environmental impact, if any, are to be assessed; for example, the benefits gained by the use of biological control agents in comparison with the control methods used at present.

The efficiency of the macroorganism shall also be described briefly, if efficiency tests have been carried out.

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| **4. Other applications and registrations** |

The form shall indicate if it is a new application or an extension of purpose of use.

If approval has been previously sought for from Finnish Food Authority or in some other EPPO member state for the same organism or an equivalent product, this shall be indicated.

If approval has been previously sought for the organism or product, the country in which the application has been made shall be filled in. Contact information and the date of the application shall also be indicated as well as the result of the review process.

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| **5. Macroorganism to which the application pertains**  |

The scientific name and the taxonomy (class, order, family, genus, species and subspecies), the common name (in Finnish and English), any alternative names, and the auctor of the macroorganism shall be filled in.

The symbiotic bacteria in entomopathogenic nematodes directly associated with the macroorganism shall be specified. Organisms used as nutrition or carriers are asked about later in the form.

The method used for the confirmation of the species shall be indicated (e.g. morphological or molecular method).

The institute or the expert that has made the confirmation shall be indicated, as well as the location where the reference specimen is deposited.

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| **6. Description of macroorganism** |

A general diagnostic description shall be provided of all the life-stages of the macroorganism, which are of significance regarding the use of the organism for biological control or pollination. Any taxonomic special characteristics or difficulties in the confirmation of the species shall be described (species complexes, cryptic species, poorly studied group).

The special characteristics of the species or strain shall be described. Such special characteristics include, for example, cold tolerance (winter survival, diapause), resistance to plant protection products (and the products to which they are resistant), differences between wild stock and commercial stock.

Where appropriate, molecular data shall be provided, such as the microsatellite markers used for the confirmation of species, particularly in the identification of populations, for species complexes and cryptic species.

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| **7. Origin and distribution of macroorganism** |

The application shall indicate, whether the stock to which it pertains has been collected from the field or cultured in the laboratory. For macroorganisms collected from the field, information shall be provided about the collection sites, e.g. the geographic area with coordinates and altitudes, as well as the dates on which the macroorganisms have been collected.

If the stock of macroorganism used in the product to which the application pertains has been cultured in the laboratory or in a production facility, the name and address of the producer as well as the location of the production facility shall be indicated. The application shall indicate how often the laboratory cultures are refreshed with wild stock, where such wild stock originates from and when the culture was last refreshed.

The area of origin of the macroorganism as well as the areas to which it has spread naturally or has been introduced by man either intentionally or accidentally shall be indicated.

The areas to which the organism has spread or has been previously introduced shall be filled in.

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| **8. Information on product**  |

The trade name of the product shall be indicated, i.e. the name under which the biological control agent or the pollinator product is marketed.

The producer and/or supplier of the product shall be indicated.

The life-stages of the macroorganism that are contained in the product shall be indicated.

Storage information shall be provided for the product (temperature, humidity, shelf life).

The information provided in the labelling shall be presented in an Appendix to the approval application.

The method of use of the product refers to the frequency of release and the dosage of the product. It shall be indicated, if the product is to be used for classical or augmentative biological control, and what the frequency of release and the dosage of the product are. Classical biological control is designed to establish the macroorganism. In augmentative control the actual macroorganism that is released or the offspring of that stock carries out the control action and the objective is not to establish the macroorganism.

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| **9. Product composition** |

Product composition refers to the other organisms associated with the macroorganism, i.e. the organic co-formulants, such as useful microbes, nutrition (plant materials, live prey organisms and other nutrients) and the carrier.

Any contaminants, such as hyperparasites of the macroorganism, shall be indicated. The prevalence and significance of contaminations shall also be described.

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| **10. Biology and ecology of macroorganism** |

A description shall be provided of the life cycle of the macroorganism; for example, how many generations does it produce in one year.

The reproduction process of the species shall be described (sexual or asexual reproduction, method of nutrition or parasitism, developmental time, reproductive capacity, lifespan).

The means of survival of the species shall be described (diapause, dormancy or migration) as well as its means of dispersal (ability to fly, migratory behaviour).

The climatic conditions prevailing in the original area are described; the optimum climatic conditions.

The environments to which the species has adapted or in which it has established itself as a result of intentional or accidental introduction shall be indicated (pastures, forests, bushes) and the factors influencing the choice of the habitat shall be described.

Any other target organisms shall be listed apart from those, which are to be controlled or pollinated with the macroorganisms.

The natural enemies of the macroorganisms shall also be indicated, including pathogens.

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| **11. Appendices** |

**Appendix 1:** Risk assessment

Instructions for risk assessment are provided in EPPO's standard PM 6/2.

*1.1. Safety and health effects*

The assessment of the risks caused by the use of macroorganisms comprises an assessment of the hazards that the organism and the product cause to plant health (e.g. does the organism act as a vector for plant diseases) and to the health of humans and animals (allergy, skin irritation).

*1.2. Environmental risk assessment*

*1.2.1. Establishment*

The applicant shall indicate if the macroorganism has established itself somewhere in the northern zone as a result of use or accidental dispersal.

The conditions shall be described, which affect the survival and reproduction of the macroorganism in the current area of distribution (including extreme conditions).

An assessment shall be presented of whether the organism is capable of establishing itself outdoors in Finland.

The physical constraints shall be indicated, such as the similarity of climate or differences between the current area of distribution and the intended area of use (temperature, altitude, humidity, daylight hours).

A description shall be provided of the ability of the macroorganism to survive and reproduce in conditions outside the normal range, the temperature thresholds for development and survival and the diapause or overwintering ability.

Any other physiological or behavioural mechanisms for survival in extreme conditions shall be indicated.

Information shall be provided about resource constraints, such as availability and utilisation of suitable hosts (target and non-target organisms) with respect to short-term and long-term survival. The availability of suitable habitats and plant nutrition in the area where the organism is to be used shall also be described.

If the organism is not assumed capable of outdoor establishment in Finland, only the above information needs to be provided.

If the organism is capable of outdoor establishment, the following fields shall also be filled in:

*1.2.2. Host species*

A list shall be provided of hosts other than the target pests, and the potential of the macroorganism to use these hosts on wild or farmed plants shall be described.

The method used for the identification of the host range shall be described (e.g. phylogenetic relationship, testing).

The direct effects of the macroorganism on the host plants of the target pest and on other plants shall be described.

*1.2.3. Dispersal*

The application shall present the direct effects of a mass release of the macroorganism in an open field or on non-target hosts and habitats around the field. This information is not required of macroorganisms released in greenhouses, but only of macroorganisms used in tunnel farming and open fields. A large number of macroorganisms can be dispersed in connection with mass release to a wider area in the environment before the populations die out, and for this reason the effects of dispersal shall be assessed.

*1.2.4. Summary of direct and indirect non-target effects*

The consequences of previous use or accidental dispersal shall be described, including effects on non-target organisms. These include displacement of original natural enemy species or competition with them in the intended area of release, as well as other constraints caused by the macroorganism to the prevalence of natural species (e.g. dispersal of pathogens).

Information shall be provided about the prevalence of natural enemies (including pathogens), which may affect the establishment of the macroorganism.

The methods used in risk assessment shall be opened and the person or organisation that has carried out the risk assessment shall be indicated.

**Appendix 2**: Description of the operator's risk management

The second part of risk assessment shall describe the operator's ability to manage the risks associated with the use of the product, providing an as accurate description of risk management as possible.

**Appendix 3**: The information provided in labelling and the producer's instructions for the use of the product.