COMMISSION DIRECTIVE 2006/50/EC

of 29 May 2006

amending Annexes IVA and IVB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [1], and in particular Article 29 thereof,

Whereas:

(1) Annexes IVA and IVB to Directive 98/8/EC set out the requirements for the dossiers to be submitted by applicants for, respectively, inclusion of an active substance consisting of micro-organisms including viruses and fungi in Annex I or IA to that Directive, and authorisation of a biocidal product based on preparations of such micro-organisms including viruses and fungi.

(2) It is necessary to adapt Annexes IVA and IVB to Directive 98/8/EC to technical progress and to developments in related legislation, in particular Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [2] and Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [3], in order to provide a better basis for carrying out the risk assessments for micro-organisms and the biocidal products containing them. In addition, there have been scientific and technical developments within the field of microbiology and biotechnology. Providing for a similar structure of the data requirements in the framework of Directive 98/8/EC with those of Directive 91/414/EEC will facilitate the work of applicants submitting dossiers within both legal frameworks and the work of the Member States authorities evaluating such dossiers. It is therefore appropriate to update the data requirements for micro-organisms including viruses and fungi currently contained in Directive 98/8/EC and to align them as far as possible with those established in the framework of Directive 91/414/EEC.

(3) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes IVA and IVB to Directive 98/8/EC are replaced by the text set out in the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 2008 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 May 2006.

For the Commission
Stavros DIMAS
Member of the Commission

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[1] OJ L 123, 24.4.1998, p. 1. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).
[2] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/39/EC (OJ L 104, 13.4.2006, p. 30).
[3] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).

ANNEX

'ANNEX IVA

DATA SET FOR ACTIVE SUBSTANCES

MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI

1. For the purposes of this Annex, the term micro-organisms shall be understood as including also viruses and fungi. Dossiers on active micro-organisms shall address at least all the points listed under "Dossier requirements" below. For all micro-organisms subject to an application for inclusion into Annex I or IA, all available relevant knowledge and information in literature must be provided. The information related to the identification and characterisation of a micro-organism including mode of action is particularly important and must be entered in sections I to IV and provides the basis for an assessment of potential impacts on human health and of environmental effects.

2. Where information is not necessary owing to the nature of the micro-organism Article 8(5) shall apply.

3. A dossier within the meaning of Article 11(1) shall be prepared on strain level of the micro-organism unless information is submitted that shows that the species is known to be sufficiently homogeneous regarding all characteristics, or the applicant provides other arguments in accordance with Article 8(5).

4. Where the micro-organism has been genetically modified within the meaning of Article 2(2) of Directive 2001/18/EC, a copy of the evaluation of the data concerning the assessment of the risks to the environment as established in Article 4(2) of that Directive, shall also be submitted.

5. If the biocidal product action is known to be partly or entirely due to the effect of a toxin/metabolite, or if significant residues of toxins/metabolites are to be expected not related to the effect of the active micro-organism, a dossier for the toxin/metabolite shall be submitted in accordance with the requirements of Annexes IIA and, where specified, the relevant parts of Annex IIIA.

Dossier requirements

SECTIONS:

I. Identity of the micro-organism

II. Biological properties of the micro-organism

III. Further information on the micro-organism

IV. Analytical methods

V. Effects on human health

VI. Residues in or on treated materials, food and feed

VII. Fate and behaviour in the environment

VIII. Effects on non-target organisms

IX. Classification and labelling

X. Summary and evaluation of sections I to IX including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

I. IDENTITY OF THE MICRO-ORGANISM

1.1. Applicant

1.2. Manufacturer

1.3. Name and species description, strain characterisation

1.3.1. Common name of the micro-organism (including alternative and superseded names)

1.3.2. Taxonomic name and strain indicating whether it is a stock variant, a mutant strain or a genetically modified organism (GMO); for viruses, taxonomic designation of the agent, serotype, strain or mutant

1.3.3. Collection and culture reference number where the culture is deposited

1.3.4. Methods, procedures and criteria used to establish the presence and identity of the micro-organism (e.g. morphology, biochemistry, serology, etc.)

1.4. Specification of the material used for manufacturing of formulated products

1.4.1. Content of the micro-organism

1.4.2. Identity and content of impurities, additives, contaminating micro-organisms

1.4.3. Analytical profile of batches

II. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM

2.1. History of the micro-organism and its uses. Natural occurrence and geographical distribution

2.1.1. Historical background

2.1.2. Origin and natural occurrence

2.2. Information on target organism(s)

2.2.1. Description of the target organism(s)

2.2.2. Mode of action

2.3. Host specificity range and effects on species other than the target organism

2.4. Development stages/life cycle of the micro-organism

2.5. Infectiveness, dispersal and colonisation ability

2.6. Relationships to known plant or animal or human pathogens

2.7. Genetic stability and factors affecting it

2.8. Information on the production of metabolites (especially toxins)

2.9. Antibiotics and other anti-microbial agents

2.10. Robustness to environmental factors

2.11. Effects on materials, substances and products

III. FURTHER INFORMATION ON THE MICRO-ORGANISM

3.1. Function

3.2. Field of use envisaged

3.3. Product type(s) and category of users for which the micro-organism should be listed in Annex I, IA or IB

3.4. Method of production and quality control

3.5. Information on the occurrence or possible occurrence of the development of resistance of the target organism(s)

3.6. Methods to prevent loss of virulence of seed stock of the micro-organism

3.7. Recommended methods and precautions concerning handling, storage, transport or fire

3.8. Procedures for destruction or decontamination

3.9. Measures in case of an accident

3.10. Procedures for waste management

3.11. Monitoring plan to be used for the active micro-organism including handling, storage, transport and use

IV. ANALYTICAL METHODS

4.1. Methods for the analysis of the micro-organism as manufactured

4.2. Methods to determine and quantify residues (viable or non-viable)

V. EFFECTS ON HUMAN HEALTH

TIER I

5.1. Basic information

5.1.1. Medical data

5.1.2. Medical surveillance on manufacturing plant personnel

5.1.3. Sensitisation/allergenicity observations

5.1.4. Direct observation, e.g. clinical cases

5.2. Basic studies

5.2.1. Sensitisation

5.2.2. Acute toxicity, pathogenicity, and infectiveness

5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness

5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness

5.2.2.3. Intraperitoneal/subcutaneous single dose

5.2.3. *In vitro* genotoxicity testing

5.2.4. Cell culture study

5.2.5. Information on short-term toxicity and pathogenicity

5.2.5.1. Health effects after repeated inhalatory exposure

5.2.6. Proposed treatment: first aid measures, medical treatment

5.2.7. Any pathogenicity and infectiveness to humans and other mammals under conditions of immunosuppression

END OF TIER I

TIER II

5.3. Specific toxicity, pathogenicity and infectiveness studies

5.4. Genotoxicity — *In vivo* studies in somatic cells

5.5. Genotoxicity — *In vivo* studies in germ cells

END OF TIER II

5.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation

VI. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED

6.1. Persistence and likelihood of multiplication in or on treated materials, feedingstuffs or foodstuffs

6.2. Further information required

6.2.1. Non-viable residues

6.2.2. Viable residues

6.3. Summary and evaluation of residues in or on treated materials, food and feed

VII. FATE AND BEHAVIOUR IN THE ENVIRONMENT

7.1. Persistence and multiplication

7.1.1. Soil

7.1.2. Water

7.1.3. Air

7.2. Mobility

7.3. Summary and evaluation of fate and behaviour in the environment

VIII. EFFECTS ON NON-TARGET ORGANISMS

8.1. Effects on birds

8.2. Effects on aquatic organisms

8.2.1. Effects on fish

8.2.2. Effects on freshwater invertebrates

8.2.3. Effects on algae growth

8.2.4. Effects on plants other than algae

8.3. Effects on bees

8.4. Effects on arthropods other than bees

8.5. Effects on earthworms

8.6. Effects on soil micro-organisms

8.7. Further studies

8.7.1. Terrestrial plants

8.7.2. Mammals

8.7.3. Other relevant species and processes

8.8. Summary and evaluation of effects on non-target organisms

IX. CLASSIFICATION AND LABELLING

The dossier shall be accompanied by a reasoned proposals for allocating an active substance which is a micro-organism to one of the risk groups specified in Article 2 of Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work [1] together with indications on the need for products to carry the biohazard sign specified in Annex II to that Directive.

X. SUMMARY AND EVALUATION OF SECTIONS I TO IX INCLUDING CONCLUSIONS OF THE RISK ASSESSMENT AND RECOMMENDATIONS

[1] OJ L 262, 17.10.2000, p. 21.

ANNEX IVB

DATA SET FOR BIOCIDAL PRODUCTS

MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI

1. For the purposes of this Annex, the term micro-organisms shall be understood as including also viruses and fungi. This Annex provides data requirements for the authorisation of a biocidal product based on preparations of micro-organisms. For all biocidal products based on preparations containing micro-organisms that are subject to application, all available relevant knowledge and information in literature should be provided. The information related to the identification and characterisation of all components in a biocidal product is particularly important and must be entered in sections I to IV and provides the basis for an assessment of possible impacts on human health and the environment.

2. Where, information is not necessary owing to the nature of the biocidal product Article 8(5) shall apply.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations [1] shall be used wherever possible to minimise animal testing.

4. Where testing is done, a detailed description (specification) of the material used and its impurities, according to the provisions of Section II, must be provided. Where necessary, data as established in Annexes IIB, IIIB shall be required for all the toxicologically/eco-toxicologically relevant chemical components of the biocidal product, in particular if the components are substances of concern as defined in Article 2(1)(e).

5. In cases where a new preparation is to be dealt with, extrapolation from Annex IVA, could be acceptable, provided that all the possible effects of the components, especially on pathogenicity and infectiveness, are evaluated.

Dossier requirements

SECTIONS:

I. Identity of the biocidal product

II. Physical, chemical and technical properties of the biocidal product

III. Data on application

IV. Further information on the biocidal product

V. Analytical methods

VI. Efficacy data

VII. Effects on human health

VIII. Residues in or on treated materials, food and feed

IX. Fate and behaviour in the environment

X. Effects on non-target organisms

XI. Classification, packaging and labelling of the biocidal product

XII. Summary and evaluation of sections I to XI including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

[1] OJ L 200, 30.7.1999, p. 1. Directive as last amended by Commission Directive 2006/8/EC (OJ L 19, 24.1.2006, p. 12).

I. IDENTITY OF THE BIOCIDAL PRODUCTS

1.1. Applicant

1.2. Manufacturer of the biocidal product and the micro-organism(s)

1.3. Trade name or proposed trade name, and manufacturer's development code number of the biocidal product

1.4. Detailed quantitative and qualitative information on the composition of the biocidal product

1.5. Physical state and nature of the biocidal product

1.6. Function

II. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT

2.1. Appearance (colour and odour)

2.2. Storage stability and shelf-life

2.2.1. Effects of light, temperature and humidity on technical characteristics of the biocidal product

2.2.2. Other factors affecting stability

2.3. Explosivity and oxidising properties

2.4. Flash point and other indications of flammability or spontaneous ignition

2.5. Acidity, alkalinity and pH value

2.6. Viscosity and surface tension

2.7. Technical characteristics of the biocidal product

2.7.1. Wettability

2.7.2. Persistent foaming

2.7.3. Suspensibility and suspension stability

2.7.4. Dry sieve test and wet sieve test

2.7.5. Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)

2.7.6. Emulsifiability, re-emulsifiability, emulsion stability

2.7.7. Flowability, pourability (rinsability) and dustability

2.8. Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered

2.8.1. Physical compatibility

2.8.2. Chemical compatibility

2.8.3. Biological compatibility

2.9. Summary and evaluation of physical, chemical and technical properties of the biocidal product

III. DATA ON APPLICATION

3.1. Field of use envisaged

3.2. Mode of action

3.3. Details of intended use

3.4. Application rate

3.5. Content of micro-organism in material used (e.g. in the application device or bait)

3.6. Method of application

3.7. Number and timing of applications and duration of protection

3.8. Necessary waiting periods or other precautions to avoid adverse effects to human and animal health and the environment

3.9. Proposed instructions for use

3.10. Category of users

3.11. Information on the possible occurrence of the development of resistance

3.12. Effects on the materials or products treated with the biocidal product

IV. FURTHER INFORMATION ON THE BIOCIDAL PRODUCT

4.1. Packaging and compatibility of the biocidal product with proposed packaging materials

4.2. Procedures for cleaning application equipment

4.3. Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment

4.4. Recommended methods and precautions concerning: handling, storage, transport or fire

4.5. Measures in the case of an accident

4.6. Procedures for destruction or decontamination of the biocidal product and its packaging

4.6.1. Controlled incineration

4.6.2. Others

4.7. Monitoring plan to be used for the active micro-organism and other micro-organism(s) contained in the biocidal product including handling, storage, transport and use

V. ANALYTICAL METHODS

5.1. Methods for the analysis of the biocidal product

5.2. Methods to determine and quantify residues

VI. EFFICACY DATA

VII. EFFECTS ON HUMAN HEALTH

7.1. Basic acute toxicity studies

7.1.1. Acute oral toxicity

7.1.2. Acute inhalation toxicity

7.1.3. Acute percutaneous toxicity

7.2. Additional acute toxicity studies

7.2.1. Skin irritation

7.2.2. Eye irritation

7.2.3. Skin sensitisation

7.3. Data on exposure

7.4. Available toxicological data relating to non-active substances

7.5. Supplementary studies for combinations of biocidal products

7.6. Summary and evaluation of effects on human health

VIII. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED

IX. FATE AND BEHAVIOUR IN THE ENVIRONMENT

X. EFFECTS ON NON-TARGET ORGANISMS

10.1. Effects on birds

10.2. Effects on aquatic organisms

10.3. Effects on bees

10.4. Effects on arthropods other than bees

10.5. Effects on earthworms

10.6. Effects on soil micro-organisms

10.7. Additional studies on additional species or higher tier studies such as studies on selected non-target organisms

10.7.1. Terrestrial plants

10.7.2. Mammals

10.7.3. Other relevant species and processes

10.8. Summary and evaluation of effects on non-target organisms

XI. CLASSIFICATION, PACKAGING AND LABELLING OF THE BIOCIDAL PRODUCT

As established in Article 20, proposals including justification for the classification and labelling of the biocidal product in accordance with the provisions set in Directive 67/548/EEC and Directive 1999/45/EC must be submitted. The classification comprises of the description of the category/categories of danger and qualifying risk phrases for all dangerous properties. On the basis of the classification, a proposal for labelling including the hazard symbol(s) and indications of danger, risk phrases and safety phrases should be given. The classification and labelling shall be in regard to the chemical substances contained in the biocidal product. If necessary, specimens of proposed packaging shall be submitted to the competent authority of a Member State.

The dossier shall be accompanied by a reasoned proposal for allocation to one of the risk groups specified in Article 2 of Directive 2000/54/EC together with indications on the need for products to carry the biohazard sign specified in Annex II to that Directive.

XII. SUMMARY AND EVALUATION OF SECTIONS I TO XI INCLUDING CONCLUSIONS OF THE RISK ASSESSMENT AND RECOMMENDATIONS'