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Information and Notices

I

(Information)

COMMISSION

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2 September 1993

(93/C 239/01)

Currency amount for one unit:

Belgian and Luxembourg franc	41,0223	United States dollar	1,15466
Danish krone	7,89098	Canadian dollar	1,53051
German mark	1,90808	Japanese yen	122,164
Greek drachma	269,961	Swiss franc	1,67831
Spanish peseta	155,533	Norwegian krone	8,32282
French franc	6,71264	Swedish krona	9,46132
Irish pound	0,823819	Finnish markka	6,84716
Italian lira	1848,34	Austrian schilling	13,4287
Dutch guilder	2,14433	Icelandic krona	81,3461
Portuguese escudo	196,408	Australian dollar	1,73764
Pound sterling	0,770187	New Zealand dollar	2,09368

The Commission has installed a telex with an automatic answering device which gives the conversion rates in a number of currencies. This service is available every day from 3.30 p.m. until 1 p.m. the following day.

Users of the service should do as follows:

— call telex number Brussels 23789;

— give their own telex code;

— type the code 'cccc' which puts the automatic system into operation resulting in the transmission of the conversion rates of the ecu;

— the transmission should not be interrupted until the end of the message, which is marked by the code 'ffff'.

Note: The Commission also has an automatic telex answering service (No 21791) and an automatic fax answering service (No 296 10 97) providing daily data concerning calculation of the conversion rates applicable for the purposes of the common agricultural policy.

(1) Council Regulation (EEC) No 3180/78 of 18 December 1978 (OJ No L 379, 30. 12. 1978, p. 1), as last amended by Regulation (EEC) No 1971/89 (OJ No L 189, 4. 7. 1989, p. 1).

Council Decision 80/1184/EEC of 18 December 1980 (Convention of Lomé) (OJ No L 349, 23. 12. 1980, p. 34).

Commission Decision No 3334/80/ECSC of 19 December 1980 (OJ No L 349, 23. 12. 1980, p. 27).

Financial Regulation of 16 December 1980 concerning the general budget of the European Communities (OJ No L 345, 20. 12. 1980, p. 23).

Council Regulation (EEC) No 3308/80 of 16 December 1980 (OJ No L 345, 20. 12. 1980, p. 1).

Decision of the Council of Governors of the European Investment Bank of 13 May 1981 (OJ No L 311, 30. 10. 1981, p. 1).

List of establishments in Romania approved for the purpose of importing fresh meat into the Community

(93/C 239/02)

Commission Decision C(93) 2359 of 23 August 1993

(Council Directive 72/462/EEC, Article 4 (1))

Approval No	Establishment/Address	Category (*)							
		SL	CP	CS	B	S/G	P	SP	SR
1	Societatea Comerciala Carne Arad SA, Arad	×	×				×		T (1)
2	Carbac SA — Bacau	×	×		×		×		
8	Faplos SA — Tomesti — IASI	×	×				×		T
A 15	S. C. Glina SA, Bucuresti		×		×		×		
20	Societatea Comerciala Antrefrig SA, Bucuresti		×		×		×		
23	Frigorifer Sibiu, Sibiu		×		×		×		
30	Antrepozitul Frigo-Carnex, Timisoara		×		×		×		
33	Carial SA, Slobozia	×	×				×		T (1)
37	Galco, Galati	×	×		×		×		T
42	Frigoriferul, Suceava		×		×		×		
60	Societea Comerciala Cicales SA, Alexandria	×	×		×		×		T
61	Carbuz SA, Buzau	×	×		×		×		T (1)
68	Societea Comerciala Comt im Carnex, Timisoara	×	×		×		×		
83	Antrepozitul Frigorific Piatra Neamt, Piatra Neamt		×		×		×		

(*) SL: Slaughterhouse
CP: Cutting premises
CS: Cold store
B: Bovine meat
S/G: Sheepmeat/goatmeat
P: Pigmeat
SP: Meat from solipeds
SR: Special remarks

T: This establishment is authorized, within the meaning of Article 4 of Directive 77/96/EEC, to perform the examination for detection of trichinae provided in Article 2 of the aforementioned Directive.

(1) Fresh meat may be introduced into the territory of the Community only until 28 February 1994.

II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive concerning the placing of biocidal products on the market

(93/C 239/03)

COM(93) 351 final — SYN 465

(Submitted by the Commission on 27 July 1993)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas provisions relating to certain dangerous substances and preparations have already been laid down in Community directives; whereas it is still necessary to establish rules in respect of other products which contain dangerous substances and which may involve risks for man and the environment;

Whereas, in 1989, at the time of the adoption of the eighth Amendment (1) to Council Directive 76/769/EEC (2) on the marketing and use of certain dangerous substances and preparations, the Council invited the Commission to develop specific measures for Community action in the field of non-agricultural pesticides;

Whereas during the discussion in the Council on Directive 91/414/EEC (3), the Council expressed concern at the lack of harmonized Community provisions for non-agricultural pesticides and invited the Commission to examine the situation in Member States and the possibility for action at Community level;

Whereas the term 'non-agricultural pesticides' was formerly used to make a distinction with plant protection products which are essentially agricultural pesticides; whereas, however, biocidal product is now a more accurate and appropriate term to describe the products covered by this Directive;

Whereas biocidal products comprise a highly diverse group of products, including wood preservatives, rodenticides, insecticides, anti-foulings, surface and water biocides, disinfectants, fumigants, preservatives for technical and household materials, preservatives for works of art, and others; whereas they can give rise to exposure of man and the environment in a great variety of ways;

Whereas biocidal products are necessary for control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured products;

Whereas the Commission review showed a diverse regulatory status in the Member States; whereas there are rules in a few of the Member States governing the placing on the market for use of biocidal products and whereas these rules differ as to the conditions for such placing on the market and whereas such differences may constitute not only barriers to trade in biocidal products but also to trade in products treated with them, thereby affecting the functioning of the internal market;

Whereas in consequence the Commission concluded there was a need for action at Community level to eliminate such barriers by harmonizing the rules relating to the placing on the market for use of biocidal products, taking as a condition a high level of protection for man and the environment;

(1) OJ No L 398, 30. 12. 1989, p. 19.
(2) OJ No L 262, 27. 9. 1976, p. 201.
(3) OJ No L 230, 19. 8. 1991, p. 1.

Whereas therefore, the Commission made a statement towards the Council proposing the development of a framework of rules; whereas, having regard to the principle of subsidiarity, decisions taken at Community level should be restricted to those necessary for the proper functioning of the common market and to avoid duplication of work by Member States taking into account the necessity to ensure a high degree of protection for man and the environment throughout the Community and whereas a directive on biocidal products (non-agricultural pesticides) is the most appropriate way of establishing such a framework;

Whereas such rules should provide that biocidal products should not be placed on the market for use unless they have been officially authorized;

Whereas such official authorization is appropriate as biocidal products consist mostly of dangerous substances and are preparations designed to have detrimental effects on the organisms they are intended to control; whereas biocidal products may have consequences other than the intended effects on the target species, they were designed for and whereas, therefore, they may especially involve risks for man and the environment;

Whereas it is appropriate that an applicant should submit dossiers and whereas it is further appropriate that the dossiers shall contain only that information which is necessary to evaluate the risks that will arise from proposed uses of the product;

Whereas it is necessary, at the time when biocidal products are authorized, to make sure that, when properly used for the purpose intended, they are sufficiently effective and have no unacceptable effect on their target species (i.e. they do not cause undesirable resistance and in the case of vertebrate animals unnecessary suffering), and have in the light of current scientific and technical knowledge no unacceptable adverse influence on the environment and, in particular, no harmful effect on human or animal health;

Whereas authorization should be limited to biocidal products containing certain active substances evaluated on the basis of their physicochemical, toxicological and ecotoxicological properties;

Whereas it is necessary to establish a Community list of active substances permitted for inclusion in biocidal products; whereas a Community procedure must be laid down for assessing whether or not an active substance can be entered in the Community list; whereas the information that interested parties must submit with a view to admission of a substance to the list has to be specified; whereas, in the interest of safety, substances on the list should be reviewed periodically, to take account of developments in science and technology;

Whereas in the light of the diversity of both the substances and products concerned, the test requirements should allow for some flexibility to suit the individual circumstances and should result in an overall risk assessment;

Whereas it is in the interest of free circulation of biocidal products as well as of goods treated with them, that authorization granted by one Member State, and tests carried out with a view to authorization, should be recognized by other Member States;

Whereas it is therefore desirable that a system for the mutual exchange of information should be established and that Member States and the Commission should make available to each other on request the particulars and scientific documentation submitted in connection with applications for authorization of biocidal products;

Whereas, Member States must be able to authorize biocidal products not complying with the abovementioned conditions for a limited period of time, especially in case of an unforeseen danger threatening man or the environment which cannot be contained by other means; whereas such authorization should be reviewed by the Commission in close cooperation with the Member States; whereas the Community procedure should not prevent Member States from authorizing for use in their territory for a limited period of time biocidal products containing an active substance not yet entered in the Community list, provided that a dossier meeting Community requirements has been submitted and the Member State believes that the active substance and the biocidal products satisfy the Community conditions set in regard to them;

Whereas active substances used in biocidal products may also be used in other preparations which have under other Community legislation, been tested on animals; whereas double testing on animals must be avoided; whereas, close coordination should be ensured with other Community legislation and in particular with Directive 91/414/EEC on the placing on the market of plant protection products;

Whereas, in order to ensure that the requirements laid down in respect of authorized biocidal products are satisfied when they are placed on the market, Member States must make provision for appropriate control and inspection arrangements;

Whereas the implementation of this Directive, the adaptation of its Annexes to the development of technical and scientific knowledge, and the registration of Community-approved active substances necessitate close cooperation between the Commission and the Member States and the applicant; whereas the procedure of the Standing Committee on Biocidal Products offers a suitable basis for this cooperation; whereas this entails transparency of the administrative procedures;

Whereas the full implementation of this Directive and especially of Article 14 (4) will not be achieved for several years, Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations can provide for a framework to complement the development of the positive list by limitations of the marketing and use of certain active substances and products or groups of these;

Whereas the Council in its resolution of 1 February 1993 (1) on a Community programme of policy and action in relation to the environment and sustainable development has approved the general approach and strategy of the programme presented by the Commission which states that economic growth and environmental quality must be viewed as mutually dependant; whereas therefore the strengthening of environmental protection requires the maintenance of the economic competitiveness of industry;

Whereas the review of active substances shall need to take account of other work programmes within the framework of other Community legislations concerned with the review or authorization of substances and products;

Whereas minimum rules concerning the use of biocidal-products at work are already laid down under directives on health and safety at work: whereas it is desirable to develop further these rules;

HAS ADOPTED THIS DIRECTIVE:

Article 1

Scope of applicability

1. This Directive concerns

(a) the authorization and the placing on the market for use of biocidal products within the Member States;

(b) the mutual acceptance of authorizations within the Community;

(c) the establishment at Community level of a positive list of active substances which may be used in biocidal products.

2. This Directive shall apply to biocidal products as defined in Article 2 (1) (a) but shall exclude products where they are covered by the following Directives for the purposes of these Directives:

(a) Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (2);

(b) Council Directives 70/524/EEC (3) and 82/471/EEC (4) on additives and substances for exclusive use in animal feedingstuffs;

(c) Council Directive 76/768/EEC (5) on cosmetic products;

(d) Council Directive 89/107/EEC of 21 December 1988 on substances used exclusively as additives to foodstuffs (6) and Council Directive 88/388/EEC of 22 June 1988 on substances used exclusively as flavourings in foodstuffs (7);

(e) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (8);

(f) Council Directive .../.../EEC concerning medical devices.

3. This Directive shall apply without prejudice to the provisions of:

(a) Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations;

(b) Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances (9);

(c) Council Regulation (EEC) No 1734/88 of 16 June 1988 on the export from and import into the Community of certain dangerous chemicals (10);

(d) Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers against dangers from exposure to chemical, physical and biological agents at work (11), and Council Directive 89/391/EEC of 12 July 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (12) and individual Directives based on these Directives;

(1) OJ No C 138, 17. 5. 1993, p. 1.

(2) OJ No 22, 9. 2. 1965, p. 369/65.
(3) OJ No L 270, 14. 12. 1970, p. 1.
(4) OJ No L 213, 21. 7. 1982, p. 8.
(5) OJ No L 262, 27. 9. 1976, p. 169.
(6) OJ No L 40, 12. 2. 1989, p. 27.
(7) OJ No L 184, 15. 7. 1988, p. 61.
(8) OJ No L 230, 19. 8. 1991, p. 1.
(9) OJ No L 33, 8. 2. 1979, p. 36.
(10) OJ No L 155, 22. 6. 1988, p. 2.
(11) OJ No L 327, 3. 12. 1980, p. 8.
(12) OJ No L 183, 29. 6. 1989, p. 1.

(e) Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (1).

4. Article 18 does not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

Article 2

Definitions

1. For the purposes of this Directive the following definitions shall apply:

(a) *biocidal products:*

active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism.

An indicative list of product types is at Annex V;

(b) *active substances*

substances, fungi and micro-organisms including viruses having general or specific action on or against harmful organisms;

(c) *harmful organism*

any organism which has an unwanted presence or a detrimental effect for man, his activities or the products he uses or produces, or for animals or for the environment;

(d) *placing on the market*

any supply, whether in return for payment or free of charge, other than for storage followed by consignment from the territory of the Community or disposal. Importation of a biocidal product into the territory of the Community shall be deemed to constitute placing on the market for the purposes of this Directive;

(e) *authorization*

administrative act by which the competent authority of a Member State authorizes, following an application submitted by an applicant, the placing on the market of a biocidal product in its territory or in a part thereof;

(f) *residues*

One or more of the substances present in a biocidal product which remains as a result of its use including the metabolites of such substances and products resulting from their degradation or reaction.

(1) OJ No L 374, 31. 12. 1990, p. 1.

2. For the purposes of this Directive the definitions for

(a) substances;

(b) preparations;

(c) scientific research and development;

(d) process-orientated research and development

laid down in Article 2 of Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances (2) shall apply.

Article 3

Authorization for placing on the market of biocidal products

1. Member States shall prescribe that a biocidal product shall not be placed on the market and used in their territory unless it has been authorized in accordance with this Directive.

2. Every application for authorization shall be decided upon within a resonable period.

3. A biocidal product that has already been authorized in one Member State shall be authorized, in another Member State within 60 days of an application being received by the other Member State, providing that the active substance of the biocidal product conforms to the entry in Annex I.

4. If in complying with Article 4 a Member State establishes that:

(a) unacceptable resistance of the target organism to the biocidal product is proven or

(b) the relevant circumstances of use, such as climate or breeding period of the target species, differ significantly from those in the Member State where the biocidal product was first authorized, and an unchanged authorization may therefore present unacceptable risks to man or the environment,

the Member State may request that the directions for use and the dose rate referred to in Article 18 (3) (e) are adjusted to the different circumstances, or, if the risk can not be prevented in any other way, the Member State may request changes to be made to the biocidal product itself so that conditions for issue of an authorization provided for in Article 4 are satisfied.

5. Notwithstanding paragraph 4 where a Member State believes a biocidal product cannot meet the conditions set out under Article 4 and consequently proposes to refuse authorization, it shall notify the Commission, other Member States and the applicant and

(2) OJ No L 196, 16. 8. 1967, p. 1 (as amended).

shall provide them with an explanatory document giving details of the product and setting out the grounds on which it proposes to refuse the authorization.

The Commission shall prepare a proposal on these matters in accordance with Article 24 for decision in accordance with the procedure laid down in Article 25 (3).

6. Member States shall prescribe that biocidal products shall be classified, packaged and labelled in accordance with the provisions of this Directive.

7. Authorizations shall be granted for a fixed period of 10 years from the date of first entry of the active substance onto Annex I; they may be renewed after verification that the conditions imposed in paragraphs 1 and 2 are still satisfied. Renewal may, where necessary, be granted only for the period necessary to allow the competent authorities of the Member States, to make such verification, where an application for renewal has been made.

8. Member States shall prescribe that biocidal product must be properly used. Proper use shall include compliance with conditions established under Article 4 and specified under the labelling provisions of this Directive. Proper use shall also involve the rational application of a combination of physical, biological, chemical or other measures as appropriate whereby the use of biocidal products is limited to the minimum necessary. Where biocidal products are used at work use shall also be in accordance with the requirements of directives for the protection of workers.

Article 4

Conditions for issue of an authorization

1. Member States shall authorize a biocidal product only if

(a) the active substance(s) included therein are listed in Annex I and any conditions laid down in the Annex are fulfilled;

(b) it is established, in the light of current scientific and technical knowledge and it is shown from appraisal of the dossier provided for in Annex III and, where specified, the relevant parts of Annex IV according to the common principles for the evaluation of dossiers, that when used as authorized and having regard to:

— all normal conditions under which the biocidal product may be used,

— how the material treated with it may be used,

— the consequences from use and disposal,

the biocidal product:

(i) is sufficiently effective;

(ii) has no unacceptable effect on the target organism;

(iii) has no harmful effects itself or as a result of its residues, on human or animal health, directly or indirectly (e.g. through drinking water, food or feed) or on groundwater;

(iv) has no unacceptable effects on the environment having particular regard to the following considerations:

— its fate and distribution in the environment; particularly contamination of water including drinking water and groundwater,

— its impact on non-target organisms;

(v) does not cause unnecessary suffering and pain to vertebrates to be controlled;

(c) the nature and quantity of its active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants, and its residues of toxicological or environmental significance, which result from authorized uses, can be dermined according to the relevant requirements in Annexes II, III and IV;

(d) its physical and chemical properties have been dertermined and deemed acceptable for purposes of the appropriate use, storage and transport of the product.

2. A biocidal product classified according to Article 18 (1) as very toxic or as a category 1 or 2 carcinogen, or mutagen or classified as toxic for reproduction category 1 or 2, shall not be authorized for marketing to, or use by the general public.

3. Authorization may be conditional on requirements relating to marketing and use necessary to ensure compliance with the provisions of paragraph 1.

4. Where other Community provisions impose requirements relevant to the conditions for the issue of an authorization and particularly where these are intended to protect the health of distributors, users, workers and consumers or animal health of distributors, users, workers and consumers or animal health or the environment, the competent authority shall take these into account when issuing an authorization and where necessary shall issue the authorization subject to those requirements.

Article 5

Review of an authorization

Authorization may be reviewed at any time if there are indications that any of the requirements referred to in Article 4 are no longer satisfied. In such instances the Member States may require the applicant for authorization or the applicant to whom a modification of authorization has been granted in accordance with Article 6 to submit further information necessary for the review. Renewal may, where necessary, be granted only for the period necessary to complete a review, and shall be granted for the period necessary to provide such further information.

Article 6

Cancellation or modification of an authorization

1. An authorization shall be cancelled if:

(a) the active substance is no longer included in Annex I;

(b) the conditions under Article 4 (1) for obtaining the authorization are no longer satisfied;

(c) it is discovered that false or misleading particulars were supplied concerning the facts on the basis of which the authorization was granted.

2. An authorization may also be cancelled if the authorization holder requests it and states the reasons for the cancellation.

3. Where a Member State cancels an authorization, it shall inform the authorization holder and it may grant a period of grace for the disposal or for storage, marketing and use of existing stocks, of a length in accordance with the reason for the cancellation without prejudice to any period provided for by decision taken under Directive 76/769/EEC or in connection with paragraph 1 (a).

4. An authorization shall be modified if, on the basis of developments in scientific and technical knowledge, the conditions of use and, in particular, manner of use or amounts used can be modified.

5. An authorization may also be modified if the authorization holder requests it and states the reasons for the modification.

6. Where a proposed modification concerns an extention of uses, Member States shall extend the authorization subject to the particular conditions placed on the active substance in Annex I.

7. Where a proposed modification of an authorization involves changes to the particular conditions placed on the active substance in Annex I, these can be made only after evaluation of the active substance, with regard to the proposed changes, in accordance with the procedures laid down in Article 10.

8. Modification shall only be granted if it is established that the conditions under Article 4 continue to be satisfied.

Article 7

Requirements for authorization

1. Application for authorization shall be made by or on behalf of the person who will be responsible for the first placing on the marktet of a biocidal product in a particular Member State and shall be to the competent authority of that Member State. Every applicant shall be required to have a permanent office within the Community.

2. Member States shall require that applicants for authorization of a biocidal product shall submit to the competent authority:

(a) a dossier on the biocidal product satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex III and, where specified, the relevant parts of Annex IX; and

(b) for each active substance in the biocidal product, a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex II and, where specified, the relevant parts of Annex IV.

3. The dossiers shall include a detailed and full decription of the studies conducted and of the methods used or a bibliographical reference to those methods. The information in the dossiers supplied according to Article 7 (2) shall be sufficient for an evaluation to be made of the effects and properties referred to in Article 4 (1) (b), (c) and (d). It shall be submitted to the competent authority in the form of technical dossiers, containing the information and results of the studies referred to in Annex II and Annex III and, where specified, the relevant parts of Annex IV.

4. Information, which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the competent authority must be submitted.

5. If the evaluation of the dossier shows that further information including information and results from further testing is necessary to evaluate the risks of the biocidal product, the competent authority shall ask the applicant to submit such information.

6. The name of an active substance must be given as registered in the list contained in Annex I to Directive 67/548/EEC or, if not included therein, as given in the European Inventory of Existing Chemical Substances (Einecs) (1), or if not included therein, it must be given its International Standards Organization (ISO) common name. If the latter is not available, the substance must be designated by its chemical designation according to IUPAC rules.

7. Tests must be conducted according to the methods described in Annex V of Directive 67/548/EEC. In the event of a method being inappropriate or not descirbed, other methods used should, whenever possible, be internationally recognized and must be justified. Tests must be conducted in accordance with the provisions laid down in Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes and Council Directive 87/18/ECC (2) of 18 December 1986 on the harmonization of laws, regulations and administrative provisions for the application of the principles of Good Laboratory Practice and the verification of their applications for tests on chemical substances.

8. Competent authorities as referred to under Article 23 shall ensure that a file is complied on each application. Each file shall contain at least a copy of the application, a record of the administrative decisions taken by the Member State concerning the application and concerning the dossiers submitted in accordance with paragraph 2 together with a summary of the latter. Member States shall on request make available to the other competent authorities and to the Commission the files provided for in this paragraph; they shall supply to them on request all information necessary for full comprehension of applications, and shall where requested ensure that applicants provide a copy of the technical documentation laid down in Article 7.

9. Member States may require that samples of the preparation and of its ingredients be provided.

Article 8

Placing on the market of active substances

Member States shall prescribe that where a substance is an active substance for use in biocidal products it may not be placed on the market for such use unless

(a) where the active substance was not on the market before the date of entry into force of this Directive, a dossier has been forwarded to a Member State, which satisfies the requirements of Article 10 (1), and is accompanied by the declaration that the active substance is intended for inclusion in a biocidal product. This shall not apply to substances for use under Article 15;

(b) it is classified, packaged and labelled in accordance with the provisions of Directive 67/548/EEC.

Article 9

Inclusion of an active substance in Annex I

1. In the light of current sientific and technical knowledge, an active substance shall be included in Annex I for an initial period not exceeding 10 years if it may be expected that biocidal products containing the acitve substance will fulfil the conditions laid down in Article 4 (1) (b), (c) and (d).

2. Inclusion of an active substance in Annex I shall, where appropriate, be subject to the following:

(i) requirements on:

(a) the minimum degree of purity of the active substance;

(b) the nature and maximum content of certain impurities;

(c) product type in which it may be used;

(d) manner of use;

(e) designation of categories of users (e.g. industrial, professional or non-professional);

(f) other particular conditions from the evaluation of the information referred to in Article 10 (2);

(ii) the establishment of the following:

(a) a suitable standard of user protection;

(b) where relevant, an acceptable daily intake for man (ADI);

(c) fate and behaviour in the environment and impact on non-target organisms.

3. The inclsusion in Annex I of an active substance shall be restricted to those product types in Annex V for which acceptable data have been submitted in accordance with Article 7.

4. The inclusion of a substance in Annex I may be renewed on one or more occasions for periods not exceeding 10 years. The initial inclusion as well as any renewed inclusion may be reviewed at any time if there

(1) OJ No C 146, 15. 6. 1990, p. 1.
(2) OJ No L 15, 17. 1. 1987, p. 29.

are indications that any of the requirements referred to in paragraph 1 are no longer satisfied. Renewal may, where necessary, be granted only for the period necessary to complete a review, where an application has been made for such renewal and shall be granted for the period necessary to provide information requested in accordance with Article 10 (2).

5. The inclusion of an active substance in Annex I may be refused or reviewed, if there is another active substance on Annex I for the same product type, or another method of control exists, which in the light of scientific or technical knowledge present significantly less risk to health or to the environment. When considering such a refusal, an evaluation of the alternative active substances or methods shall be produced in accordance with common principles for the evaluation of dossiers, to demonstrate they can be used with the same effect on the target organism without significant economic and practical disadvantages to the user. The evaluation shall be circulated in accordance with the procedures in Article 10 (2) for decision in accordance with the procedures laid down in Articles 24 and 25 (3).

Article 10

Procedure for inclusion of an active substance in Annex I

1. An active substance will be considered for inclusion in Annex I, and any changes to Annex I will be considered when:

(a) an applicant has forwarded to the competent authority of one of the Member States:

(i) a dossier for the active substance satisfying the requirements of Annex II and, where specified, the relevant parts of Annex IV;

(ii) a dossier for at least one biocidal product containing the active substances satisfying the requirements of Annex III an, where specified, the relevant parts of Annex IV;

(b) the receiving competent authority has checked the dossiers and believes them to satisfy the requirements of Annex II and Annex III and where relevant Annex IV, accepts them and agrees to the applicant forwarding a summary of the dossiers to the Commission and the other Member States.

2. The receiving competent authority shall, within six months of accepting the dossiers carry out an evaluation thereof. A copy of the evaluation shall be sent by the competent authority to the Commission, the other Member States and to the applicant, together with a recommendation for the inclusion, or otherwise, of the active substance in Annex I.

If during the evaluation of the dossiers it appears that further information is necessary for full evaluation to be made, the receiving competent authority shall ask that the applicant submit such information. The six-month period shall be suspended from the date of issue of the competent authority's request until the date the information is received. The competent authority shall inform the other Member States and the Commission of its action at the same time as it informs the applicant.

3. On receipt of the evaluation, the Commission shall, in accordance with in Article 24, prepare a proposal without undue delay for decision in accordance with the procedures laid down in Article 25 (3). The decision shall be taken at the latest 15 months after the receipt by the Commission of the evaluation referred to in paragraph 2.

Article 11

Use of data held by competent authorities for other applicants

1. Member States shall not make use of the information referred to in Annex II and the relevant parts of Annex IV for the benefit of a second or subsequent applicant:

(a) unless the second or subsequent applicant has the written agreement of the first applicant that use may be made of such information; or

(b) in the case of an active substance not on the market on the date of coming into force of this Directive, for a period of 15 years from the date of first inclusion in Annex I; or

(c) in the case of an active substance already on the market on the date of coming into force of this Directive;

(i) for a period of 10 years from the date of coming into force of this Directive for any information submitted for the purposes of this Directive except where such information is already protected under existing national rules relating to biocidal products. In such cases the information shall continue to be protected in that Member State until the expiry of any remaining period of data protection provided for under national rules, up to a maximum of 10 years from the date or coming into force of this Directive;

(ii) for a period of 10 years from the date of entry of an active substance onto Annex I for information submitted for the first time in support of the first inclusion in Annex I of either the active substance or an additional product type for that active substance;

(d) in the case of any further information submitted for the first time for any of the following:

(i) variation of the conditions of the entry on Annex I;

(ii) maintenance of the entry on Annex I

for a period of five years from the date of decision following receipt of further information unless the five-year period expires before the period provided for in paragraph 1 (b) and (c), in which case the period of five years shall be extended so as to expire on the same data as those periods.

Where an active substance is included in Annex I of this Directive and also in Annex I of Directive 91/414/EEC, the information referred to in Annex II and relevant parts of Annex IV, which is required under both Directives and has been provided under both Directives, shall benefit only from the periods of data protection provided for under Directive 91/414/EEC.

2. Member States shall not make use of the information referred to in Annex III and the relevant parts of Annex IV, for the benefit of a second or subsequent applicant:

(a) unless the second or subsequent applicant has the written agreement of the first applicant that use may be made of such information; or

(b) in the case of a biocidal product containing an active substance not on the market on the date of coming into force of this Directive; for a period of 10 years from the date of first authorization in any Member State; or

(c) in the case of a biocidal product containing an active substance already on the market on the date of coming into force of this Directive;

(i) for a period of 10 years from the date of coming into force of this Directive for any information submitted for the purposes of this Directive, except in the case where data are already protected according to existing national rules relating to biocidal products, in which case such data shall be protected in that Member State until the expiry of any remaining period of data protection provided for under those national rules, up to a maximum of 10 years from the date of coming into force of this Directive;

(ii) for a period of 10 years from the date of entry of an active substance onto Annex I, for information which is submitted for the first time in support of the inclusion in Annex I either of the active substance or of an additional product type for that active substance;

(d) in the case of any data submitted for the first time for either of the following:

(i) variation of the conditions of authorization of a biocidal product;

(ii) submission of data necessary to maintain entry of an active substance onto Annex I:

for a period of five years from the date of first receipt of further information unless the five-year period expires before the period in paragraph 2 (b) and (c) above in which case the period of five years shall be extended so as to expire on the same date as those periods.

Where a biocidal product contains an active substance which is included in Annex I of this Directive and also in Annex I of Directive 91/414/EEC, the information referred to in Annex III and relevant parts of Annex IV, which is required under both Directives and has been provided under both Directives, shall benefit only from the periods of data protection provided for under Directive 91/414/EEC.

Article 12

Second and subsequent applications for authorization

1. In the case of a biocidal product which has already been authorized in accordance with Articles 3 and 4, and without prejudice to the obligations imposed under Article 11, the competent authority may agree that a second or subsequent applicant for authorization may refer to data provided by the first applicant insofar as the second or subsequent applicant can provide evidence that the biocidal product and its active substances is the same as the one previously authorized, including degree of purity and nature of impurities.

2. Notwithstanding Article 7 (2) where the active substance is listed in Annex I:

(a) applicants for authorization of biocidal products shall, before carrying out experiments involving vertebrate animals, enquire of the competent authority of the Member State to which they intend making application:

— whether the biocidal product for which an application is to be made is the same as a biocidal product for which authorization has been granted, and

— as to the name and address of the holder or holders of the authorization or authorizations.

The enquiry shall be supported by evidence that the prospective applicant intends to apply for authorization on his own behalf and that the other information specified in Article 7 (2) is available;

(b) the competent authority of the Member State, if satisfied that the applicant intends to apply, shall provide the name and address of the holder or holders of previous relevant authorizations and shall at the time inform the holders of the authorizations of the name und address of the applicant.

The holder or holders of previous authorizations and the applicant shall take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.

Where data is requested with a view to inclusion in Annex I of an active substance already on the market on the date of entry into force of this Directive, the competent authorities of the Member States shall encourage data holders to cooperate in the provision of the requested data, with a view to limiting the duplication of testing on vertebrate animals.

If the applicant and holders of previous authorizations of the same product can still not reach an agreement on the sharing of data, Member States may introduce national measures obliging the applicant and holders of previous authorizations located within their territory to share the data with a view to avoiding duplicative testing on vertebrate animals and determine both the procedure for utilizing information, and the reasonable balance of the interests of the parties concerned.

Article 13

New information

1. Member States shall prescribe that the holder of an authorization for a biocidal product shall immediately notify the competent authority of information which they may reasonably be expected to be aware concerning an active substance or a biocidal product containing it and which may affect continuing authorization. In particular the following shall be notified:

— new knowledge or information on the effects of the active substance or biocidal product for man or the environment,

— changes in the source or composition of an active substance,

— changes in composition of a biocidal product.

2. Member States shall immediately notify other Member States and the Commission of any such information they receive concerning potentially harmful effects for man or the environment of a biocidal product, its active substances, impurities, co-formulants or residues.

Article 14

Transitional measures and derogations from the requirements

1. By way of derogation from Article 3 and 4, a Member State may authorize temporarily for a period not exceeding 120 days the placing on the market of biocidal products not complying with the provisions of this Directive for a limited and controlled use if such a measure appears necessary because of an unforseen danger which cannot be contained by other means. In this case, the Member State concerned shall immediately inform the other Member States and the Commission of its action and the justification for it. The Commission shall make a proposal and it shall be decided without delay, in accordance with the procedure laid down in Article 25, whether and under which conditions the action taken by the Member State may be extended for a period to be determined, be repeated, or be revoked.

2. By way of derogation from Article 4 (1) (a) and until an active substance is listed in Annex I a Member State may authorize provisionally, for a period not exceeeding three years, the placing on the market of a biocidal product containing an active substance not listed in Annex I and not yet available on the market on the date of coming into force of this Directive. Such an authorization may only be issued if, after evaluation of dossiers in accordance with the Article 10 the Member State believes that:

— the active substance satisfies the requirements of Article 9 and,

— the biocidal product may be expected to satisfy the conditions of Article 4 (1) (b), (c) and (d),

and no other Member State, on the basis of the summary it receives, makes legitimate objection in accordance with Article 16 (2) to the completeness of the dossiers. Where an objection is made a decision on the completeness of dossiers shall be taken in accordance with the procedures laid down in Article 25 (3) without undue delay.

If following the procedures laid down in Article 24 and 25 (3), it is decided, that the active substance does not satisfy the requirements specified in Article 9, the Member State shall ensure that the provisional authorization is cancelled.

In cases where evaluation of dossiers for the purposes of inclusion of an active substance in Annex I is not

completed when the period of three years expires, the competent authority may further provisionally authorize the product for a period not exceeding one year, providing there are good reasons to believe the active substance will satisfy the requirements of Article 9. Member States shall inform other Member States and the Commission of such action.

3. By way of further derogation from Article 4 (1), Article 7 (2) and Article 7 (3) and without prejudice to paragraph 4 and paragraph 6, a Member State may, for a period of 10 years from the date of entry into force of this Directive, authorize the placing on the market in its territory of a biocidal product containing active substances not listed in Annex I that are on the market on the date of entry into force of this Directive.

4. Following the adoption of this Directive, the Commission shall commence a 10-year programme of work for the systematic examination of active substances not on Annex I. A regulation, adopted according to the procedure laid down in Article 25 (2), will provide for all provisions necessary for the establishment and implementation of the programme. No later than two years before completion of the work programme, the Commission shall forward to the Council and the European Parliament a report on the progress achieved with the programme.

During this 10-year period, it may be decided under the procedure laid down in Article 25 (3) that an active substance shall be included in Annex I and under which conditions, or, in cases where the requirements of Article 9 are not satisfied or the requisite information and data have not been submitted within the prescribed period, that such active substance shall not be included in Annex I.

Following a decision, the Member States shall ensure that authorizations for biocidal products containing the active substances are modified or cancelled as appropriate.

5. Where following a review of an active substance it is concluded that the substance does not meet the requirements of Article 9 and consequently cannot be included in Annex I, the Commission shall bring forward proposals for restricting the marketing and use of that substance in accordance with Directive 76/769/EEC.

6. When authorizing biocidal products containing an active substance to be reviewed in accordance with paragraph 4 and before such review has taken place, Member States shall apply the conditions in Article 4 (1) (b), (c) and (d) on the basis of dossiers which address the requirements in Annex II and III.

Article 15

Research and development

(1) Member States shall prescribe that any experiment or test for the purposes of research or development involving placing on the market of an unauthorized biocidal product or an active substance intended exclusively for use in a biocidal product shall not take place unless:

(a) in the case of scientific research and development the persons concerned draw up and maintain written records detailing the identity of the product or substance, labelling data, quantities supplied and the names and addresses of those persons receiving the product or substance and compiles a dossier containing all available data on possible effects on human or animal health or impact on the environment. This information shall, as requested, be made available to the competent authority;

(b) in the case of process-orientated research and development the information required in (a) is notified to the competent authority where and before placing on the market occurs and to the competent authority of the Member State where the experiment or test is to be conducted.

2. Member States shall prescribe that an unauthorized biocidal product or an active substance for exclusive use in a biocidal product may not be placed on the market for the purpose of trials which may involve or result in release into the environment unless the competent authority has assessed the available data and issued an authorization for trials purposes which limits the quantities to be used and the areas to be treated and may impose further conditions.

3. Where trials take place in a Member State other than the Member State where placing on the market occurs, the applicant shall obtain trials authorization from the competent authority of the Member State in whose territory the trials are to be conducted.

If the proposed experiments or tests referred to in paragraph 1 and 2 are liable to have harmful effects on human or animal health or to have an unacceptable adverse influence on the environment, the Member State concerned may either prohibit them or only permit them subject to such conditions as it considers necessary to prevent those consequences.

4. Paragraph 2 shall not apply if the Member State has granted the person concerned the right to undertake certain experiments and tests and has determined the conditions under which the experiments and tests have to be undertaken.

5. Common conditions for the application of this Article, in particular the maximum quantities of active substances or biocidal products that may be released during experiments, and the minimum data to be submitted in accordance with paragraph 2, shall be adopted in accordance with the procedure laid down in Article 25 (3).

Article 16

Information exchange

1. Within a period of one month from the end of each quarter Member States shall inform each other and the Commission of any biocidal products which have been authorized within their territory or for which an authorization has been refused, modified, renewed or cancelled, indicating at least:

(a) the name or business name of the holder of the authorization;

(b) the trade name of the biocidal product;

(c) the name and amount of each active substance which it contains;

(d) the product type and the use or uses for which it is authorized;

(e) the type of formulation;

(f) any proposed limits on residues which have been established;

(g) limitations, conditions and requirements of the authorization and where relevant, the reasons for the modification or cancellation of an authorization.

2. Where a Member State receives a summary of the dossiers in accordance with Article 10 (1) (b) and has legitimate reason to believe the dossiers are incomplete it shall immediately communicate its concerns to the competent authority responsible for the evaluation of the dossiers and shall immediately inform the Commission and other Member States of its concerns.

3. Each Member State shall draw up an annual list of the biocidal products authorized in its territory and shall communicate that list to the other Member States and the Commission.

4. In accordance with the procedure laid down in Article 25 (2) a standardized information system shall be set up to facilitate the application of paragraphs 1 and 2.

Article 17

Confidentiality

1. Without prejudice to Council Directive 90/313/EEC on the freedom of access to information on the environment [1] an applicant may indicate to the competent authority the information which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially and which he therefore wishes to be kept confidential from all persons other than the competent authorities and the Commission. Full justification will be required in each case.

(2) The competent authority receiving the application shall decide which information shall be confidential within the terms of paragraph 1.

Information accepted as being confidential by the receiving competent authority shall be treated as being confidential by the other competent authorities, Member States and the Commission.

3. Confidentiality shall not in any case apply to:

(a) the name of the applicant;

(b) the name of the biocidal product manufacturer;

(c) the name of the active substance manufacturer;

(d) the names and content of the active substances or substances in the biological product and the name of the biocidal product;

(e) the name of other substances which are regarded as dangerous under Directives 67/548/EEC and contribute to the classification of the product;

(f) physico-chemical data concering the active substance and biocidal product;

(g) any ways of rendering the active substance or biocidal product harmless;

(h) a summary of the results of the tests required under Article 7 to establish the substance's or product's efficacy and effects on humans, animals and the environment;

(i) recommended methods and precautions to reduce dangers from handling, storage, transport and use as well as from fire or other hazards;

(j) methods of analysis referred to in Article 4 (1) (c);

(k) methods of disposal of the product and of its packaging;

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[1] OJ No L 158, 23. 6. 1990, p. 56.

(l) decontamination procedures to be followed in the case of accidental spillage or leakage;

(m) first aid and medical treatment to be given in the case of injury to persons.

If the applicant or manufacturer or importer of the biocidal product or active substance should later disclose previously confidential information, the competent authority shall be informed accordingly.

4. The detailed provisions and format for making information publicly available shall be decided in accordance with the procedures set out in Article 25 (2).

Article 18

Classification, packaging and labelling of biocidal products

1. Biocidal products shall be classified according to the provisions relating to classification in Directive 88/379/EEC on the classification, packaging and labelling of dangerous preparations (1).

2. Biocidal products shall be packaged according to Article 6 of Directive 88/379/EEC. In addition:

(a) products which may be mistaken for food or drink shall be packaged to minimize the likelihood of such a mistake being made;

(b) products available to the general public which may be mistaken for food or drink shall contain components to discourage their consumption.

3. Biocidal products shall be labelled according to the provisions of Directive 88/379/EEC concerning labelling. In addition the label must show clearly and indelibly the following:

(a) the identity of the active substance and its concentration in metric units;

(b) the authorization number allocated to the biocidal product by the competent authority;

(c) the type of preparation (e.g. liquid concentrates, granules, powders, solids, etc.);

(d) the uses for which the biocidal product is authorized (e.g. wood preservation, disinfection, surface biocide, anti-fouling, etc);

(e) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorization;

(f) particulars of likely or indirect adverse side effects and any directions for first aid;

(g) if accompanied by a leaflet the sentence 'Read attached instructions before use';

(h) directions for safe disposal of the biocidal product and its packaging; including where relevant any prohibition on re-use of packaging;

(i) the formulation batch number or designation and the expiry date relevant to normal conditions of storage;

and where applicable:

(j) the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by man or animals to the area where the biocidal product has been used;

(k) the categories of users to which the biocidal product is restricted;

(l) information on any specific dangers to the environment particularly concerning protection of non-target species and avoidance of contamination of water.

Member States shall require that items 3 (a), (b), (d) and where applicable (g) and (k) always be carried on the label of the product.

Member States shall permit items 3 (c), (e), (f), (h), (i), (j) and (l) to be carried elsewhere on the packaging or on an accompanying leaflet integral to the packaging. These items of information shall be regarded as label information for the purposes of this Directive.

4. By way of derogation from paragraphs 1 and 2 and the first sentence of paragraph 3, biocidal products authorized as insecticides, acaricides, rodenticides, avicides or molluscicides shall be classified packaged and labelled in accordance with Directive 78/631/EEC on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides) (1) insofar as there is no other Community provisions specifically covering these matters for such products.

(1) OJ No L 187, 16. 7. 1988, p. 14.

(1) OJ No L 206, 29. 7. 1978, p. 13.

5. Where a biocidal product identified in paragraph 4 is authorized under this Directive and is also subject to classification, packaging and labelling according to Directive 78/631/EEC by virtue of other Community provisions, Member States shall permit changes to the packaging and labelling of that product which may be required as a consequence of those provisions, insofar as they do not conflict with the requirements of an authorization issued under this Directive.

6. Member States may require the provision of samples, models or drafts of the packaging, labelling and leaflets.

Article 19

Safety data sheets

Member States shall ensure that a system of specific information (in safety-data-sheet form) is established to enable professional and industrial users of biocidal products to take the necessary measure for the protection of the environment and health safety at the workplace.

For active substances used exclusively in biocidal products safety data sheets shall be prepared in accordance with the requirements of Article 27 of Directive 67/548/EEC.

For biocidal products safety data sheets shall be prepared in accordance with Article 10 of Directive 88/379/EEC.

Article 20

Advertising

1. Member States shall require that every advertisement for a biocidal product is accompanied by the sentences 'Use biocides safely. Always read the label and product information before use'.

The sentences shall be clearly distinguishable in relation to the whole advertisement.

Member States shall prescribe that advertisers may replace the word 'biocides' in the prescribed sentences with an accurate description of the product type being advertised e.g. wood preservatives, disinfectants, surface biocides, anti-fouling products, etc.

2. Member States shall require that advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the effects of the substance on man or the environment.

Article 21

Poison control

Member States shall appoint the body or bodies responsible for receiving information on biocidal products which have been placed on the market, including information on the chemical composition, of such products, and for making such information available in cases where suspected poisoning arises from the use of biocidal products. Such information may only be used to meet any medical demand by formulating preventive and curative measures, in particular in emergencies. Member States shall ensure that the information is not used for other purposes.

Member States shall take the necessary steps to ensure that the appointed bodies provide all the requisite guarantees for maintaining the confidentiality of the information received. Member States shall ensure that the appointed bodies shall have at their disposal all the information required to carry out the tasks for which they are responsible from the manufacturers or persons responsible for marketing.

For biocidal products already on the market, Member States shall take measures to comply with this Directive within three years from the adoption thereof.

Article 22

Compliance with requirements

Member States shall make suitable arrangements for biocidal products which have been placed on the market to be officially monitored to establish whether they comply with the requirements of this Directive.

Every three years after the entry into force of this Directive, Member States shall forward to the Commission by the 30 November of the third year a report on their action in these matters together with information on any poisonings involving biocidal products. The Commission shall within one year of receipt of this information prepare and publish a composite report.

Article 23

Competent authorities

1. Member States shall designate a competent authority responsible for carrying out the duties imposed on Member States under this Directive.

2. Member States shall inform the Commission of the identity of their competent authority six months before the entry into force of this Directive.

Article 24

Commission procedures

1. When the Commission receives from a Member State either:

(a) an evaluation and recommendations concerning an active substance as foreseen in Article 10 (2) and Article 9 (5); or

(b) a proposal to refuse an authorization and an explanatory document as foreseen in Article 3 (5);

it shall allow a period of 45 days during which other Member States and the applicant may submit comments to it in writing.

2. At the end of the period for comment, the Commission shall, on the basis of:

— the documents received from the Member State evaluating the dossiers and,

— any advice obtained from advisory committees in particular the Scientific Advisory Committee on the toxicology and ecotoxicology of chemical substances as established by Commission Decision 78/618/EEC (1) and in the case of active substances included in insecticides, acaricides, rodenticides, avicides and molluscicides which are also authorized under the requirements of Directive 91/414/EEC, the Scientific Committee for Pesticides, as established by Commission Decision 78/436/EEC (2),

— comments received from other Member States and the applicants and,

— any other relevant information,

prepare a proposal for decision in accordance with the procedures laid down in Article 25 (3).

3. The applicant or his authorized representative may be asked by the Commission to submit remarks to it, in particular whenever an unfavourable decision is envisaged.

Article 25

Committees and procedures

1. The Commission shall establish a Standing Committee on Biocidal Products (the Standing Committee) to assist it. The Standing Committee shall be composed of representatives of the Member States and chaired by a representative of the Commission. The Standing Committee shall adopt its own rules of procedure.

2. For matters referred to the Standing Committee by virtue of Articles 14 (4), 16 (4) and 17 (4) the representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account.

3. For all other matters referred to the Committee in accordance with the requirements of this Directive the representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of 30 days the Council has not acted, the proposed measures shall be adopted by the Commission.

(1) OJ No L 198, 22. 7. 1978, p. 17.
(2) OJ No L 124, 12. 5. 1978, p. 16.

Article 26

Common principles for the evaluation of dossiers

The common principles for evaluation of dossiers referred to in Article 4 (1) (b) above, shall be adopted in accordance with the procedure laid down in Article 25 (3). These principles shall be regularly reviewed and where appropriate revised, in accordance with the same procedure.

Article 27

Adaptation to technical progress

The amendments necessary for adapting Annexes II, III, IV and V to technical progress shall be adopted in accordance with the procedure laid down in Article 25 (3).

Article 28

Civil and criminal liability

The granting of authorization and all other measures in conformity with this Directive shall be without prejudice to general civil and criminal liability in the Member States of the manufacturer and, where applicable, of the person responsible for placing the biocidal product on the market or using it.

Article 29

Safeguard clause

Where a Member State has valid reasons to consider that a biocidal product which it has authorized or is bound to authorize under Article 3 constitutes an unacceptable risk to human or animal health or the environment, it may provisionally restrict or prohibit the use or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision. A decision shall be taken on the matter within 90 days in accordance with the procedure laid down in Article 25 (3).

Article 30

Implementation of the Directive

1. Not later than 18 months after the date of the adoption of the Directive Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

2. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 31

This Directive is addressed to the Member States.

ANNEX I

LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL FOR INCLUSION IN BIOCIDAL PRODUCTS

ANNEX II

REQUIREMENTS FOR THE DOSSIER TO BE INTRODUCED FOR THE INCLUSION OF AN ACTIVE SUBSTANCE IN ANNEX I

PART A

Chemical substances

1. Dossiers on active substances are required to address at least all the points listed under 'Dossier requirements'. Responses are required to be supported by data.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the competent authority must be submitted.

Dossier requirements

I Applicant

II Identity of the active substance

III Physical and chemical properties of the active substance

IV Methods of detection and identification

V Effectiveness against target organisms and intended uses

VI Toxicological profile for man and animals including metabolism

VII Ecotoxicological profile including environmental fate and behaviour

VIII Measures necessary to protect man, animals and the environment

IX Classification and labelling

X Summary and evaluation of II to IX

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

I APPLICANT

1.1. Name + address.

1.2. Active substance manufacturer (name, address, location of plant).

II IDENTITY OF THE ACTIVE SUBSTANCE

2.1. Common name proposed or accepted by ISO and synonyms.

2.2. Chemical name (IUPAC nomenclature).

2.3. Manufacturer's development code number(s).

2.4. CAS and EEC numbers (if available).

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

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

2.7. Specification of purity of the active in g/kg or g/l, as appropriate.

2.8. Identity of impurities and additives (e.g. stabilizers), together with the structural formula and the possible range expressed as g/kg or g/l, as appropriate.

2.9. The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower.

III PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

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 (UV/VIS, IR, NMR), and a mass spectrum, molar extinction at relevant wavelengths, where relevant (1).

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

3.6. Solubility in organic solvents, including effect of temperature on solubility (1).

3.7. Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature (1).

3.8. Stability in organic solvents used in preparations and identity of relevant breakdown products (2).

3.9. Thermal stability, identity of relevant breakdown products.

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

3.11. Flashpoint.

3.12. Surface tension.

3.13. Explosive properties.

3.14. Oxidizing properties.

3.15. Reactivity towards container material.

IV ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

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

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

(a) soil;

(b) air;

(c) water: the applicant should confirm that the substance itself and any of its degradation products which fall within the definition of pesticides given for parameter 55 in Annex I of Directive 80/778/EEC on the quality of water intended for human consumption (OJ No L 229, 30. 8. 1980, p. 11) can be estimated with adequate reliability at the MAC specified in that Directive for individual pesticides;

(d) animal and human body fluids and tissues;

(e) food or feedingstuffs and other products where relevant.

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(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.

V EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES

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

5.2. Organism(s) controlled and products, organisms or objects to be protected.

5.3. Effects on target organisms, e.g. contact, inhalation or stomach poison, fungitoxic, or fungistatic.

5.4. Mode of action.

5.5. Field of use envisaged.

5.6. User, professional or non-professional, general public.

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

5.8. Likely tonnage to be placed on the market per year.

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

VI TOXICOLOGICAL AND METABOLIC STUDIES

6.1. Acute toxicity.

6.1.1. Oral.

6.1.2. Dermal.

6.1.3. Inhalation.

6.1.4. Skin and eye irritation.

6.1.5. Skin sensitization.

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. Short term repeated dose toxicity (28 days).

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

6.4. Sub-chronic toxicity.

90-day study, two species, one rodent and one non-rodent.

6.5. Chronic toxicity.

One rodent and one other mammalian species.

6.6. Mutagenicity studies.

6.6.1. In vitro gene mutation study in bacteria.

6.6.2. In vitro cytogenicity study in mammalian ceils.

6.6.3. In vitro gene mutation assay in mammalian ceils.

6.6.4. If positive in points 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 point 6.6.4 but positive in vitro tests then undertake a second in vivo study to examine whether mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow.

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

6.7. Carcinogenicity study.

One rodent and one other mammalian species. These studies may be combined with those in point 6.5.

6.8. Reproductive toxicity.

6.8.1. Teratogenicity test — rabbit and one rodent species.

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

6.9. Neurotoxicity study.

If the active substance is an organophosphorus compound or if there are any other indications that the test substance may have neurotoxic properties then neurotoxicity studies will be required. The test species is the adult hen unless another species is justified to be more appropriate. If appropriate, delayed neurotoxicity tests will be required. If anticholine esterase activity is detected, a test for response to reactivating agents should be considered.

6.10. Toxic effects on livestock and pets.

6.11. Studies related to the exposure of the active substance to man.

6.11.1. Food and feedingstuffs — if the active substance is to be used in preparations for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored the tests referred to in Annex IV, Part A, point 1 shall be required.

6.11.2. If any other tests related to the exposure of the active substance to man, in its proposed preparations, are considered necessary, then the test(s) in Annex IV, Part A, point 2 shall be required.

6.12. Supplementary studies.

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

6.12.2. Mechanistic study — any studies necessary to clarify effects reported in toxicity studies.

6.13. Medical data in anonymous form.

6.13.1. Medical surveillance data on manufacturing plant personnel if available.

6.13.2. Direct observation, e.g. clinical cases, poisoning incidents if available.

6.13.3. Health records, both from industry and any other availabe sources.

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

6.13.5. Diagnosis of poisoning (determination of active substance, metabolites in body fluids or exhaled air) specific signs of poisoning, clinical tests.

6.13.6. Sensitization/allergenicity observations, if available.

6.13.7. Proposed treatment: first aid measures, antidotes, medical treatment.

6.13.8. Prognosis following poisoning.

6.14. Summary of mammalian toxicology and conclusions, including no observable adverse effect level (NOAEL), no observable effect level (NOEL), overall evaluation with regard to all toxicological data and any other information concerning active substance. Where possible any suggested worker protection measures should be included in summary form.

VII ECOTOXICOLOGICAL STUDIES ON THE ACTIVE SUBSTANCE

7.1. Acute toxicity to fish.

7.2. Acute toxicity to Daphnia magna.

7.3. Growth inhibition test on algae.

7.4. Acute toxicity test on one other, non-aquatic, non-target organism.

7.5. If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in Annex IV, Parts B and C, shall be required.

Fate and behaviour in the environment

7.6. Degradation.

7.6.1. Biotic.

7.6.1.1. Ready biodegradability.

7.6.1.2. Inherent biodegradability, where appropriate.

7.6.1.3. If the result of the test in point 7.6.1.2 is negative and if the likely route of disposal of the active substance and its preparations is by sewage treatment, then the test described in Annex IV, Part C, point 4.1 shall be required.

7.6.1.4. Any other biodegradability tests that are relevant from the results in points 7.6.1.1 and 7.6.1.2.

7.6.2. Abiotic.

7.6.2.1. Hydrolysis as a function of pH and identification of breakdown product(s).

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

7.6.2.3. Phototransformation in air (estimation method), including identification of breakdown products (1).

7.6.3. If the results of point 7.6.1.2 or 7.6.1.4 indicate the need to do so, or the active substance has an overall low or absent abiotic degradation, then the tests described in Annex IV, Part B, points 1.1 and 2.1, and where appropriate the tests described in Annex IV, Part B, point 3 shall be required.

7.7. Adsorption/desorption screening test.

Where the results of this test indicate the need to do so, the test described in Annex IV, Part B, point 1.2 shall be required, and/or the test described in Annex IV, Part B, point 2.2.

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

VIII 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 reaction products, combustion gases etc.

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

8.3. Emergency measures in case of an accident.

8.4. Possibility of destruction or decontamination following release in or on the following:

(a) air;

(b) water, including drinking water;

(c) soil.

8.5. Substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (OJ No L 20, 26. 1. 1980, p. 43).

8.6. Procedures for waste management of the active substance for industry or professional users.

8.6.1. Possibility of re-use or recycling.

8.6.2. Possibility of neutralization.

8.6.3. Conditions for controlled discharge including leachate qualities on disposal.

8.6.4. Conditions for controlled incineration.

8.6.5. Others, if appropriate.

IX CLASSIFICATION AND LABELLING

Proposals including justification for the proposals for the classification and labelling of the active substance according to Directive 67/548/EEC.

— Hazard symbol(s).

— Indications of danger.

— Risk phrases.

— Safety phrases.

X SUMMARY AND EVALUATION OF II TO IX

PART B

Fungi, micro-organisms and viruses

1. Dossiers on active organisms are required to address at least all the points listed under 'Dossier requirements' below. Responses are required to be supported by data.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the competent authority must be submitted.

Dossier requirements

I Applicants details

II Identity of active organism

III Source of active organism

IV Methods of detection and identification

V Biological properties of active organism including pathogenicity and infectivity for target and non-target organisms including man

VI Effectiveness and intended uses

VII Toxicological profile for man and animals including metabolism of toxins

VIII Ecotoxicological profile including environmental fate and behaviour of the organisms and of toxins it produces

IX Measures necessary to protect man, non-target organism and the environment

X Classification and labelling

XI Summary and evaluation of II to X

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

I APPLICANT

1.1. Applicant (name, address, etc.).

1.2. Manufacturer (name, address, plant location).

II IDENTITY OF THE ORGANISM

2.1. Common name of organism (including alternative and superseded names).

2.2. Taxonomic name and strain indicating whether it is a stock variant or a mutant strain; for viruses, taxonomic designation of the agent, serotype, strain or mutant.

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.).

III SOURCE OF THE ORGANISM

3.1. Occurrence in nature or otherwise.

3.2. Isolation methods for 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 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 i.e. 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.

IV METHODS OF 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 and results obtained, including information on variability.

4.3. Methods to show microbiological purity of the final product and showing that contaminants have been controlled to an acceptable level, 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 (e.g. toxins) residues in or on treated products, foodstuffs, feedingstuffs, animal and human body fluids and tissues, soil, water and air, where relevant.

V BIOLOGICAL PROPERTIES OF THE ORGANISM

5.1. History of the organism and its uses including as far as is known its general natural history and if relevant its geographical distribution.

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

5.3. Effects on target organism. Pathogenicity or kind of antagonism to the host. Details of host specificity range should be included.

5.4. Transmissibility, infective dose and mode of action including information on presence, absence or production of toxics with, if appropriate, information on their nature, identity, chemical structure and stability and potency.

5.5. Possible effects on non-target organisms closely related to the target organism including infectivity, pathogenicity, 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.

VI EFFECTIVENESS AND INTENDED USES

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

6.2. Uses envisaged e.g. insecticide disinfectant, anti-fouling biocide, 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 management strategies to deal with this.

6.5. Effects on target organisms.

6.6. Category of user.

VII TOXICOLOGICAL AND 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:

(1) oral;

(2) dermal;

(3) inhalation;

(4) skin and where necessary eye irritation;

(5) skin sensitization and where necessary respiratory sentization; and

(6) for viruses and viroids, cell culture studies using purified infective virus and primary cell cultures of mammalian, avian and fish cells.

7.2. Sub-chronic toxicity

40-day study, two species, one rodent, one non-rodent:

(1) oral administration;

(2) other routes (inhalation, dermal) as appropriate; and

(3) for viruses and virolds 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 species, rodent and one other mammal, oral administration unless other route more appropriate.

7.4. Carcinogenicity study

May be combined with studies in point 6.3. One rodent and on other mammal.

7.5. Mutagenicity studies

As specified in Part A, point 6.6.

7.6. Reproductive toxicity

Teratogenicity test — rabbit and one rodent species. Fertility study — one species, minimum 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. Delayed neurotoxicity tests using adult hens should be performed where appropriate.

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 including:

(1) medical data in anonymous form (if available);

(2) health records, medical surveillance data on manufacturing plants personnel (if available);

(3) epidemiological data (if available);

(4) poisoning incidents data;

(5) poisoning diagnosis (signs, symptoms) including details of any analytical tests;

(6) proposed treatment of poisoning and prognoses.

7.12. Summary of mammalian toxicology — conclusions (including NOAEL, NOEL and if appropriate ADI) overall evaluation with regard to all toxicological, pathogenicity and infectivity data and any other information concerning the active organism. Where possible suggested user protection measures should be included in summary form.

VIII ECOTOXICOLOGICAL STUDIES

8.1. Acute toxicity to fish.

8.2. Acute toxicity to Daphnia magna.

8.3. Effects on algal growth (inhibition test)

8.4. Acute toxicity on one other, non-aquatic, non-target organism.

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. Potential for indirect contamination of areas adjacent to treatment areas.

8.9. In cases where toxins are produced, data as outlined in Annex II, Part A, points 7.1 to 7.5 should be produced.

Fate and behaviour in the environment

8.10. Spread, mobility, multiplication and persistence in air, soil and water.

8.11. In cases where toxins are produced, data as outlined in Annex II, Part A, points 7.6 to 7.8.

IX MEASURES NECESSARY TO PROTECT MAN, NON-TARGET ORGANISMS AND THE ENVIRONMENT

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

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

9.3. The possibility of rendering the active organism uninfective and any method for doing this.

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

9.5. Emergency measures in case of accident.

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

9.7. Possibility of destruction or decontamination following release in or into the following: air, water, soil, others if appropriate.

X CLASSIFICATION AND LABELLING

Proposals for allocation to one of the risk groups outlined in Article 2 (d) of Directive 90/679/CEE (1) with justifications for the proposal. Together with indications on the need for products to carry the biohazard sign specified in Annex II of 90/679/EEC.

XI SUMMARY AND EVALUATION OF II TO X

(1) OJ No L 374, 31. 12. 1990, p. 1.

ANNEX III

REQUIREMENTS FOR THE DOSSIER TO BE INTRODUCED FOR THE AUTHORIZATION OF A BIOCIDAL PRODUCT

PART A

Chemical products

1. Dossiers on biocidal products are required to address at least all the points listed under 'Dossiers requirements'. Responses are required to be supported by data.

2. Information which is not necessary owing to the nature of the biocidal product or of this proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the competent authority must be submitted.

Dossier requirements

I Applicant

II Identity and composition of the biocidal product

III Physical, chemical and technical properties of the biocidal product

IV Methods for identification and analysis of the biocidal product

V Intended uses of the product and efficacy for these uses

VI Toxicology data for the biocidal products (additional to that for the active substance)

VII Ecotoxicological data for the biocidal products (additional to that for the active substance)

VIII Measures to be adopted to protect man, animals and the environment

IX Classification, packaging and labelling of the biocidal product

X Summary and evaluation of II to IX

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

I APPLICANT

1.1. Applicant (name and address etc).

1.2. Manufacturer of the preparation and the active substance(s) (names and addresses, including location of plant(s)).

II IDENTITY OF THE BIOCIDAL PRODUCT

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

2.2. Detailed quantitative and qualitative information on the composition of the preparation e.g. active substance(s), impurities, adjuvants, inert components.

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

III PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT

3.1. Appearance (physical state, colour).

3.2. Explosive properties.

3.3. Oxidizing 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 — stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the biocidal product.

3.8. Technical characteristics of the preparation.

3.8.1. Wettability.

3.8.2. Persistent foaming.

3.8.3. Flowability, pourability and dustability.

3.8.4. Suspensibility and suspension stability.

3.8.5. Wet sieve test and dry sieve test.

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

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

3.8.8. Emulsifiability, re-emulsifiability, emulsion stability.

3.8.9. Wetting, adherence and distribution to target organisms.

3.9. Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorized.

3.10. If the biocidal product is to be used in the form of a bait for granules, then specify any repellants or poison control measures included with the preparation that are present to prevent action against non-target organisms.

IV METHODS OF IDENTIFICATION AND ANALYSIS

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

4.2. In so far as not covered by Annex II, point 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, where relevant in or on the following:

(a) soil;

(b) air;

(c) water (including drinking water);

(d) animal and human body fluids and tissues;

(e) treated food or feedingstuffs.

V INTENDED USES AND EFFICACY

5.1. Field of use envisaged.

5.2. Method of application.

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

5.4. Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and livestock.

5.5. Any other necessary information.

5.6. Function, e.g. fungicide, rodenticide, insecticide, bacteriocide.

5.7. Pest organism(s) controlled and products, organisms or objects to be protected.

5.8. Effects on target organisms, e.g. contact, ingestion or stomach poison, fungitoxic, fungistatic.

5.9. Mode of action in so far as not covered by Annex II, point 5.4.

5.10. User, professional or non-professional.

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

Efficacy data

5.12. Data to support the efficacy claims of the preparation label, including any available standard protocols used, laboratory tests, or where appropriate field trials. For each application a reasoned case will be required.

5.13. The effect of factors such as climate, temperature, humidity, precipitation etc. in so far as not covered by point 5.4.

5.14. Compatibility with different cultural practices and other measures that may be used against the target organism under the conditions of use envisaged.

5.15. Any other known limitations on efficacy.

5.16. Relative advantages of the preparation or its intended use compared to any existing preparations or treatment methods.

5.17. Summary and evaluation of data presented under point 5.12 to 5.17.

VI TOXICOLOGICAL STUDIES

6.1. Acute toxicity.

6.1.1. Oral.

6.1.2. Dermal.

6.1.3. Inhalation.

6.1.4. Skin and eye irritation.

6.1.5. For biocidal products that are intended to be authorized for use with other biocidal products, the mixture of preparations, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate.

6.2. Dermal absorption test, where necessary.

6.3. Available toxicological data relating to toxicologically relevant non-active substances.

6.4. Studies related to the exposure of the preparation to man.

Where necessary, the test(s) described in Annex IV, Part A shall be required for the toxicologically relevant non-active substances of the preparation.

6.5. If the biocidal product is in the form of a bait or granules, pet or livestock acceptance studies may be required.

6.6. Summary and evaluation of data presented in point 6.1 to 6.6, including where possible any suggested worker protection measures in summary form.

VII ECOTOXICOLOGICAL STUDIES ON THE BIOCIDAL PRODUCT

7.1. The information provided must, where relevant, include that referred to in Annex II, points 7.1 to 7.4.

7.2. If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in Annex IV, Parts D and E shall be required.

Fate and behaviour in the environment

7.3. The information provided must, where relevant, include that referred to in Annex II, point 7.6.

VIII MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

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

8.2. Emergency measures in case of an accident.

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

8.4. Possible routes of entry into the environment.

8.5. Identity of relevant combustion products in cases of fire.

8.6. Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public.

8.6.1. Possibility of re-use or recycling.

8.6.2. Possibility of neutralization.

8.6.3. Conditions for controlled discharge.

8.6.4. Conditions for controlled incineration.

8.6.5. Others, if appropriate.

8.7. Possibility of destruction or decontamination following release in or on the following:

(a) air;

(b) water, including drinking water;

(c) soil.

8.8. Leachate qualities on disposal, in so far as not covered by point 8.6.3 of Annex II.

8.9. Any information on authorization in other countries.

IX CLASSIFICATION, PACKAGING AND LABELLING

Proposals including justification for the classification and labelling according to Directive 88/379/EEC or, in the case of rodenticides, insecticides/acaricides, avicides and molluscicides Directive 78/631/EEC:

— hazard symbol(s),

— indications of danger,

— risk phrases,

— safety phrases,

— instructions for use,

— packaging (type, materials, size etc.), compatibility of the preparation with proposed packaging materials to include,

— specimens of the proposed packaging and of the proposed label(s) if so required.

X SUMMARY AND EVALUATION OF ALL ANNEX III INFORMATION AND REQUIREMENTS

PART B

Fungi, micro-organisms and viruses

1. Dossiers on biocidal products are required to address at least all the points listed under 'Dossier requirements'. Responses are required to be supported by data.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification acceptable to the competent authority must be submitted.

Dossier requirements

I Applicant

II Identity and composition of the biocidal product

III Technical properties of the biocidal product and any biocidal properties additional to those of the active organism

IV Methods for identification and analysis of the biocidal product

V Intended uses and efficacy for those uses

VI Toxicological information (additional to that for the active organism)

VII Ecotoxicological information (additional to that for the active organism)

VIII Measures to be adopted to protect man, non-target organisms and the environment

IX Classification, packaging and labelling of the biocidal product

X Summary of II to IX

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

I APPLICANT

1.1. Name and address etc.

1.2. Manufacturers of biocidal products and active organisms including location of plants.

II IDENTITY OF BIOCIDAL PRODUCT

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

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

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

2.4. Concentration of active organism in material used.

III 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 preparation.

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. Emulsinability, 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 to be authorized.

3.6. Wetting, adherence and distribution following application.

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

IV METHOD FOR IDENTIFICATION AND ANALYSIS OF THE BIOCIDAL PRODUCT

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. Techniques used to ensure a uniform product and assay methods for its standardization.

V INTENDED USES AND EFFICACY FOR THESE USES

5.1. Use.

Product type (e.g. wood preservative, public hygiene biocide 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. Where necessary, in the light of the test results, any specific circumstances or environmental conditions under which the product 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.

VI TOXICITY INFORMATION ADDITIONAL TO THAT REQUIRED 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 sensitization.

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

6.7. Operator exposure.

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

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

VII ECOTOXICITY INFORMATION 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.

VIII MEASURES TO BE ADOPTED TO PROTECT MAN, NON-TARGET ORGANISMS AND THE ENVIRONMENT

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

8.2. Re-entry periods, necessary waiting periods or 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.

8.5. Procedures for cleaning application equipment.

8.6. Procedures for safe disposal of the concentrated biocidal product or diluted product.

IX CLASSIFICATION, PACKAGING AND LABELLING

9.1. Proposals including justification for the classification, packaging and labelling

(i) with regard to non-biological components of the product in accordance with Directive 88/379/EEC:

— hazard symbol(s),

— indications of danger,

— risk phrases,

— safety phrases;

(ii) with regard to the active organisms labelling with the appropriate risk group as outlined in Article 2 (d) of Directive 90/679/EEC together with the biohazard sign specified in that Directive if appropriate.

9.2. Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials.

9.3. Specimens of proposed packaging.

X SUMMARY OF II TO IX

ANNEX IV

FURTHER REQUIREMENTS FOR THE DOSSIERS TO BE INTRODUCED FOR THE AUTHORIZATION OF BIOCIDAL PRODUCTS

PART A

Further human health related studies on the active substance and/or the preparation

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 where relevant its metabolites on the treated or contaminated food or feedstuffs including the kinetics of disappearance.

1.3. Overall material balance of the active substance. Sufficient residue data from supervised trials to demonstrate that residues likely to arise from 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 and other means.

1.5. If the residue of the biocidal product remains 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.

1.6. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residue of the biocidal product or 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 data submitted under 1.1 to 1.8.

2. *Other test(s) related to the exposure to man*

Suitable test(s) and a reasoned case will be required for the active substance or the preparation, as appropriate.

PART B

Further studies on the 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 processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions.

1.2. Adsorption and desorption in at least three soil types and where relevant adsorption and desorption of metabolites and degradation products.

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

1.4. Extent and nature of bound residues.

2. *Fate and behaviour in water*

2.1. Rate and route of degradation in aquatic systems (as far as is not covered by Annex II, point 7.6) including identification of metabolites and degradation products.

2.2. Adsorption and desorption in water (soil sediment systems) and where relevant adsorption and desorption of metabolites and degradation products.

3. *Fate and behaviour in air*

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, then the rate and route of degradation in air shall be determined as far as is not covered by Annex II, point 7.6.2.3.

4. *Summary and evaluation of parts 1, 2 and 3*

PART C

Further ecotoxicological studies on the active substance

1. *Effects on birds*

1.1. Acute oral toxicity — this need not be done if an avian species was selected for study in Annex II, point 7.4.

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

1.3. Effects on reproduction.

2. *Effects on aquatic organisms*

2.1. Prolonged toxicity to an appropriate species of fish.

2.2. Effects on reproduction and growth rate on an appropriate species of fish.

2.3. Bioaccumulation in an appropriate species of fish.

2.4. Daphnia magna reproduction and growth rate.

3. *Effects on other non-target organisms*

3.1. Acute toxicity to honeybees and other beneficial arthropods e.g. predators. A different test organism shall be chosen from that used in Annex II, point 7.4.

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

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

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

4. *Other effects*

4.1. Activated sludge respiration inhibition test.

5. *Summary and evaluation of parts 1, 2 and 3.*

PART D

Further studies on the fate and behaviour of the environmentally relevant components of the biocidal product in the environment

1. Where relevant all the information required in Annex IV, Part B.

2. Testing for distribution and dissipation in the following:

(a) soil;

(b) water;

(c) air.

Test requirements 1 and 2 are applicable only to ecotoxicologically relevant components of the preparation.

PART E

Further ecotoxicological studies on the biocidal products

1. *Effects on birds*

1.1. Acute oral toxicity, if not already done in accordance with Annex III, point 7.

2. *Effects on aquatic organisms*

2.1. In case of application 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.

2.1.3. The studies referred to in Annex IV, Part C points 2.1, 2.2, 2.3 and 2.4 may be required for relevant components of the preparation.

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 (flora and fauna) believed to be at risk.

3.7. If the biocidal product is in the form of bait or granules, the following will 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; in so far as not covered by Annex III, point 6.6.

4. *Summary and evaluation of Parts 1, 2 and 3.*

ANNEX V

Biocidal products shall include those product types set out below which can be used for the purposes described:

Product type	*Description of use*
Disinfectant	Disinfection of skin (human or animal) and articles intended to come into contact with skin.
Swimming pool disinfectant	Disinfection of water used for public bathing.
Food industry disinfectant	Disinfection of containers surfaces and pipework associated with the production of food and drink for humans and animals.
General biocide	Control of harmful micro-organisms in premises vehicles and areas used by humans and animals.
Sanitary biocide	Control of harmful micro-organisms in sanitary convenancies and equipment.
Air-conditioning biocide	Control of harmful organisms in air conditioning systems.
Wood preservatives	Protection of sawn timber and timber products from harmful organisms.
Textile preservatives	Protection of textiles from harmful organisms.
Masonry preservatives	Protection of masonry and other construction materials (except wood) from harmful organisms.
Consumer product preservatives	Protection of products marketed to the consumer, other than food and feed, from harmful organisms.
Industrial biocides	Control of harmful organisms affecting industrial processes.
Specialist biocides	Control of harmful organisms in connection with specific products, substances, materials, articles on areas not covered by other product types.

Product type	*Description of use*
Rodenticide	Control of rats, mice or other rodents for purposes of public health and well-being.
Avicide	Control of birds for purposes of public health and well-being.
Molluscicide	Control of snails and other molluscs, both terrestrial and aquatic for purposes of public health and well-being.
Insecticide/Acaricide	Control of insects, mites and other arthropods for purposes of public health and well-being.
Anti-fouling biocide	Control of fouling organisms on ships, boats, aquatic structures and articles.