Regulation on the terms and procedure for placing of biocides on the market

Adopted with Council of Ministers' Decree No. 323/3.12.2004

Promulgated, State Gazette No. 110/17.12.2004 (in force as of 1.01.2007)

Article 1. (1) This Regulation shall determine the terms and procedure for placing of biocides on the market.

(2) This Regulation shall also determine:

1. the form and content of the technical dossier and the documents which the applicant should submit in order to have a permit granted or a registration;

2. the form and content of the permit for placing on the market of an active substance, a biocidal product and of the registration certificate of a low-risk biocidal product;

3. the additional requirements for packaging and labelling of biocides;

4. the terms and procedure for use of the information by a consequent applicant;

5. the content of the registers of permitted active substances, permitted biocidal products and registered low-risk biocidal products;

6. the active substances and basic substances for which the permit referred to in Article 14, Paragraph 1 of the Protection Against the Harmful Impact of Chemical Substances and Preparations Act (PAHICSP) is not issued.

Article 2. A permit for placing on the market shall not be issued for active substances and basic substances listed in Appendix No. 1.

Article 3. Biocidal products may only include an active substance or active substances listed in Appendix No. 1 or in the register of permitted active substances.

Article 4. (1) The name of the active substance shall be given in accordance with Appendix No. 1 to the Regulation on the procedure and method of classification, packaging and labelling of chemical substances and preparations (promulgated, SG No. 5/2003, amended and supplemented, SG No. 66/2004), and when the active substance is not listed in Appendix No. 1, its name shall be given in accordance with Appendix No. 4 to the Regulation on the procedure and method of classification, packaging and labelling of chemical substances and preparations.

(2) Where the active substance is not listed in the appendices referred to in Paragraph 1, its name shall be determined in accordance with ISO or IUPAC.

Article 5. (1) In order to have a permit for placing a biocide on the market issued, the applicant must submit to the Ministry of Health the documents referred to in Article 18, Paragraph 1, item 1 of the PAHICSP.

(2) For a biocidal product containing an active substance which is a chemical substance, the technical dossier referred to in Article 18, Paragraph 1, item 1(b) of the PAHICSP shall be prepared in accordance with Appendix No. 2.

(3) Besides the information referred to in Paragraph 2, additional information pursuant to Appendix No. 3 shall be provided, taking into consideration the type, properties, mode and field of application of the biocidal product.

(4) For a biocidal product containing an active substance which is a micro-organism, including viruses or fungi, the technical dossier referred to in Article 18, Paragraph 1, item 1(b) of the PAHICSP shall be prepared in accordance with Appendix No. 4.

(5) For an active substance which is a chemical substance, the technical dossier referred to in Article 18, Paragraph 1, item 1(c) of the PAHICSP shall be prepared in accordance with Appendix No. 5.

(6) Besides the information referred to in Paragraph 5, additional information pursuant to Appendix No. 6 shall be provided, taking into consideration the type, properties, mode and field of application of the active substance.

(7) For an active substance which is a micro-organism, including viruses or fungi, the technical dossier referred to in Article 18, Paragraph 1, item 1(c) of the PAHICSP shall be prepared in accordance with Appendix No. 7.

Article 6. (1) In order to have a permit for an active substance issued, the applicant shall submit to the Ministry of Health the documents referred to in Article 18, Paragraph 1, item 2 of the PAHICSP.

(2) For an active substance which is a chemical substance, the technical dossier referred to in Article 18, Paragraph 1, item 2(b) of the PAHICSP shall be prepared in accordance with Appendix No. 5.

(3) Besides the information referred to in Paragraph 2, additional information pursuant to Appendix No. 6 shall be provided, taking into consideration the type, properties, mode and field of application of the active substance.

(4) For an active substance which is a micro-organism, including viruses or fungi, the technical dossier referred to in Article 18, Paragraph 1, item 2(b) of the PAHICSP shall be prepared in accordance with Appendix No. 7.

(5) For a biocidal product for whose manufacture the active substance which is a chemical substance is intended, the technical dossier referred to in Article 18, Paragraph 1, item 2(e) of the PAHICSP shall be prepared in accordance with Appendix No. 2.

(6) Besides the information referred to in Paragraph 5, additional information pursuant to Appendix No. 3 shall be provided, taking into consideration the type, properties, mode and field of application of the biocidal product.

(7) For a biocidal product for whose manufacture the active substance which is a micro-organism, including viruses or fungi, is intended, the technical dossier referred to in Article 18, Paragraph 1, item 2(e) of the PAHICSP shall be prepared in accordance with Appendix No. 4.

Article 7. (1) In order to have a registration certificate of a low-risk biocidal product issued, the applicant shall submit to the Ministry of Health the documents and information referred to in Article 19h, Paragraph 1 of the PAHICSP.

(2) The data referred to in Article 19h, Paragraph 1, items 2-10 of the PAHICSP shall be prepared in the form of a technical dossier in accordance with Appendix No. 8 on a paper or electronic carrier.

Article 8. The assessment of technical dossiers shall be carried out in accordance with Appendix No. 9.

Article 9. (1) Technical dossiers shall contain a detailed and full description the studies conducted and of the methods used or a bibliographical reference to those methods.

(2) The evaluation of the effects and properties referred to in Article 17, Paragraph 1, items 2-9 of the PAHICSP shall be carried out on the basis of the information contained in the technical dossiers.

(3) Certain information listed in the requirements to the dossiers may not be submitted where:

1. it is not related to the type of the biocide and its proposed use;

2. it is not technically possible due to the nature of the biocide, its specific properties and other technical reasons;

3. there are scientifically justified reasons related to the biocide.

(4) In the cases referred to in Paragraph 3 the applicant shall submit a written justification, such as reference to the existing frame-formulation, where the applicant holds a declaration for use of information.

Article 10. (1) The tests to determine the physico-chemical, toxicological and ecotoxicological properties of the biocides shall be conducted according to the methods described in Appendix No. 3 to the Regulation on the procedure and method of classification, packaging and labelling of chemical substances and preparations (promulgated, SG No. 5/2003, amended and supplemented, SG No. 66/2004).

(2) Where the appendix referred to in Paragraph 1 does not describe appropriate methods, the tests may be conducted using other internationally recognised methods. In such cases substantiated and complete information on the test method used must be submitted.

Article 11. The tests referred to in Article 10 shall be conducted in accordance with the requirements of the Regulation on the principles, the inspection and the certification of Good laboratory practice (promulgated, SG No. 74/2004) and in keeping with the requirements of Regulation No. 25 on the protection and humane treatment of animals used for experimental purposes (promulgated, SG No. 59/2003).

Article 12. (1) A biocide shall be placed on the market where:

1. a permit has been issued for it in compliance with the provisions of Chapter Four, Section I of the PAHICSP;

2. it has been classified, packaged and labelled in compliance with the provisions of Chapter Two of the PAHICSP

3. it does not fall under the bans or restrictions for trade or use pursuant to the Regulation on dangerous chemical substances and preparations which are subject to banned or restricted marketing and use (promulgated, SG No. 69/2002, amended and supplemented, SG No. 62/2004).

(2) The permit for placing of a biocidal product on the market shall be issued in standard format pursuant to Appendix No. 10.

(3) The permit for placing of an active substance on the market shall be issued in standard format pursuant to Appendix No. 11.

(4) The registration certificate of a low-risk biocidal product shall be issued in standard format pursuant to Appendix No. 12.

Article 13. (1) The Ministry of Health shall keep the documentation related to the issue, amendment or suspension of permits for placing on the market of biocidal products.

(2) The documentation shall be kept for the following periods of time:

1. for documents submitted on paper carrier – 10 years;

2. for electronic document carriers – 20 years.

Article 14. The packaging of biocides shall meet the following additional requirements:

1. the type, shape and/or graphic design shall be so made as to minimise the likelihood of using biocides mistakenly as food, drink or feedingstuff;

2. biocides intended for mass use which may be mistakenly used as food, drink or feedingstuff shall contain components to discourage their consumption.

Article 15. (1) The label of a biocidal product shall contain the following additional information:

1. the identity of every active substance contained in the biocidal product;

2. the concentration of every active substance contained in the biocidal product;

3. the number of the issued permit for placing on the market;

4. type of the biocidal product and field of use;

5. user category – mass or professional;

6. mode of use – working solutions, dose rate, in accordance with the conditions of the issued permit;

7. type of the biocidal product, e.g. liquid, granules or powder;

8. particulars of likely direct or indirect adverse side effects;

9. directions for first aid and antidote, where available;

10. directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging;

11. batch number;

12. manufacturing date and expiry date relevant to normal conditions of storage;

13. duration of the effect and interval to be observed between:

a) applications of the biocidal product and/or

b) application of the biocidal product and the use of the products treated and/or

c) the use of the biocidal product and the access by man or animals to the treated areas, including particulars concerning decontamination means and measures, duration of necessary ventilation of treated areas and particulars for cleaning of equipment;

14. precautionary measures during use, transport and storage, including devices for collective and personal protection, measures for protection against fire, covering of furniture or equipment, removal of food and feedingstuff and directions to prevent animals from being exposed;

15. information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water;

16. risk group and, where necessary, the biohazard sign in accordance with Regulation No. 4 on the protection of workers from the risks related to the exposure to biological agents at work (promulgated, SG No. 105/2002), where the active substance is a micro-organism.

(2) The type of the biocidal product referred to in Paragraph 1, item 4 shall be determined in accordance with Appendix No. 13.

(3) The information referred to in Paragraph 1, items 1 through 6 must always be carried on the label. The information referred to in items 7 through 16 may be carried on the packaging or on a leaflet accompanying the product and in such cases the labelling requirements shall be considered fulfilled.

(4) Where the biocidal product is placed on the market accompanied by a leaflet, the label shall also contain the sentence ‘Read the leaflet carefully before use’.

Article 16. (1) Biocidal products placed on the market shall be used in compliance with the conditions of the issued permit and the requirements listed in the label.

(2) Professional users shall also comply with the requirements of statutory instruments on health and safety at work.

Article 17. The information contained in the dossiers of permitted active substances and biocidal products and registered low-risk biocidal products may be used by the second or subsequent applicant under the following conditions:

1. the second or subsequent applicant submits a declaration for use of the information submitted by the first applicant;

2. after the expiry of a ten-year term of the issue of the permit or the registration certificate.

Article 18. (1) In the case of a biocidal product for which a permit or a registration certificate has already been issued, the Minister of Health may permit a subsequent applicant to refer to data provided by the first applicant, in so far as the applicant provides:

1. evidence that the biocidal product for which the application is filed is similar to the biocidal product already permitted or registered;

2. its active substances, including the degree of purity and the nature of impurities, are the same as those of the biocidal product already permitted or registered.

(2) In the cases referred to in Paragraph 1 the provisions of Article 17 shall be observed.

Article 19. (1) Where experiments involving vertebrate animals are necessary, before carrying them out the person intending to file an application for a permit or for registration of a biocidal product shall submit to the Ministry of Health:

1. an enquiry whether a permit or a registration certificate has been issued for a similar biocidal product,

2. a request for information as to the name and address of the holder of the permit or the registration certificate.

(2) The enquiry referred to in Paragraph 1, item 1 shall be accompanied by a declaration that the person referred to in Paragraph 1 intends to apply on his own behalf for a permit or for registration of a biocidal product and that the other information in the dossiers referred to in Article 5 and Article 7 is available.

(3) Provided that the conditions referred to in Paragraph 2 are met, the Minister of Health shall notify:

1. the subsequent applicant – of the name and address of the holder of the permit or the registration certificate;

2. the holder of the permit or the registration certificate – of the name and address of the subsequent applicant;

(4) With a view to avoiding duplicative testing on vertebrate animals:

1. the holder of the permit or the registration certificate and the subsequent applicant shall reach agreement on the sharing of data on the results from the biocide testing; and

2. the holder of the permit or the registration certificate shall declare that he provides to the subsequent applicant the results from the testing of the biocidal product already permitted or registered.

(5) In the cases referred to in Paragraph 4 the subsequent applicant shall refer to the results from the testing of an already permitted or registered biocidal product.

Article 20. (1) The Minister of Health shall keep public registers of:

1. permitted active substances;

2. permitted biocidal products;

3. registered low-risk biocidal products.

(2) The register referred to in item 1 shall contain:

1. number and date of the permit for placing an active substance on the market;

2. term of validity of the issued permit;

3. name and address of the person placing the active substance on the market;

4. name of the active substance and classification data thereof;

5. function, e.g. insecticide, fungicide or rodenticide;

6. field of application;

7. mode of use;

8. category of users;

9. changes which have occurred with relation to the recorded circumstances.

(3) The register referred to in item 2 shall contain:

1. number and date of the permit for placing a biocidal product on the market;

2. term of validity of the issued permit;

3. name and address of the person placing the biocidal product on the market;

4. name of the biocidal product;

5. name and concentration of the active substance contained in the biocidal product and information on its classification;

6. type of the biocidal product according to Appendix No. 13 and field of application;

7. type of biocidal product, e.g. liquid, granules or powder;

8. mode of use;

9. category of users;

10. date of withdrawal or termination of the permit;

11. changes which have occurred with relation to the recorded circumstances.

(4) The register referred to in item 3 shall contain:

1. number and date of the registration certificate of the low-risk biocidal product;

2. term of validity of the issued registration certificate;

3. name and address of the person placing the low-risk biocidal product on the market;

4. name of the low-risk biocidal product;

5. name and concentration of the active substance/active substances contained in the product and information on their classification;

6. type of the low-risk biocidal product according to Appendix No. 13 and field of application;

7. type of the low-risk biocidal product, e.g. liquid, granules or powder;

8. mode of use;

9. category of users.

11. date of registration strike-off;

12. changes which have occurred with relation to the recorded circumstances.

TRANSITIONAL AND FINAL PROVISIONS

§ 1. Where the data from the tests to determine the physico-chemical, toxicological and ecotoxicological properties of the biocides were generated before the coming into force of this Regulation by methods other than those laid down in Article 10, Paragraph 1, the use of such data and the need to conduct new tests by the methods laid down in Article 10, Paragraph 1 shall be decided on a case-by-case basis. When a decision is made on whether to use the data or to conduct new tests, the need to minimise testing on vertebrate animals shall be taken into account.

§ 2. This Regulation is issued pursuant to Article 16 of the Protection Against the Harmful Impact of Chemical Substances and Preparations Act.

§ 3. This Regulation shall become effective as of 1 January 2007.

Appendix No. 1

to Article 2

I. LIST OF ACTIVE SUBSTANCES FOR WHICH A PERMIT IS NOT ISSUED

NAME (according to EINECS and/or other name)	**EINECS No.**	**CAS No.**
Formaldehyde	200-001-8	50-00-0
Piperonyl butoxide/2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether	200-076-7	51-03-6
Bronopol	200-143-0	52-51-7
Bis (tributyltin) oxide	200-268-0	56-35-9
Diphenoxarsin - 10-yl oxide	200-377-3	58-36-6
gamma-HCH or gamma-BHC/Lindane/ 1,2,3,4,5,6-hexachlorocyclohexane	200-401-2	58-89-9
Chlorocresol	200-431-6	59-50-7
Dimethoate	200-480-3	60-51-5
Dichlorvos	200-547-7	62-73-7
Ethyl alcohol	200-578-6	64-17-5
Formic acid	200-579-1	64-18-6
Benzoic acid	200-618-2	65-85-0
Propan-2-ol	200-661-7	67-63-0
Salicylic acid	200-712-3	69-72-7
Propan-1-ol	200-746-9	71-23-8
Ethylene oxide	200-849-9	75-21-8
1,3-Dibromo-5,5-dimethylhydantoin	201-030-9	77-48-5
Citric acid	201-069-1	77-92-9
Linalool	201-134-4	78-70-6
2-Chloroacetamide	201-174-2	79-07-2

Bromoacetic acid	201-175-8	79-08-3
Glycollic acid	201-180-5	79-14-1
Peracetic acid	201-186-8	79-21-0
L (+) lactic acid	201-196-2	79-33-4
Warfarin	201-377-6	81-81-2
Diphacinone/Diphacin, Ramik, Diphenadione	201-434-5	82-66-6
Anthraquinone	201-549-0	84-65-1
Trichlorocyanuric acid/Symclosene	201-782-8	87-90-1
Chloroxylenol	201-793-8	88-04-0
Biphenyl-2-ol/o-Phenylphenol	201-993-5	90-43-7
Naphthalene	202-049-5	91-20-3
Dichlorophen	202-567-1	97-23-4
Triclocarban	202-924-1	101-20-2
Geraniol	203-377-1	106-24-1
1,4-Dichlorobenzene	203-400-5	106-46-7
Glyoxal	203-474-9	107-22-2
m-Cresol	203-577-9	108-39-4
Sorbic acid	203-768-7	110-44-1
Glutaraldehyde/glutaral	203-856-5	111-30-8
Nonanoic acid	203-931-2	112-05-0
Methyl-nonylketone	203-937-5	112-12-9
N-(2-Ethylhexyl)-8,9,10-trinorborn-5-ene-2,3-dicarboximide	204-029-1	113-48-4
Propoxur	204-043-8	114-26-1
1,3-Dichloro-5,5-dimethylhydantoin	204-258-7	118-52-5
Clorophene	204-385-8	120-32-1
Benzyl benzoate	204-402-9	120-51-4
Benzethonium chloride	204-479-9	121-54-0
Malathion	204-497-7	121-75-5
Fenitrothion	204-524-2	122-14-5
2-Phenoxyethanol	204-589-7	122-99-6
Cetylpyridinium chloride	204-593-9	123-03-5
Octanoic acid	204-677-5	124-07-2
Carbon dioxide	204-696-9	124-38-9
Sodium dimethylarsinate	204-708-2	124-65-2
Nitromethylidynetrimethanol	204-769-5	126-11-4
Chloramine-T/Tosylchloramide sodium	204-854-7	127-65-1
Potassium dimethyldithiocarbamate	204-875-1	128-03-0
Sodium dimethyldithiocarbamate	204-876-7	128-04-1
Warfarin sodium	204-929-4	129-06-6
Sodium pentachlorophenolate	205-025-2	131-52-2
Sodium 2-biphenylate	205-055-6	132-27-4

Captan	205-087-0	133-06-2
Folpet	205-088-6	133-07-3
Methyl anthranilate	205-132-4	134-20-3
N,N-Diethyl-m-toluamide	205-149-7	134-62-3
Thiram	205-286-2	137-26-8
Ziram	205-288-3	137-30-4
Potassium methyldithiocarbamate	205-292-5	137-41-7
Metam-sodium	205-293-0	137-42-8
Disodium cyanodithiocarbamate	205-346-8	138-93-2
1,3-Bis(hydroxymethyl)urea	205-444-0	140-95-4
Nabam	205-547-0	142-59-6
Sodium hydrogencarbonate	205-633-8	144-55-8
Thiabendazole	205-725-8	148-79-8
Benzothiazole-2-thiol	205-736-8	148-30-4
Naled	206-098-3	300-76-5
Diuron	206-354-4	330-54-1
Diazinon	206-373-8	333-41-5
Decanoic acid	206-376-4	334-48-5
Cyanamide	206-992-3	420-04-2
2-Hydroxy-4-isopropyl-2,4,6-cycloheptatrien-1-one	207-880-7	499-44-5
Sodium benzoate	208-534-8	532-32-1
Dazomet	208-576-7	533-74-4
Allethrin/Pynamin forte	209-542-4	584-79-2
Phthalaldehyde	211-402-2	643-79-8
Tolylfluanid	211-986-9	731-27-1
Hydroxyl-2-pyridone	212-506-0	822-89-9
2,6-dimethyl-1,3-dioxan-4-yl acetate	212-579-9	828-00-2
Terbutryn	212-950-5	886-50-0
Dichlofluanid	214-118-7	1085-98-9
Copper thiocyanate	214-183-1	1111-67-7
Tetradonium bromide	214-291-9	1119-97-7
d-Tetramethrin	214-619-0	1166-46-7
4,5-Dichloro-3H-1,2-dithiol-3-one	214-754-5	1192-52-5
Diarsenic pentaoxide	215-116-9	1303-28-2
Diboron trioxide	215-125-8	1303-86-2
Zinc oxide	215-222-5	1314-13-2
Trizinc diphosphide	215-244-5	1314-84-7
Zinc sulphide	215-251-3	1314-98-3
Copper oxide	215-269-0	1317-38-0
Dicopper oxide	215-270-7	1317-39-1
Disodium tetraborate, anhydrous	215-540-4	1330-43-4

Chromium trioxide	215-607-8	1333-82-0
Copper salt of the naphthenic acids	215-657-0	1338-02-9
2-Butanone, peroxide	215-661-2	1338-23-4
Monolinuron	217-129-5	1746-81-2
2,4-Dichlorobenzyl alcohol	217-210-5	1777-82-8
Chlorothalonil	217-588-1	1897-45-6
Fluometuron	218-500-4	2164-17-2
4-(2-Nitrobutyl) morpholine	218-748-3	2224-44-4
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	219-145-8	2372-82-9
Tolnaftate	219-266-6	2398-96-1
2-Bromo-1-(4-hydroxyphenyl) ethan-1-one	219-655-0	2491-38-5
2,2′-Dithiobis[N-methylbenzamide]	219-768-5	2527-58-4
1,2-Benzisothiazol-3(2H)-one	220-120-9	2634-33-5
2-methyl-2H-isothiazol-3-one	220-239-6	2682-20-4
Sulphuryl difluoride	220-281-5	2699-79-8
Troclosene sodium	220-767-7	2893-78-9
Sodium dichloroisocyanurate dihydrate	220-767-7	51580-86-0
Chlorpyrifos	220-864-4	2921-88-2
Mecetronium ethyl sulphate	221-106-5	3006-10-8
Bis(trichloromethyl) sulphone	221-310-4	3064-70-8
Triclosan	222-182-2	3380-34-5
Oct-1-ene-3-ol	222-226-0	3391-86-4
Sodium 5-chloro-2-[4-chloro-2-[[[(3,4-dichlorophenyl)amino]carbonyl]amino]phenoxy]benzenesulphonate	222-654-8	3567-25-7
(Ethylenedioxy)dimethanol	222-720-6	3586-55-8
Chlorophacinone	223-003-0	3691-35-8
Dipyrithione	223-024-5	3696-28-4
Sodium 2,4,6-trichlorophenolate	223-246-2	3784-03-0
Pyridine-2-thiol 1-oxide, sodium salt	223-296-5	3811-73-2
Methenamine 3-chloroallylochloride	223-805-0	4080-31-3
2,2′,2″-(Hexahydro-1,3,5-triazine-1,3,5-triyl)-triethanol	225-208-0	4719-04-4
Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d] imidazole-2,5(1H,3H)-dione	226-408-0	5395-50-6
Chlorpyrifos-methyl	227-011-5	5598-13-0
N,N′-methylenebismorpholine	227-062-3	5625-90-1
Coumatetralyl	227-424-0	5836-29-3
Terbuthylazine	227-637-9	5915-41-3
(R) – (+)-Limonene	227-813-5	5989-27-5
Methylene dithiocyanate	228-652-3	6317-18-6
1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione	229-222-8	6440-58-0
(2-bromo-2-nitrovinyl)benzene	230-515-8	7166-19-0
Didecyldimethylammonium chloride	230-525-2	7173-51-5

Prometryn	230-711-3	7287-19-6
Silver	231-131-3	7440-22-4
Copper	231-159-6	7440-50-8
Sulphur dioxide	231-195-2	7446-09-5
Calcium dihexa-2,4-dienoate	231-321-6	7492-55-9
Iodine	231-442-4	7553-56-2
Polyvinylpyrrolidone iodine	polymer	25655-41-8
Silicon dioxide — amorphous	231-545-4	7631-86-9
Sodium hydrogensulphite	231-548-0	7631-90-5
Hydrogen chloride / Hydrochloric acid	231-595-7	7647-01-0
Sodium chloride	231-598-3	7647-14-5
Sodium bromide	231-599-9	7647-15-6
Orthophosphoric acid	231-633-2	7664-38-2
Sodium hypochlorite	231-668-3	7681-52-9
Disodium disulphite	231-673-0	7681-57-4
Tetramethrin/Neopynamin	231-711-6	7696-12-0
Potassium permanganate	231-760-3	7722-64-7
Hydrogen peroxide	231-765-0	7722-84-1
Nitrogen	231-783-9	7727-37-9
7a-Ethyldihydro-1H,3H,5Hoxazolo[3,4-c]oxazole	231-810-4	7747-35-5
Sodium sulphite	231-821-4	7757-83-7
Sodium chloride	231-836-6	7758-19-2
Copper sulphate	231-847-6	7758-98-7
Silver nitrate	231-853-9	7761-88-8
Sodium chlorate	231-887-4	7775-09-9
Disodium peroxodisulphate /Sodium persulphate	231-892-1	7775-27-1
Calcium hypochlorite	231-908-7	7778-54-3
Chlorine	231-959-5	7782-50-5
Silver chloride	232-033-3	7783-90-6
Creosote	232-287-5	8001-58-9
Bone oil/animal oil	232-294-3	8001-85-2
Rape oil	232-299-0	8002-13-9
Natural pyrethrins and pyrethroids	232-319-8	8003-34-7
Garlic extract	232-371-1	8008-99-9
Lignin	232-682-2	9005-53-2
Boric acid	233-139-2	10043-35-3
Chlorine dioxide	233-162-8	10049-04-4
Potassium sulphite	233-321-1	10117-38-1
Sodium hydrogen 2,2′-methylenebis {4-chlorophenolate}	233-457-1	10187-52-7
2,2-Dibromo-2-cyanoacetamide	233-539-7	10222-01-2
Oxine-copper	233-841-9	10380-28-6

Sodium dichromate	234-190-3	10588-01-9
Carbendazim	234-232-0	10605-21-7
Disodium octaborate tetrahydrate	234-541-0	12280-03-4
Trimagnesium diphosphide	235-023-7	12057-74-8
Copper(II) carbonate-copper(II) hydroxide (1:1)	235-113-6	12069-69-1
Zineb	235-180-1	12122-67-7
Ammonium bromide	235-183-8	12124-97-9
Hexaboron dizinc undecaoxide / Zinc borate	235-804-2	12767-90-7
Pyrithione zinc	236-671-3	13463-41-7
Dodecylguanidine monohydrochloride	237-030-0	13590-97-1
Potassium 2-biphenylate	237-243-9	13707-65-8
Bromine chloride	237-601-4	13863-41-7
(benzyloxy)methanol	238-588-8	14548-60-8
Phoxim	238-887-3	14816-18-3
Bis(1-hydroxy-1H-pyridine-2-thionato-O,S)copper	238-984-0	14915-37-8
Chlorotoluron	239-592-2	15545-48-9
Sodium p-chloro-m-cresolate	239-825-8	15733-22-9
Chloralose	240-016-7	15879-93-3
Dipotassium disulphite	240-795-3	16731-55-8
Methomyl	240-815-0	16752-77-5
Hexafluorosilicic acid	241-034-8	16961-83-4
Chlorhexidine Digluconate	242-354-0	18472-51-0
Benzoxonium chloride	243-008-1	19379-90-9
p-{(Diiodomethyl)sulphonyl}toluene	243-468-3	20018-09-1
Copper dihydroxide	243-815-9	20427-59-2
Disilver oxide	243-957-1	20667-12-3
Aluminium phosphide	244-088-0	20859-73-8
(benzothiazol-2-ylthio)methyl thiocyanate	244-445-0	21564-17-0
Bendiocarb	245-216-8	22781-23-3
Prallethrin	245-387-9	23031-36-9
Potassium sorbate	246-376-1	24634-61-5
alpha, alpha′, alpha″-trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol	246-764-0	25254-50-6
2-Octyl-2H-isothiazol-3-one	247-761-7	26530-20-1
cis-Tricos-9-ene	248-505-7	27519-02-4
Dimethyloctadecyl[3-(trimethoxysilyl) propyl]ammonium chloride	248-595-8	27668-52-6
N-tert-butyl-N-cyclopropyl-6-(methylthio)-1,3,5-triazine-2,4-diamine	248-872-3	28159-98-0
S-Bioallethrin/Esbiol	249-013-5	28434-00-6
Bioresmethrin	249-01-40	28434-01-7
Bromadiolone	249-205-9	28772-56-7
Pirimiphos-methyl	249-528-5	29232-93-7

Trans-isopropyl-3-{{(ethylamino)-methoxyphosphinothioyl}oxy}-crotonate	250-517-2	31218-83-4
(Z,E)-Tetradeca-9,12-dienyl-acetate	250-753-6	31654-77-0
Bromochloro-5,5-dimethylimidazolidine-2,4-dione	251-171-5	32718-18-6
Amitraz	251-375-4	33089-61-1
Isoproturon	251-835-4	34123-59-6
N-{{(4-Chlorophenyl)amino}carbonyl}-2,6-difluorobenzamide	252-529-3	35367-38-5
1-[2-(Allyloxy)-2-(2,4-Dichlorophenyl)ethyl]-1H-imidazole	252-615-0	35554-44-0
Imazalil	252-615-0	73790-28-0
Azamethiphos	252-626-0	35575-96-3
2-Bromo-2-(bromomethyl)pentanedinitrile	252-681-0	35691-65-7
Cyphenothrin / cyclopropanecarboxylate	254-484-5	39515-40-7
Dimethyltetradecyl[3-(trimethoxysilyl)propyl]ammonium chloride	255-451-8	41591-87-1
Citriodiol	255-953-7	42822-86-6
4,4-Dimethyloxazolidine	257-048-2	51200-87-4
Ethyl N-acetyl-N-butyl-.beta.-alaninate	257-835-0	52304-36-6
Cypermethrin	257-842-9	52315-07-8
Permethrin	258-067-9	52645-53-1
Deltamethrin	258-256-6	52918-63-5
Empenthrin / vaportrin	259-154-4	54406-48-3
3-iodo-2-propynyl butylcarbamate	259-627-5	55406-53-6
Tetrakis(hydroxymethyl)phosphonium sulphate (2:1)	259-709-0	55566-30-8
Difenacoum	259-978-4	56073-07-5
Brodifacoum	259-980-5	56073-10-0
Propiconazole	262-104-4	60207-90-1
4,5-Dichloro-2-octyl-2Hisothiazol-3-one	264-843-8	64359-81-5
2-Chloro-N-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl] benzamide	264-980-3	64628-44-0
Oxazolidin	266-235-8	66204-44-2
N-Cyclopropyl-1,3,5-triazine-2,4,6-triamine	266-257-8	66215-27-8
cis-4-[3-(p-tert-Butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine	266-719-9	67564-91-4
Cyfluthrin	269-855-7	68359-37-5
Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides	269-919-4	68391-01-5
Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides	270-325-2	68424-85-1
Quaternary ammonium compounds, di-C8-10-alkyldimethyl, chlorides	270-331-5	68424-95-3
Fatty acids, coco, reaction products with diethanolamine	270-430-3	68440-04-0
Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, salts with 1,2-benzisothiazol-3(2H)-one 1,1-dioxide (1:1)	273-545-7	68989-01-5
Sodium N-(hydroxymethyl)glycinate	274-357-8	70161-44-3

Amines, C10-16-alkyldimethyl, N-oxides	274-687-2	70592-80-2
Pentapotassium bis(peroxymonosulphate) bis(sulphate)	274-778-7	70693-62-8
Octenidine dihydrochloride	274-861-8	70775-75-6
1,3-didecyl-2-methyl-1H-imidazolium chloride	274-948-0	70862-65-6
Ethyl {2-(4-phenoxyphenoxy)ethyl}carbamate / Fenoxycarb	276-696-7	72490-01-8
1-{ 1-[1,3-Bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl}-1,3-bis(hydroxymethyl)urea / Diazolidinylurea	278-928-2	78491-02-8
Magnesium-monoperoxyphthalat-hexahydrate	279-013-0	844665-66-7
Tributyltetradecylphosphonium chloride	279-808-2	81741-28-8
Margosa extract	283-644-7	84696-25-3
Tar acids, polyalkylphenol fraction	284-893-4	84989-05-9
Melaleuca alternifolia, ext. / Australian tea tree oil	285-377-1	85085-48-9
2,4,8,10-Tetra(tert-butyl)-6-hydroxy-12H-dibenzo[d,g][1,3,2]dioxaphosphocin – 6-oxide, sodium salt	286-344-4	85209-91-2
Stannane, tributyl-, mono(-naphthenoyloxy) derivs.	287-083-9	85409-17-2
Quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides	287-089-1	85409-22-9
Quaternary ammonium compounds, C12-14-alkyl {(ethylphenyl)methyl}dimethyl, chlorides	287-090-7	85409-23-0
alpha.-Cyano-4-fluoro-3-phenoxybenzyl [1.alpha (S*),3 alpha.]-(±)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	289-244-9	86560-93-2
Chrysanthemum cinerariaefolium, ext.	289-699-3	89997-63-7
Urea, N,N′-bis(hydroxymethyl)-, reaction products with 2-(2-butoxyethoxy) ethanol, ethylene glycol and formaldehyde	292-348-7	90604-54-9
Juniper, Juniperus mexicana, ext	294-461-7	91722-61-1
Lavandin oil	294-470-6	91722-69-9
Pine ext.	304-455-9	94266-48-5
Quaternary ammonium compounds, [2-[[2-[(2-carboxyethyl)(2-hydroxyethyl)amino]ethyl]amino]-2-oxoethyl]coco alkyldimethyl, hydroxides, inner salts	309-206-8	100085-64-1
Corn cob, powdered	310-127-6	99999-99-4
1-(3,5-Dichloro-4-(1,1,2,2-tetrafluoroethoxy) phenyl)-3-(2,6-difluorobenzoyl)urea / Hexaflumuron	401-400-1	86479-06-3
1,3-Dichloro-5-ethyl-5-methylimidazolidine-2,4-dione	401-570-7	89415-87-2
Tebuconazole	403-640-2	107534-96-3
Reaction products of N-C12-14-alkylpropylenediamine and L-glutamates	403-950-8	164907-72-6
Mixture of: (C8-18)alkylbis(2-hydroxyethyl)ammonium bis(2-ethylhexyl)phosphate; (C8-18)alkylbis(2-hydroxyethyl)ammonium 2-ethylhexylhydrogenphosphate	404-690-8	68132-19-4
Transfluthrin	405-060-5	118712-89-3
Hydramethylnon	405-090-9	67485-29-4
3-Phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether / Etofenprox	407-980-2	80844-07-1

6-(Phthalimido)peroxyhexanoic acid	410-850-8	128275-31-0
Methyl neodecanamide	414-460-9	105726-67-8
Lambda cyhalothrin	415-130-7	91465-08-6
Flufenoxuron	417-680-3	101463-69-8
5-Chloro-2-(4-chlorphenoxy)-phenol	418-890-8	3380-30-1
2-Butyl-benzo[d]isothiazol-3-one	420-590-7	04299-07-4
Flocoumafen	421-960-0	90035-08-8
Icaridine	423-210-8	119515-38-7
Fipronil	424-610-5	120068-37-3
cis-1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	426-020-3	51229-78-8
Imidacloprid	428-040-8	138261-41-3
Thiamethoxam	428-650-4	153719-23-4
Imiprothrin	428-790-6	72963-72-5
Pyriproxyfen	429-800-1	95737-68-1
3-Benzo(b)thien-2-yl-5,6-dihydro-1,4,2-oxathiazine,4-oxide	431-030-6	163269-30-5
Reaction products of diisopropanolamine with formaldehyde (1:4)	432-440-8	220444-73-5
Chloromethyl n-octyl disulfide	432-680-3	180128-56-7
Reaction product of dimethyl adipate, dimethyl glutarate, dimethyl succiante with hydrogen peroxide / Perestane	432-790-1	
Bis(3-aminopropyl)-octylamine	433-340-7	86423-37-2
(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine	433-460-1	210880-92-5
(E)-2-Octadecenal		51534-37-3
(E,Z)-2,13-Octadecadienal		99577-57-8
Silver-zinc-aluminium-boronphosphate glass		398477-47-9
Silver sodium hydrogen zirconium phosphate		
Peroxyoctanoic acid		33734-57-5
Cyclohexylhydroxydiazene 1-oxide, potassium salt		66603-10-9
Silica, amorphous, crystallinefree		112945-52-5
Silver zeolite A		
Silicium dioxide / Kieselguhr		61790-53-2
Bromethalin		63333-35-7
S-Methoprene		65733-16-6
S-Hydroprene		65733-18-8
Esfenvalerate		66230-04-4
Alpha-cypermethrin		67375-30-8
Abamectin (Mixture of avermectin B1a;> 80 % EINECS 265-610-3, and avermectin B1b; < 20 % EINECS 265-611-9)		71751-41-2
Biphenate/Bifenthrin		82657-04-3
Difethialone		104653-34-1
Guazatine triacetate		115044-19-4
Chlorfenapyr		122453-73-0
Silver zeolite		130328-18-6

Silver-zinczeolite		130328-20-0
d-Phenothrin		188023-86-1
S-Cyphenothrin		
Bioallethrin/d-trans-Allethrin		
d-Allethrin		
Esbiothrin		
Polymer of N-Methylmethanamine (EINECS 204-697-4) with (chloromethyl)oxirane (EINECS 203-439-8) / Polymeric quaternary ammonium chloride	polymer	25988-97-0
Homopolymer of 2-tert-butylaminoethyl methacrylate (EINECS 223-228-4)	polymer	26716-20-1
Polymer of formaldehyde and acrolein	polymer	26781-23-7
Monohydrochloride of polymer of N,N -1,6-hexanediylbis[N′-cyanoguanidine] (EINECS 240-032-4) and hexamethylenediamine (EINECS 240-679-6) /Polyhexamethylene biguanide (monomer: 1,5-bis(trimethylen)-guanylguanidinium monohydrochloride)	polymer	27083-27-8/ 32289-58-0
N,N,N′,N′ — Tetramethylethylenediamine-bis(2-chloroethyl) ether copolymer	polymer	31075-24-8
Poly-(hexamethylendiamine guanidinium chloride)	polymer	57028-96-3
Polyhexamethylene biguanide	polymer	91403-50-8
N,N-Didecyl(-N-methyl-poly(oxyethyl)ammoniumpropionate	polymer	94667-33-1
Copolymer of 2-propenal and propane-1,2-diol	polymer	191546-07-3
N-Didecyl-N-dipolyethoxyammonium borate / Didecylpolyoxethylammonium borate	polymer	214710-34-6
Oligo(2-(2-ethoxy)ethoxyethylguanidinium chloride)	polymer	374572-91-5
Sodium lignosulfonate	natural polymer	8061-51-6
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6)	mixture	55965-84-9
Amines, n-C10-16-alkyltrimethylenedi-, reaction products with chloroacetic acid	mixture	139734-65-9
Quaternary ammonium iodides	mixture	308074-50-2
Mixture of 1-phenoxypropan-2-ol (EINECS 212-222-7) and 2-phenoxypropanol (EINECS 224-027-4)	mixture	
Active Chlorine: manufactured by the reaction of hypochlorous acid and sodium hypochlorite produced in situ	mixture	
Potassium salts of fatty acids (C15-21)	mixture	
Quaternary ammonium compounds (benzylalkyldimethyl (alkyl from C8-C22, saturated and unsaturated, tallow alkyl, coco alkyl, and soya alkyl) chlorides, bromides, or hydroxides) / BKC	Mixture of EINECS listed substances	
Quaternary ammonium compounds (dialkyldimethyl (alkyl from C6-C18, saturated and unsaturated, and tallow alkyl, coco alkyl, and soya alkyl) chlorides, bromides, or methylsulphates) / DDAC	Mixture of EINECS listed substances	

Quaternary ammonium compounds (alkyltrimethyl (alkyl from C8-C18, saturated and unsaturated, and tallow alkyl, coco alkyl, and soya alkyl) chlorides, bromides, or methylsulphates) / TMAC	Mixture of EINECS listed substances	
Bacillus sphaericus	Micro-organisms	143477-72-7
Bacillus thuringiensis subsp. Israelensis Serotype H14	Micro-organisms	
Bacillus subtilis	Micro-organisms	

II. LIST OF BASIC SUBSTANCES FOR WHICH A PERMIT IS NOT ISSUED

1. Carbon dioxide
2. Nitrogen
3. Ethanol
4. 2-propanol
5. Acetic acid
6. Kieselguhr

Appendix No. 2
to Article 5, Paragraph 2

Main dossier requirements for a biocidal product with an active substance which is a chemical substance

The dossiers shall address at least all the points listed under 'Dossier requirements'. The information is required to be supported by the respective data. The dossier requirements must be in line with technical development.

Certain information included in the requirements need not be supplied where it is not technically possible or scientifically necessary to supply the information, or owing to the nature of the biocidal product or its intended use. In such cases the applicant shall submit an acceptable written justification, such as reference to the existence of a frame-formulation, where the applicant holds a declaration for use of information.

Information may be derived from existing data where an acceptable justification is provided and the requirements of the regulation are complied with. Wherever possible, the requirements of Regulation No. 25 on the protection and humane treatment of animals used for experimental purposes (SG No. 59/2003) should be observed to minimise animal testing.

I. Content

1. Information on the person placing the biocidal product on the market and on the manufacturer of the biocidal product and the active substance.

2. Identity of the biocidal product.

3. Physical and chemical properties of the biocidal product

4. Methods for detection and analysis

5. Intended field of application and efficacy.

6. Toxicology data (additional to that for the active substance).

7. Ecotoxicology data (additional to that for the active substance).

8. Measures necessary to protect man, non-target organisms and the environment.

9. Classification, packaging and labelling of the biocidal product

10. Summary of Sections 2 to 9.

II. Dossier requirements:

1. Information on the person placing the biocidal product on the market and on the manufacturer of the biocidal product and the active substance.

1.1 Name, address, telephone number of the person placing the biocidal product on the market.

1.2. Name and address of the manufacturer of the biocidal product and address of the manufacturing facility.

1.3. Name and address of the manufacturer of the active substance and address of the manufacturing facility.

2. Identity of the biocidal product.

2.1. Trade name or proposed trade name of the biocidal product, and manufacturer's code number, if appropriate.

2.2. Detailed quantitative and qualitative information on the composition of the biocidal product, incl. active substance(s), impurities, adjutants, inert components, etc.

2.3. Physical state and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution.

3. Physical, chemical and technical properties

3.1. Appearance (physical state, colour).

3.2. Explosive properties.

3.3. Oxidising properties.

3.4. Flash-point and other indications of flammability or spontaneous ignition.

3.5. Acidity/alkalinity and if necessary pH value (1% in water).

3.6. Relative density.

3.7. Storage — stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the biocidal product. Reactivity towards container material.

3.8. Technical characteristics of the biocidal product (e.g. wettability, persistent foaming, flowability, pourability and dustability).

3.9. Physical and chemical compatibility with other products including biocidal products with which it is used.

4. Analytical methods of identification and analysis

4.1. Analytical method for determining the concentration of the active substance in the biocidal product

4.2. Analytical methods including recovery rates and the limits of determination for toxicologically and ecotoxicologically relevant components of the biocidal product and/or residues thereof in the following:

a) soil;

b) air;

c) water (including drinking water);

d) biological samples – animal and human body fluids and tissues.

e) Treated food or feedingstuffs.

Methods not indicated with relation to the requirements of Appendix No. 5, item 4.2 are presented.

5. Intended field of application and efficacy

5.1. Type of the biocidal product according to Appendix No. 13 and field of use envisaged.

5.2. Method of application including description of system used, where one is envisaged.

5.3. Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used(e.g. cooling water, water used for heating purposes, surface water).

5.4. Number and timing of applications, and where relevant, additional information on any particular requirements relating to geographical variations, climatic variations, or necessary waiting periods between:

a) applications of the biocidal product and/or

b) application of the biocidal product and the use of the products treated and/or

c) the use of the biocidal product and the access by man or animals to the treated areas.

5.5. Function, e.g. bactericide, fungicide, insecticide, rodenticide, etc.

5.6. Organisms to be controlled and products, organisms or objects to be protected.

5.7. Effects on target organisms

5.8. Mode of action, including time delay, in so far as not covered by Appendix No. 5, item 5.4.

5.9. User category (mass and/or professional)

Efficacy data.

5.10. The proposed label claims for the product and efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate..

5.11 Any other known limitations on efficacy including resistance.

6. Toxicological studies

6.1. Acute toxicity

For the purposes of items 6.1.1 - 6.1.3 biocidal products other than gases shall be tested via at least two routes of administration, one of which should be the oral route. The choice of the second route will depend on the nature of the product and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route.

6.1.1. Oral.

6.1.2. Dermal.

6.1.3. Inhalation.

6.1.4. For biocidal products that are intended to be used with other biocidal products, where possible and necessary, the mixture of products shall be tested for acute dermal toxicity and skin and eye irritation.

6.2. Skin and eye irritation. Studies for eye irritation shall not be required where evidence of corrosivity is available.

6.3. Skin sensitisation.

6.4. Information on dermal absorption.

6.5. Available toxicological data on risk substances contained in the biocidal product, other than the active substance.

6.6. Information related to the exposure of man, including manufacturers and users.

Where necessary, the tests described in Appendix No. 5 shall be required for the toxicologically relevant non-active substances.

7. Ecotoxicological studies

7.1. Foreseeable routes of entry into the environment on the basis of the use envisaged.

7.2. Information on the ecotoxicology of the active substance in the biocidal product, where this cannot be extrapolated from the information on the active substance itself.

7.3. Ecotoxicological information relating to exotoxicological relevant non-active substances contained in the biocidal product, such as information from safety data sheets.

8. Measures to protect man, animals and the environment.

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

8.2. Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; in so far as not covered by Appendix No. 5, item 8.3.

8.3. Procedures, if any, for cleaning application equipment.

8.4. Identity of gases and combustion products generated in cases of fire.

8.5. Procedures for waste management of the biocidal product and its packaging, e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration for different use categories.

8.6. Possibility of destruction or decontamination following release in the following:

a) air;

b) water (including drinking water);

c) soil.

8.7. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms.

8.8. Information on any repellents or poison control measures included in the biocidal product that are present to prevent adverse effects on non-target organisms.

9. Classification, packaging and labelling

9.1. Proposal for classification and labelling.

9.2. Proposal for safety-data sheet, where appropriate.

9.3. Category/categories of danger, hazard symbols and indications of danger, risk phrases, safety phrases.

9.4.. Packaging

9.4.1. Material, type, shape and graphic design of the packaging

9.4.2 Compatibility of the biocidal product with the material

9.4.3. Volume/capacity

10. Summary and evaluation of Sections 2 to 9.

Appendix No. 3
to Article 5, Paragraph 3

Additional information on a biocidal product with an active substance which is a chemical substance

The dossiers shall address at least all the points listed under 'Dossier requirements'. The information is required to be supported by the respective data. The dossier requirements must be in line with technical development.

Certain information included in the requirements need not be supplied where it is not technically possible or scientifically necessary to supply the information, or owing to the nature of the biocidal product or its intended use. In such cases the applicant shall submit an acceptable written justification, such as reference to the existence of a frame-formulation, where the applicant holds a declaration for use of information.

Information may be derived from existing data where an acceptable justification is provided and the requirements of the regulation are complied with. Wherever possible, the requirements of Regulation No. 25 on the protection and humane treatment of animals used for experimental purposes (SG No. 59/2003) should be observed to minimise animal testing.

Dossier requirements

I. Further human health-related studies.

1. Food and feedingstuffs studies

1.1. If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin.

1.2. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product.

2. Other tests related to the exposure to humans – conducted where necessary.

II. Further studies on fate and behaviour in the environment.

1. Where relevant all the information required in Appendix No. 6, Section VII may be requested.

2. Testing for distribution in the following:

a) soil;

b) water;

c) air.

Test requirements 1 and 2 above are applicable only to ecotoxicologically relevant components of the biocidal product.

III. Further ecotoxicological studies

1. Effects on birds.

1.1. Acute oral toxicity, if not already done in accordance with Appendix No. 2, Section 7.

2. Effects on aquatic organisms.

2.1. In case of application of the biocidal product on, in, or near to surface waters.

2.1.1. Particular studies with fish and other aquatic organisms.

2.1.2. Residue data in fish concerning the active substance and including toxicologically relevant metabolites in fish.

2.1.3. Where necessary, the studies referred to in Appendix No. 6, Section VIII, items 2.1, 2.2, 2.3 and 2.4 may be required for relevant components of the biocidal product.

2.2. If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms under field conditions.

3. Effects on other non-target organisms.

3.1. Toxicity to terrestrial vertebrates (other than birds).

3.2. Acute toxicity to honeybees.

3.3. Effects on beneficial arthropods other than bees.

3.4. Effects on earthworms and other soil non-target macro-organisms, believed to be at risk.

3.5. Effects on soil non-target micro-organisms.

3.6. Effects on any other specific, non-target organisms from the flora and fauna believed to be at risk.

3.7. If the biocidal product is in the form of bait or granules, the following studies shall be required:

3.7.1. Supervised trials to assess risks to non-target organisms under field conditions.

3.7.2. Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk.

4. Summary and evaluation of items 1, 2 and 3.

Appendix No. 4
to Article 5, Paragraph 4

Main dossier requirements for a biocidal product with an active substance which is a micro-organism, including viruses and fungi

The dossiers shall address at least all the points listed under ‘Dossier requirements’. The information is required to be supported by the respective data. The dossier requirements must be in line with technical development.

Certain information included in the requirements need not be supplied where it is not technically possible or scientifically necessary to supply the information, or owing to the nature of the biocidal product or its intended use. In such cases the applicant shall submit an acceptable written justification, such as reference to the existence of a frame-formulation, where the applicant holds a declaration for use of information.

Information may be derived from existing data where an acceptable justification is provided and the requirements of the regulation are complied with. Wherever possible, the requirements of Regulation No. 25 on the protection and humane treatment of animals used for experimental purposes (SG No. 59/2003) should be observed to minimise animal testing.

I. Content

1. Information on the person placing the biocidal product on the market and on the manufacturer of the biocidal product and the active substance.

2. Identity and composition of the biocidal product.

3. Technical properties and all biocidal properties other than those of the active organism.

4. Methods for identification and analysis.

5. Field of application and efficacy.

6. Toxicology data (additional to that for the active organism).

7. Ecotoxicology data (additional to that for the active organism).

8. Measures necessary to protect man, non-target organisms and the environment.

9. Classification, packaging and labelling of the biocidal product.

10. Summary of Sections 2 to 9.

1. Information on the person placing the biocidal product on the market and on the manufacturer of the biocidal product and the active substance.

1.1 Name, address, telephone number of the person placing the biocidal product on the market.

1.2. Name and address of the manufacturer of the biocidal product and address of the manufacturing facility.

1.3. Name and address of the manufacturer of the active organism and address of the manufacturing facility.

2. Identity of the biocidal product.

2.1 Trade name or proposed trade name, and manufacturer's code number, if appropriate.

2.2 Detailed quantitative and qualitative information on the composition of the biocidal product (active organisms, inert components, adjutants, etc.)

2.3 Physical state and nature of the biocidal product (emulsifiable concentrate, wettable powder, etc.)

2.4. Concentration of the active organism in the material used.

3. Technical and biological properties

3.1. Appearance (colour and odour).

3.2. Storage — stability and shelf-life. Effects of temperature, method of packaging and storage, etc. on retention of biological activity.

3.3. Methods for establishing storage and shelf-life stability.

3.4. Technical characteristics of the biocidal product.

3.4.1. Wettability.

3.4.2. Persistent foaming.

3.4.3. Suspensibility and suspension stability.

3.4.4. Wet sieve test and dry sieve test.

3.4.5. Particle size distribution, content of dust/fines, attrition and friability.

3.4.6. In the case of granules, sieve test and indications of weight distribution of the granules, at least of the fraction with particle sizes bigger than 1 mm.

3.4.7. Content of active substance in or on bait particles, granules or treated material.

3.4.8. Emulsifiability, re-emulsifiability, emulsion stability.

3.4.9. Flowability, pourability and dustability.

3.5. Physical and chemical compatibility with other products including biocidal products with which its use is authorised.

3.6. Wetting, adherence and distribution following application.

3.7. Any changes to biological properties of the organism as a result of formulation, in particular changes in pathogenicity on infectivity.

4. Methods for identification and analysis

4.1. Analytical methods for determining the composition of the biocidal product.

4.2. Methods for determining residues (e.g. biotest).

4.3. Methods used to show microbiological purity of the biocidal product.

4.4. Methods used to show the biocidal product to be free from any human and other mammalian pathogens or, if need be, from pathogens harmful to non-target organisms and the environment.

4.5. Procedures and methods used to ensure stability and uniformity of the biocidal product and standardisation.

5. Field of application and efficacy.

5.1. Type of the biocidal product (e.g. wood preservative, insecticide, etc.)

5.2. Details of intended use, (e.g. types of harmful organism controlled, materials to be treated, etc.)

5.3. Application rate.

5.4. Specific circumstances or environmental conditions under which the active organism may or may not be used.

5.5. Method of application.

5.6. Number and timing of applications.

5.7. Proposed instructions for use.

Efficacy data

5.8 Preliminary range-finding tests.

5.9. Field experimentation.

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

5.11. Effects on the quality of materials or products treated.

6. Toxicology data (additional to that for the active organism).

6.1. Oral single dose.

6.2. Percutaneous single dose.

6.3. Inhalation.

6.4. Skin and where relevant eye irritation.

6.5. Skin sensitisation.

6.6. Available toxicological data relating to non-active substances.

6.7. User exposure

6.7.1. Data on percutaneous absorption/inhalation depending on formulation and method of application.

6.7.2 Likely user exposure under field conditions, including where relevant quantitative analysis of user exposure.

7. Ecotoxicology data (additional to that required for the active organism).

7.1. Observations concerning undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms or persistence in the environment.

8. Measures necessary to protect man, non-target organisms and the environment.

8.1 Recommended methods and precautions concerning handling, storage, transport or use.

8.2. Interval to be observed between: applications of the biocidal product and/or application of the biocidal product and the use of the products treated and/or the use of the biocidal product and the access by man or animals to the treated areas, as well as other precautions to protect humans and animals

8.3. Emergency measures in case of an accident

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

9. Classification, packaging and labelling

9.1. Justified proposal for the classification, packaging and labelling

9.1.1. Category/categories of danger, hazard symbols and indications of danger, risk phrases, safety phrases of the chemical compounds

9.1.2. Risk group in which the active organism is classified and, where necessary, the biohazard sign in accordance with Regulation No. 4 on the protection of workers from the risks related to the exposure to biological agents at work (promulgated, SG No. 105/2002).

9.2. Packaging

9.2.1. Material, type, shape and graphic design of the packaging

9.2. 2. Compatibility of the biocidal product with the material

9.2.3. Volume

9.3. Specimen of proposed packaging.

10. Summary of Sections 2 to 9.

Appendix No. 5
to Article 5, Paragraph 5

Main dossier requirements for an active substance which is a chemical substance

The dossiers shall address at least all the points listed under ‘Dossier requirements’. The information is required to be supported by the respective data. The dossier requirements must be in line with technical development.

Certain information included in the requirements need not be supplied where it is not technically possible or scientifically necessary to supply the information, or owing to the nature of the biocidal product or its intended use. In such cases the applicant shall submit an acceptable justification, such as reference to the existence of a frame-formulation, where the applicant holds a declaration for use of information.

I. Content

1. Information on the person placing the active substance on the market and on the manufacturer of the active substance

2. Identity of the active substance

3. Physical and chemical properties of the active substance

4. Methods of detection and identification

5. Effectiveness against target organisms and intended uses

5. Toxicological profile for man and animals including metabolism

7. Ecotoxicological profile including environmental fate and behaviour

8. Measures necessary to protect man, animals and the environment

9. Classification and labelling

10. Summary and evaluation of Sections 2 to 9.

II. Dossier requirements

1. Information on the person placing the active substance on the market and on the manufacturer of the active substance.

1.1 Name, address, telephone number of the person placing the active substance on the market.

1.2 Name and address of the manufacturer of the active substance and address of the manufacturing facility.

2. Identity

2.1. Common name by ISO and synonyms

2.2 Chemical name (IUPAC nomenclature)

2.3. Manufacturer's code number.

2.4. CAS and EC numbers, if available.

2.5. Molecular and structural formula (including full details of any isomeric composition), molecular mass.

2.6. Method of manufacture (syntheses pathway in brief terms) of active substance.

2.7. Specification of purity of the active substance (in g/kg or g/l).

2.8. Identity of impurities and additives (e.g. stabilisers), structural formulae and possible range (expressed as g/kg or g/l).

2.9. The origin of natural active substances or their precursors (e.g. an extract of a flower).

2.10. Exposure data in conformity with Appendix No. 3 to Article 4, Paragraph 2, item 3 of the Regulation on the procedure and method of notification of new chemical substances (promulgated, SG No. 67/2002).

3. Physical and chemical properties.

3.1 Melting point, boiling point, relative density [(1)].

3.2. Vapour pressure (in Pa) [(1)].

3.3. Appearance (physical state, colour) [(2)].

3.4. Absorption spectra – ultraviolet/visible (UV/VIS), infrared (IR), nuclear magnetic resonance (NMR), a mass spectrum, and molar extinction at relevant wavelengths, where relevant [(1)].

3.5. Solubility in water, including effect of pH (5 to 9) and temperature on solubility [(1)].

3.6. Partition coefficient n-octanol/water, including effect of pH (5 to 9) and temperature on its value [(1)].

3.7. Thermal stability. Identity of relevant breakdown products.

3.8. Flammability including auto-flammability and identity of combustion products.

3.9. Flash-point

3.10. Surface tension.

3.11. Explosive properties.

3.12. Oxidising properties.

3.13. Reactivity towards container material.

4. Analytical methods of detection and identification.

4.1. Analytical methods for determination of the pure active substance and, where appropriate, the degradation products, isomers and impurities of the active substance and additives (e.g. stabilisers).

4.2. Analytical methods, including recovery rates and the limits of determination for the active substance, and for residues thereof in the following:

a) soil;

b) air;

c) water (including drinking water)

The applicant should confirm that the active substance itself and any of its degradation products which fall within the definition of pesticides given in the "Notes" to Table B "Chemical indicators" in Appendix No. 1 to Article 3, item 2 of Regulation No. 9 on the quality of water intended for human consumption (promulgated, SG No. 30/2001) can be estimated with adequate reliability at the MAC (maximum allowable concentration) specified in the above regulation.

d) biological samples – animal and human body fluids and tissues.

5. Effectiveness against target organisms and intended uses

5.1. Function, e.g. fungicide, rodenticide, insecticide, bactericide.

5.2. Organisms to be controlled and products, organisms or objects to be protected.

5.3. Effects on target organisms and recommended concentrations at which the active substance should be used.

5.4. Mode of action, including time delay.

5.5. Field of use envisaged.

5.6. User category (mass or professional).

5.7. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies.

5.8. Likely quantity of the active substance to be placed on the market per year.

6. Toxicological studies, including metabolic studies.

6.1. Acute toxicity

For the purposes of items 6.1.1 - 6.1.3 substances other than gases shall be tested via at least two routes of administration, one of which should be the oral route. The choice of the second route will depend on the nature of the active substance and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route.

6.1.1. Oral.

6.1.2. Dermal.

6.1.3. Inhalation.

6.1.4. Skin and eye irritation. Studies for eye irritation shall not be required where evidence of corrosivity is available.

6.1.5. Skin sensitisation.

6.2. Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study.

For the following studies, 6.3 (where necessary), 6.4, 6.5, 6.7 and 6.8, the required route of administration is the oral route unless it can be justified that an alternative route is more appropriate

6.3. Repeated dose toxicity (28 days).

This study is not required when a sub-chronic toxicity study is available in a rodent.

6.4. Subchronic toxicity – repeated (90-day) study, two species, one rodent and one non-rodent.

6.5. Chronic toxicity – study of two test species (one rodent and one other mammalian species).

The study for chronic toxicity shall not be required if convincing evidence is provided that such a study is not necessary.

6.6. Mutagenicity studies

6.6.1. *In-vitro* gene mutation study in bacteria.

6.6.2. *In-vitro* cytogenicity study in mammalian cells.

6.6.3. *In-vitro* gene mutation assay in mammalian cells.

6.6.4. If positive in 6.6.1, 6.6.2 or 6.6.3, then an *in-vivo* mutagenicity study will be required (bone marrow assay for chromosomal damage or a micronucleus test).

6.6.5. If negative in 6.6.4 but positive *in-vitro* tests then undertake a second *in-vi*vo study to examine the genotoxic effect in tissue other than bone marrow.

6.6.6. If positive in 6.6.4 then a test to assess possible germ cell effects may be required.

6.7. Carcinogenicity study

Study of two test species (one rodent and one other mammalian species). These studies may be combined with those in 6.5.

The arcinogenicity study shall not be required if convincing evidence is provided that such a study is not necessary.

6.8. Reproductive toxicity.

In specific cases the applicant may declare that such a study is not necessary and must provide convincing evidence thereof.

6.8.1. Teratogenicity test — study of two mammalian species (rabbit and one rodent species).

6.8.2. Fertility study (at least two generations, one species, male and female).

6.9. Medical data in anonymous form.

6.9.1. Medical surveillance data on manufacturing plant personnel (if available).

6.9.2. Direct observation of poisoning incidents, if data is available.

6.9.3. Health records – from industry or any other available sources.

6.9.4. Epidemiological studies on the general population, if available.

6.9.5. Diagnosis of poisoning, including specific signs of poisoning, clinical and paraclinical tests, if available.

6.9.6. Sensitisation/allergenicity observations, if available.

6.9.7. Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment.

6.9.8. Prognosis following poisoning.

6.10. Summary of studies of mammals, including no observed adverse effect level (NOAEL), no observed effect level (NOEL), overall evaluation with regard to all toxicological data and any other

information concerning the active substance. Where possible any suggested worker protection measures should be included in summary form.

7. Ecotoxicological studies.

7.1. Acute toxicity to fish.

7.2. Acute toxicity to Daphnia magna.

7.3. Growth inhibition test on algae.

7.4. Inhibition to microbiological activity.

7.5. Bioconcentration. Fate and behaviour in the environment.

7.6. Degradation.

7.6.1. Biotic degradation.

7.6.1.1. Ready biodegradability.

7.6.1.2. Inherent biodegradability, where appropriate.

7.6.2. Abiotic degradation.

7.6.2.1. Hydrolysis as a function of pH and identification of breakdown products.

7.6.2.2. Phototransformation in water including identity of the products of transformation[(1)].

7.7. Adsorption/desorption screening test.

Where the results of this test indicate the need to do so, the test described in Appendix 6, section 7, item 1.2 and/or in Appendix 6, section 7, item 2.2 shall be required.

7.8. Summary of ecotoxicological effects and fate and behaviour in the environment.

8. Measures necessary to protect man, animals and the environment

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

8.2. In case of fire – nature of combustion gases and reaction products, means for achieving the best fire-fighting effect.

8.3. Emergency measures in case of an accident.

8.4. Possibility of destruction or decontamination following release in the air, water, including drinking water, and soil.

8.5. Procedures for waste management of the active substance for professional users.

8.5.1. Possibilities of reuse or recycling.

8.5.2. Possibilities of neutralisation of effects.

8.5.3. Conditions for controlled discharge, including qualities of wastewater.

8.5.4. Conditions for controlled incineration of residues.

8.6. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms.

9. Classification and labelling.

9.1. Justified proposal for the classification and labelling.

9.1.1. Category/categories of danger, hazard symbols and indications of danger, risk phrases, safety phrases.

10. Summary and evaluation of Sections 2 to 9.

Notes:

(1) These data must be submitted for the purified active substance of stated specification.

(2) These data must be submitted for the active substance of stated specification.

Appendix No. 6
to Article 5, Paragraph 6

Additional data set on an active substance which is a chemical substance

The dossiers shall address at least all the points listed under 'Dossier requirements'. The information is required to be supported by the respective data. The dossier requirements must be in line with technical development.

Certain information included in the requirements need not be supplied where it is not technically possible or scientifically necessary to supply the information, or owing to the nature of the biocidal product or its intended use. In such cases the applicant shall submit an acceptable written justification, such as reference to the existence of a frame-formulation, where the applicant holds a declaration for use of information.

I. Physical and chemical properties

1. Solubility in organic solvents, including effect of temperature on solubility. These data shall be provided for the chemically purified active substance of the respective specification.

2. Stability in organic solvents used in biocidal products; identity of relevant breakdown products. These data must be submitted for the active substance of stated specification.

II. Analytical methods for detection and identification.

1. Analytical methods, including recovery rates and the limits of determination for the active substance, and for residues thereof, in/on food or feedstuffs and other products where relevant.

III. Toxicological studies, including metabolic studies

1. Neurotoxicity study

Neurotoxicity studies will be required if the active substance is an organophosphorus compound or if there are any other indications of neutrotoxicity. The test species is the adult hen or another more appropriate test species.

If appropriate, delayed neurotoxicity tests will be required. If anticholine esterase activity is detected a test for response to reactivating agents should be considered.

2. Toxic effects on livestock and pets.

3. Studies related to the exposure of the active substance to humans.

4. Food and feedingstuffs studies.

If the active substance is contained in biocidal products for use where food for human consumption is prepared, consumed or stored (where feedingstuff for livestock is prepared, consumed or stored) the tests referred to in Section V, item 1 shall be required

5. If any other tests related to the exposure of the active substance are considered necessary, then the tests referred to in Section VI, item 2 shall be required.

6. If the active substance is used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, where different from those identified in animals, shall be required.

7. Mechanistic study of toxic effects — any studies necessary to clarify effects reported in toxicity studies.

IV. Ecotoxicological studies

1. Acute toxicity test on one other non-target organism (with the exception of aquatic organisms).

2. If the results of the ecotoxicological studies and the use of the active substance indicate possible danger for the environment, then the tests described in Sections VII and VIII shall be required.

3. If the result of the test referred to in Appendix No. 5, item 7.6.1.2 is negative and if the likely route of disposal of the active substance is by sewage treatment, then the tests described in Section VIII, item 4.1 shall be required.

4. Depending on the results of the tests referred to in Appendix No. 5, item 7.6.1.1 and item 7.6.1.2, other biodegradability tests of the active substance may be required.

5. Test for phototransformation in air (estimation method to be indicated); the test should include identification of breakdown products. These data must be submitted for the chemically purified active substance of stated specification.

6. The tests described in Section VII, item 1.1, item 2.1 and item 3 (where appropriate) shall be required if the results from Appendix No. 5, item 7.6.1.2 or from paragraph 4, above, indicate the need to do so, or the active substance has an overall low or absent abiotic degradation.

V. Measures necessary to protect humans, animals and the environment.

1. Identification of any substances falling within the scope of Appendix No. 1 and Appendix No. 2 to Regulation No. 1 on the exploration, use and protection of groundwater (promulgated, SG No. 25/2000).

VI. Further human health-related studies.

1. Food and feedingstuffs studies.

1.1. Identification of degradation and reaction products and of metabolites of the active substance in treated or contaminated foods or feedstuffs.

1.2. Behaviour of the residue of the active substance, its degradation products and its metabolites on the treated or contaminated food or feedstuffs, including the kinetics of disappearance.

1.3. Overall material balance for the active substance. Sufficient residue data from supervised trials to demonstrate that residues likely to arise from the proposed use would not be of concern for human or animal health.

1.4. Estimation of potential or actual exposure of the active substance to humans through diet (food) and other means.

1.5. If residues of the active substance remain on feedingstuffs for a significant period of time, then toxicokinetic studies in livestock shall be required to permit evaluation of residues in food of animal origin.

1.6. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the active substance.

1.7. Proposed acceptable residues and the justification of their acceptability.

1.8. Any other available information that is relevant.

1.9. Summary and evaluation of Sections 1.1 to 1.8.

2. Other tests related to the exposure to humans (conducted where necessary).

VII. Further studies on fate and behaviour of the active substance in the environment.

1. Fate and behaviour in soil.

1.1. Rate and route of degradation including identification of the transformation processes involved, the metabolites and degradation products in at least three soil types under appropriate conditions.

1.2. Absorption and desorption in at least three soil types and, where relevant, absorption and desorption of metabolites and degradation products.

1.3. Mobility (migration) in at least three soil types and where relevant mobility of metabolites and degradation products.

1.4. Extent and nature of residues.

2. Fate and behaviour in water

2.1. Rate and route of degradation in aquatic systems, including identification of metabolites and degradation products, as far as such data are not presented with relation to the requirements of Appendix No. 5, item 7.6.

2.2. Absorption and desorption in water (soil sediment systems) and, where relevant, absorption and desorption of metabolites and degradation products.

3. Fate and behaviour in air

The rate and route of degradation of the active substance in air shall be determined (as far as tests have not been conducted with relation to the requirements of Section IV, item 5), in the following cases: if the active substance is to be used in preparations for fumigants, if it is to be applied by a spray method, if it is volatile, or if any other information indicates that this is relevant.

4. Summary and evaluation of items 1, 2 and 3.

VIII. Further ecotoxicological studies.

1. Effects on birds.

1.1. Acute oral toxicity — this need not be done if an avian species was selected for study in Section IV, item 1.

1.2. Short-term toxicity — eight-day dietary study in at least one test species (other than chickens).

1.3. Effects on reproduction.

2. Effects on aquatic organisms.

2.1. Chronic toxicity to fish.

2.2. Effects on reproduction and growth rate of fish.

2.3. Bioaccumulation in fish.

2.4. *Daphnia magna* reproduction and growth rate.

Studies of fish shall be conducted with one species which has been selected as most appropriate.

3. Effects on other non-target organisms.

3.1. Acute toxicity to honeybees and other beneficial arthropods. A different test animal shall be chosen from that used in Section IV, item 1.

3.2. Toxicity to earthworms and to other soil non-target macro-organisms.

3.3. Effects on other soil non-target organisms.

3.4. Effects on any other specific, non-target organisms from the flora and fauna believed to be at risk.

4. Other effects.

4.1. Activated sludge respiration inhibition test.

5. Summary and evaluation of sections 1, 2, 3 and 4.

Appendix No. 7
to Article 5, Paragraph 7

Main dossier requirements for an active substance an active substance which is a micro-organism, including viruses and fungi

The dossiers shall address at least all the points listed under 'Dossier requirements'. The information is required to be supported by the respective data. The dossier requirements must be in line with technical development.

Certain information included in the requirements need not be supplied where it is not technically possible or scientifically necessary to supply the information, or owing to the nature of the biocidal product or its intended use. In such cases the applicant shall submit an acceptable justification, such as reference to the existence of a frame-formulation, where the applicant holds a declaration for use of information.

I. Content

1. Information on the person placing the active substance on the market and on the manufacturer of the active substance.

2. Identity of the active organism.

3. Source of the active organism.

4. Methods of detection and identification.

5. Biological properties of the active organism, including pathogenicity and infectivity for target and non-target organisms and for man.

6. Effectiveness and intended uses.

7. Toxicological profile for man and animals including metabolism of toxins.

8. Ecotoxicological profile, including environmental fate and behaviour of the organisms and of toxins they produce.

9. Measures necessary to protect man, non-target organisms and the environment.

10. Classification and labelling

11. Summary and evaluation of Sections 2 to 10.

II. Dossier requirements

1. Information on the person placing the active substance on the market and on the manufacturer of the active substance

1.1 Name, address, telephone number of the person placing the active substance on the market.

1.2 Name and address of the manufacturer of the active substance and address of the manufacturing facility.

2. Identity of the organism

2.1. Common name and synonyms.

2.2. Taxonomic name and strain indicating whether it is a stock variant or a mutant strain. For viruses the taxonomic designation of the agent, serotype, strain or mutant shall be given.

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

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

3. Source of the organism.

3.1 Occurrence in nature or otherwise.

3.2. Isolation methods for the organism or active strain.

3.3. Culture methods.

3.4. Production methods, including details of containment and procedure to maintain quality and ensure a uniform source of active organism. For mutant strains detailed information should be provided on their production and isolation, together with all known differences between the mutant strains and parent and naturally occurring strains.

3.5 Composition of the final active organism material: nature, purity, identity, properties, content of any impurities and extraneous organisms.

3.6. Methods to prevent contamination of seed stock and loss of virulence of seed stock.

3.7. Procedures for waste management.

4. Methods of organism detection and identification.

4.1. Methods for establishing the presence and identity of the organism.

4.2. Methods for establishing the identity and purity of seed stock from which batches are produced; results obtained, including information on variability.

4.3. Methods to show the microbiological purity of the final product and limitation of contaminants to acceptable levels; the results obtained and information on variability.

4.4. Methods used to show that there are no human or other mammalian pathogens as contaminants in the active agent, including, in the case of protozoa and fungi, the effects of temperature (35°C and other relevant temperatures).

4.5. Methods to determine viable and non-viable residues (e.g. toxins) in or on treated products, foodstuffs, feedingstuffs, animal and human body fluids and tissues, soil, water and air, where relevant.

5. Biological properties of the organism

5.1. Characteristics of the organism and its uses, including its origin and its geographical distribution, if relevant.

5.2. Relationship to existing pathogens of vertebrates, invertebrates, plants or other organisms.

5.3. Effects on target organisms. Pathogenicity or kind of antagonism to the host. Details of host specificity range for the active organism.

5.4. Transmissibility, infective dose and mode of action, including information on presence, absence or production of toxins. In the case of presence or production of toxins – information on the nature, identity, chemical structure, stability and biological effects of the toxins.

5.5. Possible effects on non-target organisms closely related to the target organisms (e.g. having the same habitat), including infectivity, pathogenicity, and transmissibility.

5.6. Transmissibility to other non-target organisms.

5.7 Any other biological effects on non-target organisms when properly used.

5.8. Infectivity and physical stability when properly used.

5.9. Genetic stability under environmental conditions of proposed use.

5.10. Any pathogenicity and infectivity to man and animals under conditions of immunosuppression.

5.11. Pathogenicity and infectivity for known parasites/predators of the target species.

6. Effectiveness and intended uses

6.1. Target organisms and materials, substances, organisms or products to be treated or protected.

6.2. Uses envisaged (e.g. insecticide, disinfectant, etc.)

6.3. Information or observations on undesirable or unintended side effects.

6.4. Information on the occurrence or possible occurrence of the development of resistance and possible methods for prevention and control.

6.5. Effects on target organisms.

6.6. Category of use.

7. Toxicological studies, including metabolic studies

7.1. Acute toxicity.

In cases where a single dose is not appropriate, a set of range finding tests must be carried out to reveal highly toxic agents and infectivity.

7.1.1. Oral.

7.1.2. Dermal.

7.1.3. Inhalation.

7.1.4. Skin and, where necessary, eye irritation.

7.1.5. Skin sensitisation and, where necessary, respiratory sensitisation.

7.1.6. For viruses and viroids, data from cell culture studies using purified infective virus and primary cell cultures of mammalian, avian and fish cells shall be provided.

7.2. Sub-chronic toxicity – 40-day study, two species, one rodent, one non-rodent.

7.2.1. Oral administration.

7.2.2. Other routes (inhalation, dermal), as appropriate.

7.2.3. For viruses and viroids – test for infectivity carried out by bio assay or on a suitable cell culture (at least seven days after administration to test animals).

7.3. Chronic toxicity – two test species (rodent and one other mammal), oral administration or another more appropriate route.

7.4. Carcinogenicity study - may be combined with studies in 7.3. Two test species are required (one rodent and one other mammalian species).

7.5. Mutagenicity studies – conducted in accordance with the requirements of Appendix No. 5, Section 6, item 6.6.

7.6. Reproductive toxicity

Teratogenicity test — rabbit and one rodent species; fertility study — one species (minimum of two generations, male and female).

7.7. Metabolism studies – basic toxicokinetics, absorption (including dermal absorption), distribution and excretion in mammals, including elucidation of metabolic pathways.

7.8. Neurotoxicity studies – required where there is any indication of anticholinerterase activity or other neurotoxic effects. Adult hens may be used to perform delayed neurotoxicity tests.

7.9. Immunotoxicity studies (e.g. allergenicity).

7.10 Incidental exposure studies – required where the active substance will be in products for use where human food or animal feedingstuffs are prepared, consumed or stored and where humans, livestock or pets are likely to be exposed to treated areas or materials.

7.11. Human exposure data:

7.11.1. Medical data in anonymous form, if available.

7.11.2. Health records and medical surveillance data on active substance manufacturing plants personnel, if available.

7.11.3. Epidemiological data, if available.

7.11.4. Poisonous incidents data, if available.

7.11.5. Diagnosis of poisoning (specific signs, clinical and paraclinical tests).

7.11.6. Proposed treatment of poisoning and prognoses.

7.12. Summary of mammalian toxicology — conclusions, including no-observed-adverse-effect levels (NOAEL), no observed effect level (NOEL) and if appropriate admissible daily intake (ADI), overall evaluation with regard to all toxicological, pathogenicity and infectivity data and any other information concerning the active organism and, where possible, suggested user protection measures.

8. Ecotoxicological studies

8.1. Acute toxicity to fish.

8.2. Acute toxicity to *Daphnia magna*.

8.3. Effects on algae growth (inhibition test).

8.4. Acute toxicity on other, non-aquatic, non-target organisms.

8.5. Pathogenicity and infectivity for honeybees and earthworms.

8.6. Acute toxicity and/or pathogenicity and infectivity for other non-target organisms believed to be at risk.

8.7. Effects (if any) on other flora and fauna.

8.8. In cases where toxins are produced, data as outlined in Appendix No. 5, Section VII, items 7.1 to 7.5 should be produced.

Fate and behaviour in the environment

8.9. Fate and behaviour in the environment – spread, mobility, multiplication and persistence in air, soil and water.

8.10. In cases where toxins are produced, data as outlined in Appendix No. 5, Section VII, items 7.6 to 7.5 should be produced. -7.8.

9. Measures necessary to protect humans, non-target organisms and the environment.

9.1. Methods and precautions to be taken for storage, handling, transport and use; or in the event of fire or other likely incident.

9.2. Any circumstances or environmental conditions under which the active organism should not be used.

9.3. Appropriate methods for rendering the active organism non-infective.

9.4. Consequences of the contamination of air, soil and water, particularly drinking water.

9.5. Emergency measures in case of an accident.

9.6. Procedures for waste management of the active organism, including qualities of wastewater on disposal.

9.7. Possibility of destruction or decontamination of the active organism following release in or into the air, water, soil, or other media.

10. Classification and labelling

Proposals for classification of the micro-organism in one of the risk groups outlined in Regulation No. 4 on the protection of workers from the risks related to the exposure to biological agents at work (promulgated, SG No. 105/2002), together with indications on the need for products to carry the biohazard sign.

11. Summary and evaluation of Sections 2 to 10.

Appendix No. 8
to Article 7, Paragraph 2

Main dossier requirements for a low-risk biocidal product

The dossiers shall address at least all the points listed under 'Dossier requirements'. The information is required to be supported by the respective data. The dossier requirements must be in line with technical development.

Certain information included in the requirements need not be supplied where it is not technically possible or scientifically necessary to supply the information, or owing to the nature of the biocidal product or its intended use. In such cases the applicant shall submit an acceptable written justification, such as reference to the existence of a frame-formulation, where the applicant holds a declaration for use of information.

Information may be derived from existing data where an acceptable justification is provided and the requirements of the regulation are complied with. Wherever possible, the requirements of Regulation No. 25 on the protection and humane treatment of animals used for experimental purposes (SG No. 59/2003) should be observed to minimise animal testing.

Dossier requirements

1. Information on the person placing the biocidal product on the market and on the manufacturer of the biocidal product and the active substance.

1.1 Name, address, telephone number of the person placing the biocidal product on the market.

1.2. Name and address of the manufacturer of the low-risk biocidal product if it is different from the person referred to in Paragraph 1.1.

1.3. Name and address of the manufacturer of the active substance if it is different from the person referred to in Paragraph 1 or item 1.2;

2. Identity

2.1. Trade name of the low-risk biocidal product.

2.2. Composition of the low-risk biocidal product.

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

2.2.1.1. Data on the active substance – dossier for the active substance pursuant to Appendix No. 5 and, where necessary, the respective data referred to in Appendix No. 6 or dossier pursuant to Appendix No. 7.

2.2.1.2. Information on the other components of the low-risk biocidal product.

2.3. Information on the physical and chemical properties, suitable for the mode of use, the field of application and the method of storage – data pursuant to Appendix No. 2, Section 3 or data pursuant to Appendix No. 3, Section 3 shall be provided.

3. Intended use

3.1. Type of product pursuant to Appendix No. 13

3.2. Field of application

3.3. Method of application3.4. Category of users

4. Efficacy

5. Analytical methods for determination of the type and the nature of the active substance in the low-risk biocidal product and its residues

6. Information on the classification, packaging and labelling, including a draft-design for the label.

Appendix No. 9
to Article 8

Common principles for the evaluation of the technical dossiers for biocides

Contents

A. INTRODUCTION

1. This Appendix lays down principles to ensure that evaluations made and decisions taken concerning the authorisation of a biocidal product containing an active substance which is a chemical substance will result in an efficient and comprehensive level of protection for humans, animals and the environmental compartments in accordance with Article 17, Para. 1, items 2-8 of the PAHICSP.

2. In order to ensure an efficient and comprehensive level of protection for humans, animals and the environmental compartments, any risks arising from the use of a biocidal product shall be identified and an assessment shall be carried out to determine the acceptability of any risks identified during the proposed normal use of the biocidal product. This assessment shall take into account the risks associated with the individual components of the biocidal product.

3. A risk assessment on the active substance or substances present in the biocidal product is always required. This assessment should have been carried out when a permit for placing the active substance on the market was issued and when it was listed in the register referred to in Article 15, Paragraph 1, item 1 of the PAHICSP. This risk assessment shall entail hazard identification, dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be made, a qualitative assessment shall be produced.

4. Additional risk assessments shall be carried out, in the same manner as described above, on any other substance of concern present in the biocidal product, where relevant for the intended use.

5. Data required in order to carry out a risk assessment are detailed in Appendices Nos. 2, 3, 4, 5, 6 and 7. Taking into account the wide variety of biocidal product types referred to in Appendix No. 13, the data are flexible according to the product type and associated risks. In conducting the risk assessment, due consideration should be taken of the requirements of Articles 17 and 18 of this Regulation in order to avoid duplication of data submissions. The minimum set of data required for an active substance in any biocidal product type shall be that detailed in Appendices No. 1 through 7 of the Regulation on the procedure and method of notification of new chemical substances (promulgated, SG No. 67/2002). These data will already have been submitted and assessed as part of the risk assessment required for the issue of a permit for placing an active substance on the market. Data may also be required on a substance of concern present in a biocidal product.

6. The results of the risk assessments carried out on an active substance and on a substance of concern present in the biocidal product shall be integrated to produce an overall risk assessment for the biocidal product itself.

7. When making evaluations and taking decisions concerning the authorisation of a biocidal product:

a) relevant and reasonably available technical or scientific information on the properties of the biocidal product, its components, metabolites, or residues shall be taken into consideration;

b) justifications submitted by the applicant for not supplying certain data shall be evaluated.

8. When evaluating tender dossiers it should be taken into account that many biocidal products present only minor differences in composition. With relation to this the concept of establishing frame-formulations may be applied.

9. The requirements referred to in this appendix shall also apply to low-risk biocidal products which shall be registered pursuant to the procedure described in Article 19h of the PAHICSP.

10. The application of these common principles shall facilitate the decision whether to permit the placing on the market of a biocidal product, and whether to include restrictions or other conditions on its use. In certain cases additional data may be required before an authorisation decision can be made.

11. During the process of evaluation and decision-making the Ministry of Health (MH) and the applicant shall cooperate actively in order to resolve any questions related to:

a) provision of additional data or studies and/or

b) clarification of the conditions for the use and/or

c) modification of the composition of the biocidal product in order to ensure full compliance with the requirements of this Appendix and this Regulation.

These actions shall apply especially for small and medium-sized enterprises without prejudicing the level of protection afforded to the population, non-target organisms and the environment.

12. During the evaluation and decision-making process conclusions must be based on scientific principles, preferably recognised at international level, and be made with the benefit of expert advice.

B. EVALUATION

I. GENERAL PRINCIPLES

1. The data submitted in support of an application for authorisation of a biocidal product shall be examined for completeness and overall scientific value. These data shall be utilised to carry out a risk assessment of the proposed use of the biocidal product.

2. A risk assessment on the active substances present in the biocidal product is always required. If there are any substances of concern present in the biocidal product, then a risk assessment shall be carried out for each of these as well. The risk assessment shall cover the proposed use of the product together with a realistic worst-case scenario, including any relevant production and disposal issue either of the biocidal product itself or any material treated with it.

3. For each active substance and each substance of concern present in the biocidal product, the risk assessment shall entail a hazard identification and the establishment of appropriate no-observed-adverse-effect levels (NOAEL), where possible. It shall also include a dose (concentration) — response (effect) assessment, together with an exposure assessment and a risk characterisation.

4. The results arrived at from a comparison of the exposure to the no-effect level concentrations for each of the active substances or substances of concern shall be integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available, the results of the qualitative assessments shall be integrated.

5. The risk assessment shall determine:

a) the risk to humans and non-target organisms;

b) the risk to the environment;

c) the measures necessary to protect humans, non-target organisms and the environment during both the proposed use of the biocidal product and in a realistic worst-case situation.

6. In certain cases it may be concluded that further data are required before a risk assessment can be finalised. These shall be kept to the necessary minimum.

II. EFFECTS ON HUMANS

1. The risk assessment shall take account of the potential effects arising from the use of the biocidal product and the populations liable to exposure.

2. The effects mentioned in (1) above result from the properties of the active substance and any substance of concern present. These effects are:

a) acute and chronic toxicity;

b) irritation;

c) corrosivity;

d) sensitization;

e) repeated dose toxicity;

f) mutagenicity;

g) carcinogenicity;

h) reproduction toxicity;

i) neurotoxicity;

j) any other special properties of the active substance or substance of concern;

k) other effects due to physico-chemical properties.

3. The populations mentioned in (1) above are:

a) professional users;

b) non-professional users;

c) humans exposed indirectly via the environmental compartments.

4. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the product being classified in one or more categories of danger referred to in Article 2 of the PAHICSP, then dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation shall be required.

5. Where the results of the tests appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern have not lead to classification of the biocidal product in one or more categories of danger, then risk characterisation in relation to that effect shall not be necessary, unless there are other reasonable grounds for concern, e.g. adverse environmental effects or unacceptable residues.

6. When carrying out a dose (concentration) —response (effect) assessment on an active substance or a substance of concern, items 7, 8, 9 and 10 shall apply.

7. For repeated dose toxicity and reproductive toxicity the "dose response" relationship shall be assessed for each active substance or substance of concern and, where possible, the no-observed-adverse-effect level (NOAEL) identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified.

8. For acute toxicity, corrosivity and irritation, it is not usually possible to derive a NOAEL or LOAEL on the basis of tests conducted in accordance with the requirements of this Regulation. For acute toxicity, the LD_{50} (median lethal dose) or LC_{50} (median lethal concentration) value or, where the fixed dose procedure has been used, the discriminating dose shall be derived. For the other adverse effects it shall be sufficient to determine whether the active substance or substance of concern present in the biocidal product has an inherent capacity to cause such effects during use of the product.

9. For mutagenicity and carcinogenicity it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product. If a certain active substance or a substance of concern identified as a carcinogen is non-genotoxic, it will be appropriate to identify a NOAEL or LOAEL, as described in item 7.

10. With respect to skin sensitisation and respiratory sensitisation, in so far as there is no consensus on the possibility of identifying a dose/concentration below which adverse effects are unlikely to occur in a subject already sensitised to a given substance, it shall be sufficient to evaluate whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product.

11. Data on toxic effects on humans (clinical and epidemiological data, as well as information gained from manufacture) is of significance to risk assessment and shall be given special consideration.

12. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed indirectly via the environmental compartments) for which exposure to a biocidal product occurs or can reasonably be foreseen. The objective shall be to make a quantitative or qualitative estimate of the dose/concentration of each active substance or substance of concern to which a population is, or may be exposed during use of the biocidal product.

13. The exposure assessment shall be based on the information in the technical dossier provided in conformity with Articles 5, 6 and 7 of this Regulation and on any other available information. Particular account shall be taken of:

a) reliable data from exposure measurement;

b) the form in which the biocide is marketed;

c) the type of the biocidal product according to Appendix No. 13;

d) the application method and application frequency;

e) the physico-chemical properties of the product;

f) the likely routes of exposure and potential for absorption;

g) the frequency and duration of exposure;

h) the type and size of specific exposed populations where such information is available.

14. When conducting the exposure assessment special consideration shall be given to representative and reliable data from exposure measurement. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. These models shall:

a) make a best possible estimation of the exposure, taking into account realistic parameters and assumptions;

b) be applied taking into account possible elements of uncertainty;

c) be validated with measurements carried out under circumstances relevant for the use of the model;

d) be relevant to the conditions in the area of use.

Relevant data from substances with analogous properties, use and exposure patterns shall also be considered.

15. Where, for any of the effects set out in item 2 a NOAEL or LOAEL had been identified, the risk characterisation shall entail comparison of the NOAEL or LOAEL with the evaluation of the exposure levels to which the population will be exposed. Where a NOAEL or LOAEL cannot be established, a qualitative comparison shall be made.

III. EFFECTS ON ANIMALS

1. The risks posed to animals from the biocidal product shall be considered using the same principles as described in the section dealing with effects on humans.

IV. EFFECTS ON THE ENVIRONMENT

1. The risk assessment shall take account of any adverse effects arising in any of the environmental compartments (air, soil and water, including sediment) and of the biota following the use of the biocidal product.

2. The hazard identification shall take into account the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. In the process of classification of the biocidal product dose (concentration) —response (effect) assessment, exposure assessment and risk characterisation shall be carried out.

3. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern has been conducted but the results have not led to classification of the biocidal product in one or more categories of danger, then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern. Such grounds may derive from the properties and effects of any active substance or substance of concern, in particular:

a) data on bioaccumulation;

b) characteristics of persistence in the environment;

c) shape of the toxicity/time curve in ecotoxicity testing;

d) indications of other adverse effects obtained from toxicity studies (e.g. mutagenic effects);

e) data on structurally analogous substances;

f) endocrine effects.

4. A dose (concentration) — response (effect) assessment shall be carried out in order to predict the exposure level below which adverse effects in the environmental compartments are not expected to occur. This assessment shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as the predicted no-effect concentration (PNEC). In some cases where it is not possible to establish a PNEC, a qualitative estimation of the relationship has to be made.

5. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of this Regulation. The PNEC shall be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g. LD_{50} (median lethal dose), LC_{50} (median lethal concentration), EC_{50} (median effective concentration), IC_{50} (average inhibiting concentration of a given parameter, e.g. growth), NOAEL, or LOAEL.

6. The safety assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. As a rule, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor.

The safety assessment factor shall be used in assessing risk to the environment pursuant to the Regulation on final assessment of the risk to man and the environment of new chemical substances (promulgated, SG No. 67/12.07.2002, effective 01.01.2004).

7. For each environmental compartment an exposure assessment shall be carried out in order to predict the concentration likely to be found of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). In cases where it is not possible to establish a PEC, a qualitative estimate of exposure has to be made.

8. The predicted environmental concentration (PEC) or the qualitative estimate of exposure need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions, including any relevant contribution from material treated with biocidal products, are known or are reasonably foreseeable.

9. The PEC, or qualitative estimation of exposure, shall be determined taking account of the following data on the biocidal product, depending on the specific case:

a) reliable data from exposure measurement;

b) the form in which the biocide is placed on the market;

c) the type of the biocide pursuant to Appendix No. 13;

d) the application method and frequency;

e) the physico-chemical properties;

f) breakdown/transformation products;

g) likely pathways to environmental compartments and potential for adsorption/desorption and degradation,

h) the frequency and duration of exposure;

10. When conducting the exposure assessment special consideration shall be given to representative and reliable data from exposure measurement. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall correspond to the requirements of Section II "Effects on humans", item 14. Depending on the specific case, relevant data from substances with analogous properties, use and exposure patterns may also be considered

11. For any given environmental compartment, the risk characterisation shall entail comparison of the PEC with the PNEC and calculation of the PEC/PNEC ratio.

12. If it is not possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.

V. Adverse effects

1. It shall be necessary to submit data in order to assess whether the biocidal product does not cause unnecessary suffering and pain in its effect on target vertebrates. This shall include an evaluation of the mechanism by which the effect is obtained and the observed effects on the behaviour and health of the vertebrates. Where the intended effect is to kill the vertebrate, the time necessary to obtain the death of the target vertebrate and the conditions under which death occurs shall be evaluated.

2. Where relevant, the possibility of the development of resistance to an active substance by the target organism shall be evaluated.

3. If there are indications, the possibility that other adverse effects may occur shall be evaluated, for example an adverse reaction to fastenings and fittings used in wood following the application of a wood preservative.

VI. Efficacy

1. Data shall be submitted and evaluated to ascertain if the efficacy claims of the biocidal product can be substantiated. Data submitted by the applicant or held by the Ministry of Health must be able to demonstrate the efficacy of the product when used in accordance with the conditions of the permit.

2. Testing should be carried out according to Community guidelines if these are available and applicable. Where appropriate, the following may be used as well:

a) European or other international standard methods (ISO, CEN or other international organisations);

b) national standard methods;

c) industry methods (accepted by the MH and/or the Ministry of Environment and Water);

d) individual biocidal product producer methods (accepted by the MH and/or the Ministry of Environment and Water);

e) data from the actual development of the biocidal product (accepted by the MH and/or the Ministry of Environment and Water).

Field data can be used as well.

VII. Summary

1. For an overall assessment of the biocidal product, the results for the active substance together with the results for the substances of concern from the assessment of risk to man, animals, and the environment shall be combined. This assessment should take account of any likely synergistic effects of the active substance and substances of concern.

2. For the overall assessment of biocidal products containing more than one active substance any adverse effects of these substances shall also be combined.

C. Decision-making

I. General principles

1. Subject Part D, item 3, the MH shall come to a decision regarding the permit to place a biocidal product on the market as a result of the overall assessment of the risks arising from each active substance and each substance of concern present in the biocidal product. The risk assessment shall cover the normal use of the biocidal product together with a realistic worst-case scenario, including any relevant production and disposal issue either of the biocidal product itself or any material treated with it.

2. The decision shall be made on one of the following conclusions for each product type pursuant to Appendix No. 13 and for each area of use of the biocidal product for which application has been made:

a) the biocidal product cannot be permitted;

b) the biocidal product can be authorised subject to specific conditions/restrictions;

c) more data is required before a decision can be made.

3. If the conclusion arrived is that additional information or data are required, then the need for any such information or data shall be justified. This required additional information or data for the risk assessment shall be the minimum necessary.

4. When a decision is made to permit a biocidal product based on a frame formulation, the requirements concerning the frame formulation shall be applied.

5. When a decision is made to permit a low-risk biocidal product, the requirements concerning such products shall be applied.

6. Permits shall only be granted to those biocidal products which:

a) when used according to their envisage conditions of use, do not present an unacceptable risk to humans, non-target organisms or the environment;

b) are sufficiently effective;

c) contain active substances determined by this Regulation or listed in the register referred to in Article 15, Paragraph 1, item 1 of the PAHICSP.

7. Where appropriate, when the permit is issued, conditions or restrictions on use shall be imposed. These conditions/restrictions shall be selected on the basis of the nature and extent of the expected advantages and the risks likely to arise from the use of the biocidal product.

8. In the decision-making process the following shall be taken into consideration:

a) the results of the risk assessment, in particular the relationship between exposure and effect;

b) the nature and severity of the effect;

c) the risk management which can be applied;

d) the field of use;

e) the efficacy;

f) the physical properties;

g) the benefits of using the biocide.

9. When a decision is made, the uncertainty arising from the variability in the data used in the evaluation shall be taken into account.

10. Biocidal products placed on the market shall be used in compliance with the requirements of the permit issued, including with respect to the mode of use (working solutions, dose rate).

11. In order to have a permit issued, the applicant shall propose a label in accordance with the requirements of this Regulation, and, where relevant, the safety-data sheet referred to in Article 7b of the PAHICSP:

12. The applicant shall proposes packaging and, where appropriate, the procedures for destruction or decontamination of the biocide and its packaging or any other material contaminated by it. The proposed packaging and procedures shall conform to the statutory requirements.

II. Effects on humans

1. The placing on the market of a biocide shall not be permitted if the risk assessment confirms that, in the envisaged application including a realistic worst possible scenario, the product presents an unacceptable risk to humans.

2. When a decision is made to permit the placing on the market of a biocide, the possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environmental compartments, shall be considered.

3. When a decision is made to permit the placing on the market of a biocide, data on the relationship between the exposure and the effect/response shall be used. A number of factors need to be considered when examining this relationship and one of the most important is the nature of the adverse effect of the substance. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, reproduction toxicity. Account shall be taken of the physico-chemical properties, and any other adverse properties of the active substance or substance of concern present in the biocide.

4. Where possible, the results obtained shall be compared with those obtained from previous risk assessments for an identical or similar adverse effect and a decision shall be made on an appropriate margin of safety (MOS). The MOS value is typically 100 but an MOS higher or lower than this may be appropriate depending on, among other things, the nature of the critical toxicological effect.

5. If appropriate, a condition for permitting a biocide may be the wearing of personal protective equipment (devices for respiratory protection, protective clothing, gloves, goggles, etc.) order to reduce exposure for professional operators. Personal protective equipment must be readily available and easily accessible.

6. A biocidal product intended for mass use shall not be permitted if the wearing of personal protective equipment would be the only possible method for reducing exposure.

7. A biocidal product shall not be issued where the level of exposure cannot be reduced to an acceptable level.

8. Biocidal products classified as toxic, very toxic, carcinogenic (category 1 or 2), mutagenic (category 1 or 2) and classified as toxic for reproduction (category 1 or 2) shall not be authorised for non-professional use.

III. Effects on animals

1. A biocidal product shall not be permitted if the risk assessment confirms that, in intended use, the product presents an unacceptable risk to non-target animals.

2. When making decisions, the risks posed to animals shall be assessed using the same relevant criteria as described in the section dealing with effects on humans.

IV. Effects on the environment

1. A biocidal product shall not be permitted if the risk assessment confirms that the active substance, or any substance of concern, or any degradation, or reaction product presents an unacceptable risk in any of the environmental compartments (water, including sediment, soil and air) and/or non-target animals.

In considering the acceptability of the risk and when coming to a final decision in accordance with Part D, item 2, the criteria referred to in items 4 – 12 shall be taken into account.

2. The basic tool used in the decision making is the PEC/PNEC ratio. Where these concentrations are not available, a qualitative estimation shall be used. Due consideration shall be given to the elements of uncertainty and variability which occur when estimating concentrations.

In the determination of the PEC the most appropriate model should be used, taking into account the environmental fate and behaviour of the biocidal product.

3. For any given environmental compartment if the PEC/PNEC ratio is equal to or less than 1, the risk characterisation shall be that no further information and/or testing are necessary.

If the PEC/PNEC ratio is greater than 1, on the basis of the size of that ratio and on other relevant factors pursuant to Part B “Evaluation”, Section IV "Effects on the environment”, item 3, it shall be judged if risk reduction measures are necessary, or if further information and/or testing are required to clarify the concern, or if the product cannot be permitted at all.

Water

4. A biocidal product shall not be permitted if under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in water, incl. its sediments, has an unacceptable impact on non-target species (in the aquatic, marine or estuarine environment), unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

5. A biocidal product shall not be permitted if under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in groundwater exceeds the lower of the following concentrations:

a) the maximum permissible concentration laid down by Regulation No. 9 on the quality of water intended for human consumption (promulgated, SG No. 30/2001), or

b) the maximum concentration as laid down when permitting the active substance on the basis of appropriate data, in particular toxicological data

The biocidal product may be permitted if it is scientifically demonstrated that under relevant field conditions the lower of the two concentrations is not exceeded.

6. A biocidal product shall not be permitted if the foreseeable concentration of the active substance or a substance of concern or of relevant metabolites, breakdown or reaction products to be expected in surface water or its sediments after use of the biocidal product under the proposed conditions of use:

a) exceeds the values laid down by Regulation No. 9 on the quality of water intended for human consumption (promulgated, SG No. 30/2001) and Regulation No. 12 on the quality required of surface water intended for the abstraction of drinking water (promulgated, SG No. 63/2002) in the areas of water abstraction, before it is taken to the drinking water supply facilities,

b) has an impact deemed unacceptable on non-target species.

The biocidal product may be permitted if it is scientifically demonstrated that under relevant field conditions these concentrations are not exceeded.

7. The proposed instructions for use of the biocidal product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of water or its sediments is minimised.

Soils

8. Where unacceptable contamination of soil is likely to occur, the biocidal product shall not be permitted if the active substance or substance of concern contained in it, after use of the biocidal product:

a) during tests in the field, persists in soil for more than one year, or

b) during laboratory tests, forms non-extractable residues in amounts exceeding 70 % of the initial dose after 100 days with a mineralization rate of less than 5% in 100 days, or

c) has adverse effects on non-target species.

The biocidal product may be permitted if it is scientifically demonstrated that under relevant field conditions there is no unacceptable accumulation in soil.

Air

9. A biocidal product shall not be permitted where there is a foreseeable possibility of unacceptable effects on the air compartment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Effects on target organisms

10. A biocidal product shall not be permitted where there is a foreseeable possibility of non-target organisms being exposed, if for any active substance or substance of concern present in it:

a) the PEC/PNEC is above 1, or

b) the bioconcentration factor related to fat tissues in non-target vertebrates is above 1.

The biocidal product may be permitted if it is clearly established in the risk assessment that under field conditions no unacceptable effects occur for non-target organisms, either directly or indirectly, after use of the product according to the proposed conditions of use.

11. A biocidal product shall not be permitted where there is a foreseeable possibility of aquatic organisms, including marine and estuarine organisms, being exposed to the biocidal product if for any active substance or substance of concern in it:

a) the PEC/PNEC is above 1, unless it is clearly established in the risk assessment that under field conditions the viability of aquatic organisms including marine and estuarine organisms is not threatened by the biocidal product according to the proposed conditions of use, or

b) the bioconcentration factor is greater than 1,000 for substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable, unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of exposed organisms, including marine and estuarine organisms, after use of the biocidal product according to the proposed conditions of use.

By way of derogation from item 11, the MH may permit the placing on the market of an anti-fouling product used on commercial, public service and naval seagoing vessels for a period of up to 10 years from the date on which this Regulation enters into force, if similar fouling control cannot be achieved by other practicable means. When implementing this provision, the MH shall take into account relevant International Maritime Organisation (IMO) resolutions and recommendations.

12. The biocidal product shall not be permitted where there is a reasonably foreseeable possibility of micro-organisms in sewage treatment plants being exposed to the biocidal product if for any active substance, substance of concern, relevant metabolite, breakdown or reaction product the PEC/PNEC ratio is above 1, unless it is clearly established in the risk assessment that under

field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of such micro-organisms.

V. Adverse effects

1. If the development of resistance to the active substance in the biocidal product is likely, steps shall be taken to minimise the consequences of this resistance. This may involve modification of the conditions of the permit or even refusal of a permit.

2. A permit for a biocidal product intended to control vertebrates shall not be given unless:

a) death is synchronous with the extinction of consciousness, or,

b) death occurs immediately, or,

c) vital functions are reduced gradually without signs of obvious suffering.

For repellent products, the intended effect shall be obtained without unnecessary suffering and pain for the target vertebrate.

VI. Efficacy

1. A biocidal product which does not possess acceptable efficacy when used in accordance with the conditions specified on the proposed label or with other conditions of the permit shall not be permitted.

2. The level, consistency and duration of protection, control or other intended effects must, as a minimum, be similar to those resulting from suitable reference products, where such products exist, or to other means of control. Where no reference products exist, the biocidal product must give a defined level of protection or control in the areas of proposed use. Conclusions as to the performance of the biocidal product must be valid for all areas of proposed use and for all areas, except where the proposed label prescribes that the biocidal product is intended for use in specific conditions and circumstances.

VII. Summary

1. For an overall assessment of the biocidal product, the MH shall combine the conclusions arrived at regarding the effects of the active substance or the substances of concern from the assessment of risk to man, animals, and the environment. A summary should also be made of the efficacy and of the adverse effects.

2. The results shall be:

a) a summary of the effects of the biocidal product on humans;

b) a summary of the effects of the biocidal product on animals;

c) a summary of the effects of the biocidal product on the environment;

d) a summary of the efficacy assessment;

e) a summary of adverse effects.

D. Overall integration of conclusions

1. For an overall assessment the MH shall combine the conclusions with regard to the effects of a given biocidal product on humans, animals and the environment and shall prepare an overall conclusion for the global effect of the biocidal product.

2. Before a decision is made to permit a biocidal product, due consideration shall be taken of any relevant adverse effects, the efficacy of the product and the benefits of using it.

3. The MH shall ultimately decide whether or not the biocidal product can be permitted and whether this permit shall be subject to any restrictions or conditions in conformity with this Appendix and this Regulation.

Note:

a) "Hazard identification" is the identification of the adverse effects which a biocidal product may cause.

b) "Dose (concentration) — response (effect) assessment" is the estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

c) "Exposure assessment" is the determination of the emissions, pathways and rates of movement of an active substance or a substance of concern in a biocidal product and its transformation or degradation in order to estimate the concentration/doses to which human populations, animals or environmental compartments are or may be exposed.

d) "Risk characterisation" is the estimation of the incidence and severity of the adverse effects likely to occur in a human population, animals and/or environmental compartments due to actual or predicted exposure to any active substance or substance of concern in a biocidal product. This may include 'risk estimation' i.e. the quantification of that likelihood.

e) "Environment" – water, including sediment, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with other living organisms.

Appendix No. 10
to Article 12, Paragraph 2

P E R M I T

FOR PLACING ON THE MARKET OF A BIOCIDAL PRODUCT

№...../

Pursuant to Article 14, Paragraph 1 of the Protection Against the Harmful Impact of Chemical Substances and Preparations Act and with relation to application submitted under incoming No. …….
I authorise the placing on the market of:

I. Trade name of the biocidal product

.....

II. Name and address of the person placing the biocidal product on the market

.....

III. Name and address of the manufacturer of the biocidal product

.....
.....

IV. Type of biocidal product pursuant to Appendix No. 13

.....

V. Type of the biocidal product (granules, liquid, powder, etc.)

.....

VI. Information on the active substance/substances present in the biocidal product

A. Chemical substance

Chemical name	
CAS and EC numbers, if available.	
Percentage in the composition of the biocidal product	

B. Micro-organism

Common name and synonyms	
Taxonomic name	
Strain	
Concentration of the active substance in the composition of the biocidal product;	

VII. Field/fields of application

.....

.....

VIII. Method of application

.....

.....……

IX. Classification of the biocidal product

A. Biocidal product containing an active substance/substances which is/are chemical substance/substances

Hazard symbols and indications of danger

.....

R-phrases

.....

B. Biocidal product containing an active substance/active substances which is/are micro-organisms, including viruses and fungi

1. Hazard symbols and indications of danger and R-phrases for the chemicals present in the product

.....

2. Risk group in which the active organism is classified in accordance with Regulation No. 4 on the protection of workers from the risks related to the exposure to biological agents at work (promulgated, SG No. 105/2002).

.....

.....

X. Information on the packaging (type, capacity/volume)

.....

.....

XI. Category of users

.....

.....

XII. Specific requirements and/or limitations.

Appendix No. 11
to Article 12, Paragraph 3

P E R M I T

FOR PLACING ON THE MARKET OF AN ACTIVE SUBSTANCE

№...../

pursuant to Art. 14, Para. 1 of the Protection Against the Harmful Impact of Chemical Substances and Preparations Act and with relation to application submitted under incoming No. …….

I authorise the placing on the market of:

I. Name of the active substance

A. Chemical substance

Chemical name	
CAS and EC numbers, if available.	
Percentage in the composition of the biocidal product	

B. Micro-organism

Common name and synonyms	
Taxonomic name	
Strain	
Concentration of the active organism in the composition of the biocidal product	

II. Name and address of the person placing the active substance on the market

.....
.....

III. Name and address of the manufacturer of the active substance

.....
.....

IV. Function, e.g. fungicide, rodenticide, insecticide, bactericide.

V. Type of the biocidal product according to Appendix No. 13 in whose composition the active substance may be included

VI. Type of the active substance (granules, liquid, powder, etc.)

VII. Field/fields of application

.....
.....

VIII. Method of application

.....
.....

IX. Classification of the active substance
A. Chemical substance
Hazard symbols and indications of danger
.....
R-phrases
.....

B. Micro-organisms, including viruses and fungi
Risk group in which the active organism is classified in accordance with Regulation No. 4 on the protection of workers from the risks related to the exposure to biological agents at work (promulgated, SG No. 105/8.11.2002).
.....
.....
X. Information on the packaging (type, capacity/volume)
.....
.....
XI. Category of users
.....
.....

XII. Specific requirements and/or limitations.

Appendix No. 12
to Article 12, Paragraph 4

CERTIFICATE
OF REGISTRATION OF A BIOCIDAL PRODUCT

№...../

pursuant to Art. 14, Para. 2 of the Protection Against the Harmful Impact of Chemical Substances and Preparations Act and with relation to application submitted under incoming No. …….

I authorise the placing on the market of:

I. Trade name of the biocidal product
.....
II. Name and address of the person placing the biocidal product on the market
.....
III. Name and address of the manufacturer of the biocidal product
.....
.....
IV. Type of biocidal product pursuant to Appendix No. 13
.....
V. Type of the biocidal product (granules, liquid, powder, etc.)
.....
VI. Information on the active substance/substances present in the biocidal product

A. Chemical substance

Chemical name	
CAS and EC numbers, if available.	
Percentage in the composition of the biocidal product	

B. Micro-organism

Common name and synonyms	
Taxonomic name	
Strain	
Concentration of the active organism in the composition of the biocidal product	

VII. Field/fields of application

.....
.....

VIII. Method of application

.....
.....

IX. Classification of the biocidal product

A. Biocidal product containing an active substance/substances which is/are chemical substance/substances

Hazard symbols and indications of danger

.....

R-phrases

.....

B. Biocidal product containing an active substance/active substances which is/are micro-organisms, including viruses and fungi

1. Hazard symbols and indications of danger and R-phrases for the chemicals present in the product

.....

2. Risk group in which the active organism is classified in accordance with Regulation No. 4 on the protection of workers from the risks related to the exposure to biological agents at work (promulgated, SG No. 105/2002).

.....
.....

X. Information on the packaging (type, capacity/volume)

.....…….
.....

XI. Category of users

.....
.....

XII. Specific requirements and/or limitations.

Appendix No. 13
to Article 15, Paragraph 2

Biocide Types

Group 1

Disinfectants and general biocides

This group excludes cleaning and washing products (liquids and powders) that are not intended to have a biocidal effect.

Subgroup 1: Human hygiene biocidal products

Subgroup 2: Disinfectants and other biocidal products used professionally and non-professionally to protect public health

Biocides from this subgroup are used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals. Usage areas include swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil, substrates in playgrounds, etc. This group includes biocides which are used as algaecides.

Subgroup 3. Veterinary hygiene biocidal products

Biocides from this subgroup are used for veterinary hygiene purposes, including products used in areas in which animals are housed, kept or transported.

Subgroup 4. Food and feed area disinfectants

Biocides from this subgroup are used for the disinfection of equipment, containers, consumption utensils, surfaces, pipework, etc. associated with the production, transport, storage or consumption of food, feed or drink, including drinking water, for humans and animals.

Subgroup 5. Drinking water disinfectants

Biocides from this subgroup are used for the disinfection of drinking water (for both humans and animals).

Group 2

Preservatives

Subgroup 6. In-can preservatives

Biocides from this subgroup are used for the preservation of manufactured products in containers from microbial deterioration to ensure their shelf life. This group does not include foodstuffs and feedingstuffs.

Subgroup 7. Film preservatives

Biocides from this subgroup are used for the preservation of films or coatings from microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works, etc.

Subgroup 8. Wood preservatives

Biocides from this subgroup are used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms.

Subgroup 9. Fibre, leather, rubber and polymerised materials preservatives

Biocides from this subgroup are used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.

Subgroup 10. Construction material preservatives (with the exception of wood)

Biocides from this subgroup are used for preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack.

Subgroup 11. Preservatives for liquid-cooling and processing systems

Biocides from this subgroup are used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.

This subgroup does not include biocides used for the preservation of drinking water.

Subgroup 12. Slimicides

Biocides from this subgroup are used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp in paper manufacturing, porous sand strata in oil extraction, etc.

Subgroup 13. Metalworking-fluid preservatives

Biocides from this subgroup are used for the preservation of metalworking fluids by the control of microbial deterioration.

Group 3

Biocides for pest control

Subgroup 14. Rodenticides

Biocides from this subgroup are used for the control of mice, rats or other rodents.

Subgroup 15. Avicides

Biocides from this subgroup are used for the control of damage-causing birds.

Subgroup 16. Molluscicides

Biocides from this subgroup are used for the control of molluscs (mussels and snails).

Subgroup 17. Piscicides

Biocides from this subgroup are used for the control of fish. Products for the treatment of fish diseases are excluded.

Subgroup 18. Insecticides, acaricides and products to control other arthropods

Biocides from this subgroup are used for the control of arthropods (e.g. insects, arachnids and crustaceans).

Subgroup 19. Repellents and attractants

Biocides from this subgroup are used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting. This group includes biocides that are used for human or veterinary hygiene either directly or indirectly.

Group 4

Other biocides

Subgroup 20. Biocides for the preservation of food or feedstocks by the control of harmful organisms.

Subgroup 21. Antifouling biocides

Biocides from this subgroup are used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

Subgroup 22. Embalming and taxidermist fluids

Biocides from this subgroup are used for the disinfection and preservation of human or animal corpses, or parts thereof.

Subgroup 23. Products for control of other vertebrates

Biocides from this subgroup are used for control of other damage-causing vertebrates (e.g. foxes, jackals).

Note:

The biocide types referred to in this Appendix do not include substances and products which are regulated by special laws, such as human medicine and veterinary medicine pharmaceutical products, cosmetic products, foodstuffs and feedingstuffs, radioactive substances and wastes and nuclear materials, waste, chemical substances and preparation in transit through the territory of the Republic of Bulgaria which are not processed or treated on the territory of the country, dangerous chemical substances and preparations transported by rail, sea, air or other land or water ways, invasive medical products or medical products intended for direct physical contact with the human body, plant protection products.