Annex 9 to the Ministerial Decree 89/2004. (V. 15.) FVM

Requirements for the data to be submitted for the authorization of products, safeners, synergists, co-formulants, adjuvants, equipment and materials used for plant protection purposes and macro-organisms of plant protection effect not qualified as plant protection products

PART A

Requirements for the data to be submitted for the authorization of products, safeners, synergists, co-formulants, adjuvants of plant protection effect not qualified as plant protection products

1. General data concerning the product

1.1 Applicant (name, address, etc.)
1.2 Manufacturer of the formulation and the active substance(s) (name, address, etc. including premises)
1.3 Trade name or proposed trade name, and manufacturer's development code number for the formulation, if appropriate
1.4 Detailed qualitative information on the composition of the formulation (active substance(s). impurities, additives, inert components, etc.); active substance content with tolerance level (in g/kg or g/l)
1.5 Physical state and nature of the formulation (emulsifiable concentrate, wettable powder, solution, etc.)
1.6 Function

2. Physical, chemical and technical properties of the formulation

2.1 Appearance (colour and odour)
2.2 Risk of explosion and oxidizing properties
2.3 Flash point and other indications of flammability or spontaneous ignition
2.4 Acidic/alkaline chemical reaction and pH value (1% concentration in water)
2.5 Viscosity, surface tension
2.6 Relative density
2.7 Corrosiveness
2.8 Storage stability - stability and shelf-life; effects of light, temperature and humidity on technical characteristics of the plant protection product
2.8.1 for solid formulations: at high temperature
2.8.2 for liquid formulations: at low temperature, at high temperature

Data on physical and chemical properties necessary for authorization shall be submitted in agreement with the competent authority.

2.9. Physical and chemical compatibility with other products the authorisation for use of which is proposed
2.10 Wetting, adherence and distribution on target plants

3. Data on application

3.1 Field of use (e.g. field, glasshouse, food and feed storage, home garden)
3.2 Effects on pests

3.3 Details of intended use (e.g. types of harmful organisms to be controlled and/or plants or plant products to be protected)
3.4 If necessary, in the light of the test results, any specific agricultural, phytosanitary and/or environmental criteria which are conditions or obstacle to the use of the formulation
3.5 Application rate
3.6 Concentration of active substance in material used (e.g. in the diluted spray, bait or on the treated seed)
3.7 Method of application
3.8 Number and timing of applications and duration of protection
3.9 Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops
3.10 Proposed instructions for use

4. Further information on the product

4.1 Packaging (type, materials, size, etc.)
4.2 Procedures for cleaning application equipment
4.3 Waiting periods (re-entry time, pre-harvest interval), or other precautionary measures to protect humans and animals
4.4 Recommended methods and precautions concerning handling, storage, transport or fire
4.5 Emergency measures in case of accident
4.6 Identity of combustion products relevant to cases of fire
4.7 Procedures for destruction or decontamination of the plant protection product and the packing
4.7.1 Possibility of destruction
4.7.2 Controlled discharge
4.7.3 Controlled incineration
4.7.4 Water purification
4.7.5 Others

5. Analytical methods

5.1. Validated analytical method(s) for testing active substance(s)
5.2. Analytical method(s) including recovery rates and the limits of determinations for pesticide residues

6. Efficacy data

6.1 Results of field trials
6.2 Phytotoxicity to treated plants (including different crops), or to treated plant products
6.3 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or treated plant parts used for propagating purposes (e.g. seeds, twigs, cuttings)
6.4 Summary and evaluation of data under points 6.1 to 6.3

7. Toxicological data

7.1 Acute toxicity
7.1.1 Oral

7.1.2 Dermal
7.1.3 Inhalation
7.1.4 Skin and eye irritation
7.1.5 Skin sensitisation
7.1.6 Where appropriate, acute dermal toxicity, skin and eye irritation for combinations of plant protection products for which authorization for use is sought in such combinations
7.2. Available toxicological data relating to additives and co-formulants

8. Residues in or on treated plants, plant products, food and feed

8.1. Metabolism, distribution and expression of residues in plants or livestock
8.2. Residue analytical studies, if relevant

9. Ecotoxicological studies

9.1 Toxicity to aquatic organisms
9.1.1. Acute toxicity to rainbow trout or zebrafish
9.1.2. Acute toxicity to *Daphnia magna*
9.1.3. Growth inhibition to algae
9.1.4. Other aquatic toxicity studies
9.2 Toxicity to terrestrial organisms
9.2.1. Acute oral and contact toxicity to honey-bees
9.2.2. Toxicity data concerning other terrestrial organisms, review of literature
9.3 Data on the environmental fate and behaviour of the active substance
9.4 Risk assessment

10. Further information

10.1 Information on authorization in other countries
10.2 Information on established maximum residue levels (MLR) in other countries
10.3 Proposals including justification for the classification and labelling
-Hazard symbol(s)
-Indications to hazard
-Risk (R) phrases
-Safety (S) phrases
10.4 Proposals for risk and safety phrases
10.5 Specimens of proposed packaging
10.6 Safety data sheet of the product

PART B

Requirements for the data to be submitted for the authorization of equipment used for plant protection purposes

1. Identity of the equipment used for plant protection purposes

1.1 Applicant (name, address, etc.)
1.2 Manufacturer of the equipment and the active substance(s) (name, address, etc. including premises)

1.3 Trade name or proposed trade name
1.4 Function (attractant, repellent, etc.)

2. Data on application

2.1 Field of use (e.g. field, glasshouse, food and feed storage, home garden)
2.2 If necessary, in the light of the test results, any specific agricultural, phytosanitary and/or environmental criteria which are conditions or obstacle to the use of the formulation
2.3 Materials used for the operation of the equipment
2.4 Method of application
2.5 Proposed instructions for use
2.6 Qualification referring to use
2.2 Detailed technical description of the equipment used for plant protection purposes

PART C

Requirements for the data to be submitted for the authorization of formulations containing macro-organisms

1. General data on the formulation containing macro-organisms

1.1. Trade name of the product
1.2. Use category
1.3. Concentration of the macro-organisms
1.4. Formulation
1.5. Name, address, premises, etc. of the manufacturer of the macro-organism and the formulations
1.6. Name and address of the distributor
1.7. Data of the packaging unit
1.7.1. filling weight and volume
1.7.2. sizes
1.7.3. materials used for packaging
1.7.4. mode of sealing
1.7.5. test results certifying reliability of packaging
1.8. Risk category used in international transport
1.9. Mode of storage
1.10. Shelf-life
1.11. If the formulation is patent protected in Hungary, date of patent registration

2. Biological properties

2.1. Scientific (Latin and Hungarian) names, indicating the strain, of the macro-organism
2.2. Mode of the identification and description of the macro-organism (morphology)
2.3. Origin and natural occurrence of the macro-organism (geographical region, host, etc.)
2.3. Range of hosts and prays
2.4. Code/strain number
2.5. Mode of mass reproduction of the macro-organism (natural collection, availability of mass culturing)
2.6. Geographical distribution of the macro-organism

2.7. Mode of spreading of the released macro-organism
2.8. Biological description of life cycle and host specificity
2.9. Natural enemies (hyperpredator, hyperparasite)
2.10. Function of the macro-organism
2.11. Its role in spreading other pests
2.12. Composition of co-formulant
2.13. Moisture content
2.14. Cold and heat resistance/tolerance
2.15. Packing unit
2.16. Light tolerance
2.17. Storage stability (temperature, humidity, duration)
2.18. Other indication of fire safety, as stated on the packaging
2.19. Short description of the production
2.20. Description of quality control

3. Biological activity of the product containing the macro-organism

3.1. Mode of action
3.2. Mode of biological activity
3.3. Duration of the biological control effect of the macro-organism
3.4. Biological efficiency on the target organism
3.5. Optimal environmental conditions of the biological effect, developmental stage of the host animal
3.6. Data on resistance and tolerance (climatic and other environmental parameters, etc.)
3.7. Recommendation for use
3.7.1. mode of use (mode and place of application, light sensitivity, pesticide sensitivity)
3.7.2. field of use envisaged (greenhouse, field, indoor, etc.)
3.7.3. crop (e.g. tomatoes, etc)
3.7.4. target pest(s)
3.7.5. dose (area m^2 or plant)
3.7.6. number of releases on the treated area
3.7.7. date of treatment, number of replicates
3.7.8. efficacy guaranteed by the distributor
3.7.9. suitability for using in integrated production
3.8. Mode and parameters of application
3.9. Proposal for combined use with other macro-organisms
3.10. Waste management and decontamination of packaging

4. Toxicological data of the macro-organisms concerning pesticides and other chemicals and micro-organisms to (IOBC risk scale 1-4)

5. Environmental data of the macro-organism

5.1. Effects on human and animal health
5.1.1. Irritation (skin, eye)
5.1.2. Toxicity
5.1.3. Allergenic effect
5.1.4. Infectiveness
5.1.5. Carcinogenicity
5.1.6. Teratogenicity

5.1.7. Food contamination
5.2. Effects on non-target organisms
5.2.1. Mobility, spreading capacity of the macro-organism
5.2.2. Effects on vertebrates
5.1.2.1. Warm-blooded animals
5.1.2.2. Cold-blooded animals
5.2.3. Effects on invertebrates
5.2.3.1. Arthropods (predators, parasitoids, pollinating insects and other species)
5.2.3.2. Other invertebrates (earthworms, etc.)
5.2.4. Effects on plants
5.2.5. Effects on micro-organisms
5.3. Other environmental effects
5.3.1. Migration capacity of the macro-organism
5.3.1.1. temporary
5.3.1.2. permanent
5.3.2. Effects on the balance of ecosystem
5.3.2.1. temporary
5.3.2.2. permanent
5.4. Effects on groundwater
5.5. Effects on soil fauna
5.6. Capacity of the macro-organism to transfer genetic material

6. Food-hygienic aspects of the use of products containing macro-organisms

6.1. Occurrence of macro-organisms and their non-viable residues on the crop at harvest

7. Other information

7.1. Information on the authorization and eventual restrictions of the product in other countries
7.2. Other proposals, data

8. Annexes required

8.1. Draft label, in case of small packing unit, draft label for the small packaging
8.2. Proposal for test methods of official quality controls (quantitative: population number, body size, etc.; methods for quality evaluation: viability, release rate, mobility, fecundity, longevity, activity, etc.)
8.3. References and publications
8.4. Certificate for dispatching the samples necessary for authorization.