Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (repealed)

DIRECTIVE 98/8/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 February 1998

concerning the placing of biocidal products on the market (repealed)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission[(1)],

Having regard to the opinion of the Economic and Social Committee[(2)],

Acting in accordance with the procedure laid down in Article 189b of the Treaty[(3)] in the light of the joint text approved on 16 December 1997 by the Conciliation Committee,

(1) Whereas, in their resolution of 1 February 1993 on a Community programme of policy and action in relation to the environment and sustainable development[(4)], the Council and the representatives of the Governments of the Member States, meeting within the Council, approved the general approach and strategy of the programme presented by the Commission, in which the need for risk management of non-agricultural pesticides is emphasised;

(2) Whereas, both when the eighth Amendment[(5)] to 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 dangerous substances and preparations[(6)] was adopted in 1989 and during the discussion in the Council on Directive 91/414/EEC concerning the placing of plant protection products on the market[(7)], the Council expressed concern at the lack of harmonised Community provisions for biocides, formerly known as non-agricultural pesticides, and invited the Commission to examine the situation in Member States and the possibility for action at Community level;

(3) Whereas biocidal products are necessary for the 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 biocidal products can pose risks to humans, animals and the environment in a variety of ways due to their intrinsic properties and associated use patterns;

(4) Whereas the Commission review showed differences in the regulatory situation in the Member States; whereas such differences may constitute barriers not only to trade in biocidal products but also to trade in products treated with them, thereby affecting the functioning of the internal market; whereas, therefore, the Commission proposed the

development of a framework of rules relating to the placing on the market for use of biocidal products, taking as a condition a high level of protection for humans, animals and the environment; 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; whereas a directive on biocidal products is the most appropriate way of establishing such a framework;

(5) Whereas the framework of rules should provide that biocidal products should not be placed on the market for use unless they have complied with the relevant procedures of this Directive;

(6) Whereas, to take account of the specific nature of some biocidal products and the risks associated with their proposed use, it is appropriate to provide for simplified authorisation procedures, including registration;

(7) Whereas it is appropriate that the applicant submit dossiers which contain information which is necessary to evaluate the risks that will arise from proposed uses of the product; whereas a common core data set for active substances and for biocidal products in which they are contained is necessary so as to assist both the applicants seeking authorisation and those carrying out the evaluation to decide on the authorisation; whereas, furthermore, specific data requirements need to be elaborated for each of the product types covered by this Directive;

(8) Whereas it is necessary, when biocidal products are being authorised, to make sure that, when properly used for the purpose intended, they are sufficiently effective and have no unacceptable effect on the target organisms such as resistance or unacceptable tolerance, and, in the case of vertebrate animals, unnecessary suffering and pain, and have, in the light of current scientific and technical knowledge, no unacceptable effect on the environment and, in particular, on human or animal health;

(9) Whereas it is necessary to provide common principles for the evaluation and authorisation of biocidal products to ensure a harmonised approach by Member States;

(10) Whereas Member States should not be prevented from imposing additional requirements on the use of biocidal products in so far as these additional requirements are in conformity with Community law and in particular do not run counter to the provisions of this Directive; whereas such provisions are intended to protect the environment and human and animal health by means such as epidemic control and food and feedingstuff protection;

(11) Whereas, in the light of the diversity of both the active substances and the biocidal products concerned, the data and test requirements should suit the individual circumstances and result in an overall risk assessment;

(12) 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 an active substance to the list has to be specified; whereas active substances on the list

should be reviewed periodically, and, if appropriate, compared with each other under specific conditions, to take account of developments in science and technology;

(13) Whereas, when due account is taken of products which pose only a low risk, their active substances should be incorporated in a specific annex; whereas substances the main use of which is non-pesticidal but which have some minor use as a biocide either directly, or in a product consisting of an active substance and a simple diluent should be incorporated in a separate specific annex;

(14) Whereas when an active substance is evaluated for its entry or otherwise in the relevant annexes of the Directive, it is necessary for such an evaluation to cover, where appropriate, the same aspects as those covered by the evaluation made under Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[(8)] and Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances[(9)] as far as the risk assessment is concerned; whereas, therefore, the risks associated with the production, use and disposal of the active substance and materials treated with it are to be considered in a similar way as they are in the aforementioned legislation;

(15) Whereas it is in the interest of the free circulation of biocidal products, as well as of materials treated with them, that authorisation granted by one Member State should be recognised by other Member States subject to the specific conditions contained in this Directive;

(16) Whereas, while envisaging harmonised provisions for all biocidal product types, including those intended to control vertebrates, the actual use of such types might give rise to concern; whereas therefore Member States should be allowed, subject to the Treaty, to derogate from the principle of mutual recognition for biocidal products falling under three particular types of biocides whenever intended to control particular kinds of vertebrates, in so far as such derogations are justified and do not jeopardise the purpose of this Directive;

(17) 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 authorisation of biocidal products;

(18) Whereas it should be possible for Member States to authorise, for a limited period of time, biocidal products which do not comply with the abovementioned conditions, especially in the event of an unforeseen danger threatening humans, animals or the environment which cannot be contained by other means; whereas the Community procedure should not prevent Member States from authorising, for a limited period of time for use in their territory, 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 concerned believes that the active substance and the biocidal product satisfy the Community conditions set for them;

(19) Whereas it is essential that this Directive help to minimise the number of tests on animals and that testing should be made dependent on the purpose and use of a product;

(20) Whereas close coordination should be ensured with other Community legislation and in particular with Directive 91/414/EEC, the Directives concerned with the protection of water and those concerned with the contained use and deliberate release of genetically modified organisms;

(21) Whereas the Commission is to draw up technical notes for guidance in particular on the implementation of the authorisation procedures, the entry of active substances in the appropriate Annexes, the Annexes relating to data requirements and the Annex dealing with the common principles;

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

(23) Whereas the implementation of this Directive, the adaptation of its Annexes to the development of technical and scientific knowledge and the inclusion of active substances in the appropriate Annexes necessitate close cooperation between the Commission, the Member States and the applicants; whereas, in cases where the procedure of the Standing Committee on Biocidal Products is to be applied, this constitutes a suitable basis for such cooperation;

(24) Whereas an agreement on a *modus vivendi* between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the EC Treaty was reached on 20 December 1994[(10)];

(25) Whereas the Commission will apply the *modus vivendi* to the implementing measures flowing from this Directive that it envisages adopting, including those concerning Annexes IA and IB;

(26) Whereas, since the full implementation of this Directive, and especially the review programme, will not be achieved for several years, Directive 76/769/EEC provides 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 thereof;

(27) Whereas the review programme on active substances will need to take account of other work programmes within the framework of other Community legislation concerned with the review or authorisation of substances and products or relevant international Conventions;

(28) Whereas the costs of the procedures associated with the operation of the Directive need to be recovered from those seeking to place, or placing, biocidal products on the market and from those supporting the entries of active substances in the relevant Annexes;

(29) Whereas minimum rules concerning the use of biocidal products at work are laid down under Directives on health and safety at work; whereas it is desirable to develop further rules in this area,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Scope

1 This Directive concerns:

a the authorisation and the placing on the market for use of biocidal products within the Member States;

b the mutual recognition of authorisations 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(l)(a) but shall exclude products that are defined or within the scope of the following instruments 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[(11)],

b Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States on veterinary medicinal products[(12)],

c Council Directive 90/677/EEC of 13 December 1990 extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological medicinal products[(13)],

d Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products[(14)],

e Council Directive 92/74/EEC of 22 September 1992 widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products[(15)],

f Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[(16)],

g Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[(17)],

h Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[(18)],

i Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption[(19)], Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production[(20)] and European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners[(21)],

j Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs[(22)],

k Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk based products[23],

l Council Directive 89/437/EEC of 20 June 1989 on hygiene and health problems affecting the production and the placing on the market of egg products[24],

m Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products[25],

n Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[26],

o Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[27], Council Directive 82/471/EEC of 30 June 1982 on certain products used in animal nutrition[28] and Council Directive 77/101/EEC of 23 November 1976 on the marketing of straight feedingstuffs[29],

p Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[30],

q Council Directive 95/5/EC of 27 February 1995 amending Directive 92/120/EEC on the conditions for granting temporary and limited derogations from specific Community health rules on the production and marketing of certain products of animal origin[31],

r Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[32].

3 This Directive shall apply, without prejudice to relevant Community provisions or measures taken in accordance with them, in particular, to:

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[33],

b Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances[34],

c Council Regulation (EEC) No 2455/92 of 23 July 1992 concerning the export and import of certain dangerous chemicals ([35]),

d Council Directive 80/1107/EEC of 27 November 1980, on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work[36], Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[37] and individual Directives based on these Directives,

e Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations or administrative provisions of the Member States concerning misleading advertising[38].

4 Article 20 shall 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 by chemical or biological means.

An exhaustive list of 23 product types with an indicative set of descriptions within each type is given in Annex V.

b *Low-risk biocidal product*

A biocidal product which contains as active substance(s) only one or more of those listed in Annex IA and which does not contain any substance(s) of concern.

Under the conditions of use, the biocidal product shall pose only a low risk to humans, animals and the environment.

c *Basic substance*

A substance which is listed in Annex I B, whose major use is non-pesticidal but which has some minor use as a biocide either directly or in a product consisting of the substance and a simple diluent which itself is not a substance of concern and which is not directly marketed for this biocidal use.

The substances, which could potentially enter Annex IB in accordance with the procedure laid down in Articles 10 and 11, are *inter alia* the following:

— carbon dioxide,
— nitrogen,
— ethanol,
— 2-propanol,
— acetic acid,
— kieselguhr.

d *Active substance*

A substance or micro-organism including a virus or a fungus having general or specific action oh or against harmful organisms.

e *Substance of concern*

Any substance, other than the active substance, which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to create such an effect.

Such a substance, unless there are other grounds for concern, would be normally a substance classified as dangerous according to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[(39)], and present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Article 3 of Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[(40)].

f *Harmful organism*

Any organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment.

g *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.

h *Placing on the market*

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

i *Authorisation*

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

j *Frame-formulation*

Specifications for a group of biocidal products having the same use and user type.

This group of products must contain the same active substances of the same specifications, and their compositions must present only variations from a previously authorised biocidal product which do not affect the level of risk associated with them and their efficacy.

In this context, a variation is the allowance of a reduction in the percentage of the active substance and/or an alteration in percentage composition of one or more non-active substances and/or the replacement of one or more pigments, dyes, perfumes by others presenting the same or a lower risk, and which do not decrease its efficacy.

k *Registration*

An administrative act by which the competent authority of a Member State, following an application submitted by an applicant, after verification that the dossier meets the relevant requirements of this Directive, allows the placing on the market of a low-risk biocidal product in its territory or in a part thereof.

l *Letter of access*

A document, signed by the owner or owners of relevant data protected under the provisions of this Directive, which states that these data may be used by the competent authority for the purpose of granting an authorisation or a registration of a biocidal product under this Directive.

2 For the purposes of this Directive the definitions for:

a substance,

b preparation,

c scientific research and development,

d process-orientated research and development

laid down in Article 2 of Council Directive 67/548/EEC shall apply.

Article 3

Authorisation 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 authorised in accordance with this Directive.

2 By way of derogation from paragraph 1:

(i) Member States shall, subject to registration, allow the placing on the market and use of a low-risk biocidal product, provided that a dossier in accordance with Article 8(3) has been submitted and verified by the competent authorities.

Unless otherwise specified, all provisions relating to authorisation under this Directive shall also apply to registration.

(ii) Member States shall allow the placing on the market and use of commodity substances for biocidal purposes once they have been entered in Annex IB.

3

(i) Every application for authorisation shall be decided on without undue delay.

(ii) For applications for biocidal products that require registration, the competent authority shall take a decision within a period of 60 days.

4 Member States shall, on request, or may, on their own initiative, and where relevant, establish a frame-formulation and communicate it to the applicant when issuing an authorisation for a particular biocidal product.

Without prejudice to Articles 8 and 12 and providing that the applicant has a right of access to the frame-formulation in the form of a letter of access, when a subsequent application for authorisation for a new biocidal product is based on this frame-formulation, the competent authority shall take a decision with regard to this application within a period of 60 days.

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

6 Without prejudice to Article 7(1), authorisations shall be granted for a maximum period of 10 years from the date of first or renewed inclusion of the active substance in Annex I or I A for the product type, without exceeding the deadline specified for the active substance in Annex I or I A; they may be renewed after verification that the conditions imposed in Article 5(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.

7 Member States shall prescribe that biocidal products are to be properly used. Proper use shall include compliance with conditions established pursuant to Article 5 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

Mutual recognition of authorisations

1 Without prejudice to Article 12, a biocidal product that has already been authorised or registered in one Member State shall be authorised or registered in another Member State within 120 days, or 60 days respectively, of an application being received by the other Member State, provided that the active substance of the biocidal product is included in Annex I or I A and conforms to the requirements thereof. For the mutual recognition of authorisations, the application shall include a summary of the dossier as required in Article 8(2)(a) and Annex II B, Section X and a certified copy of the first authorisation granted. For mutual recognition of registration of low-risk biocidal products, the application shall include the data requirements of Article 8(3), except for the efficacy data for which a summary shall suffice.

The authorisation may be subject to provisions resulting from the implementation of other measures in accordance with Community law, relating to the conditions for distribution and use of biocidal products intended to protect the health of the distributors, users and workers concerned.

This mutual recognition procedure shall be without prejudice to measures taken by Member States pursuant to Community law intended to protect the health of workers.

2 If, in accordance with Article 5, a Member State establishes that:

a the target species is not present in harmful quantities,

b unacceptable tolerance or resistance of the target organism to the biocidal product is demonstrated, or

c 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 authorised, and an unchanged authorisation may therefore present unacceptable risks to humans or the environment,

the Member State may request that certain conditions referred to in Article 20(3)(e), (f), (h), (j) and (1) be adjusted to the different circumstances, so that conditions for issue of an authorisation laid down in Article 5 are satisfied.

3 Where a Member State believes that a low-risk biocidal product which has been registered by another Member State does not comply with the definition provided for in Article 2(1)(b), it may provisionally refuse registration thereof and shall immediately communicate its concerns to the competent authority responsible for the verification of the dossier.

If, within a maximum period of 90 days, an agreement is not reached between the authorities concerned, the matter will be forwarded to the Commission for a decision in accordance with the procedure laid down in paragraph 4.

4 Notwithstanding paragraphs 2 and 3, where a Member State believes a biocidal product authorised by another Member State cannot meet the conditions set out pursuant to Article 5(1) and consequently proposes to refuse the authorisation or the registration or to restrict the authorisation under certain conditions, it shall notify the Commission, other Member States and the applicant and shall provide them with an explanatory document containing the name of the product and its specification and setting out the grounds on which it proposes to refuse or to restrict the authorisation.

The Commission shall prepare a proposal on these matters in accordance with Article 27 for a decision in accordance with the procedure laid down in Article 28(2).

5 If the procedure laid down in paragraph 4 leads to the confirmation of a refusal of a second or subsequent registration by a Member State, the Member State that had previously registered the low-risk biocidal product shall, where deemed appropriate by the Standing Committee, take this refusal into consideration and review its registration according to Article 6.

If this procedure confirms the initial registration, the Member State having introduced the procedure shall register the low-risk biocidal product concerned.

6 By way of derogation from paragraph 1, Member States may refuse, subject to the Treaty, mutual recognition of authorisations granted for product types 15, 17 and 23 of Annex V provided that such a limitation can be justified and does not jeopardise the purpose of the Directive.

Member States shall inform each other and the Commission of any decision taken in this respect and indicate the reasons therefor.

Article 5

Conditions for issue of an authorisation

1 Member States shall authorise a biocidal product only if

a the active substance(s) included therein are listed in Annex I or IA and any requirements laid down in these Annexes are fulfilled;

b it is established, in the light of current scientific and technical knowledge, and is shown from appraisal of the dossier provided for in Article 8, according to the common principles for the evaluation of dossiers as laid down in Annex VI, that, when used as authorised 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 effects on the target organisms, such as unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates,

(iii) has no unacceptable 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, indoor air or consequences in the place of work) or on surface water and groundwater,

(iv) has no unacceptable effect itself, or as a result of its residues, on the environment having particular regard to the following considerations:

— its fate and distribution in the environment; particularly contamination of surface waters (including estuarian and seawater), groundwater and drinking water,

— its impact on non-target organisms;

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 authorised uses, can be determined according to the relevant requirements in Annex IIA, IIB, IIIA, IIIB, IVA or IVB;

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

2 A biocidal product classified according to Article 20(1) as toxic, very toxic or as a category 1 or 2 carcinogen, or as a category 1 or 2 mutagen or classified as toxic for reproduction category 1 or 2, shall not be authorised for marketing to, or use by the general public.

3 Authorisation may be conditional on, and must stipulate the conditions 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 authorisation and for use of the biocidal product, and particularly where these are intended to protect the health of distributors, users, workers and consumers or animal health or the environment, the competent authority shall take these into account when issuing an authorisation and where necessary shall issue the authorisation subject to those requirements.

Article 6

Review of an authorisation

During the period for which an authorisation has been granted, it may be reviewed at any time, e.g. following information received according to Article 14, if there are indications that any of the conditions referred to in Article 5 are no longer satisfied. In such instances the Member States may require the authorisation holder, or the applicant to whom a modification of the authorisation has been granted in accordance with Article 7, to submit further information necessary for the review. If need be, the authorisation may be prolonged only for the period necessary to complete the review, but shall be prolonged for the period necessary to provide for further information.

Article 7

Cancellation or modification of an authorisation

1 An authorisation shall be cancelled if:

a the active substance is no longer included in Annex I or IA as required by Article 5(l)(a);

b the conditions within the meaning of Article 5(1) for obtaining the authorisation are no longer satisfied;

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

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

3 When a Member State intends to cancel an authorisation, it shall inform and hear the authorisation holder. When cancelling the authorisation, the Member State may grant a period of grace for the disposal or for the 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 pursuant to Directive 76/769/EEC or in connection with paragraph l(a).

4 Where a Member State considers it necessary, on the basis of developments in scientific and technical knowledge and to protect health and the environment, it shall modify the conditions of use of an authorisation and, in particular, the manner of use or the amounts used.

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

6 Where a proposed modification concerns an extension of uses, a Member State shall extend the authorisation subject to the particular conditions placed on the active substance listed in Annex I or IA.

7 Where a proposed modification of an authorisation involves changes to the particular conditions placed on the active substance listed in Annex I or IA, such changes 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 11.

8 Modifications shall be granted only if it is established that the conditions within the meaning of Article 5 remain satisfied.

Article 8

Requirements for authorisation

1 Application for authorisation shall be made by, or on behalf of, the person who will be responsible for the first placing on the market 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 an applicant for authorisation of a biocidal product shall submit to the competent authority:

a a dossier or a letter of access for the biocidal product satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex IIB and, where specified, the relevant parts of Annex IIIB, and

b for each active substance in the biocidal product, a dossier or a letter of access satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex IIA and, where specified, the relevant parts of Annex IIIA.

3 By way of derogating from paragraph 2(a), Member States shall require a dossier comprising the following data for a low-risk biocidal product:

(i) applicant:

1.1. name and address,

1.2. manufacturers of the biocidal product and the active substances,

(names and addresses including location of manufacturer of the active substance)

1.3. where appropriate, a letter of access to any relevant data needed,

(ii) identity of the biocidal product:

2.1. trade name,

2.2. full composition of the biocidal product,

2.3. physical and chemical properties as referred to in Article 5(1)(d),

(iii) intended uses:

3.1. product type (Annex V) and field of use,

3.2. category of users,

3.3. method of use,

(iv) efficacy data,

(v) analytical methods,

(vi) classification, packaging and labelling, including a draft label, according to Article 20,

(vii) safety data sheet prepared in accordance with Article 10 of Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations, and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous substances[41], or Article 27 of Directive 67/548/EEC.

4 The dossiers shall include a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to those methods. The information in the dossiers supplied in accordance with Article 8(2) shall be sufficient for an evaluation to be made of the effects and properties referred to in Article 5(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 Annexes IIA and IIB and, where specified, the relevant parts of Annexes IIIA and IIIB.

5 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. Such a justification may be the existence of a frame-formulation which the applicant has the right to access.

6 If the evaluation of the dossier shows that further information, including data 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. The time period for the evaluation of the dossier shall start only after the dossier is complete.

7 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 the name is not included therein, as given in the European Inventory of Existing Chemical Substances (Einecs), or, if the name is not included therein, the active substance must be given its International Standards Organisation (ISO) common name. If the latter is not available, the substance must be designated by its chemical designation according to International Union of Pure and Applied Chemistry (IUPAC) rules.

8 As a general principle, tests must be conducted according to the methods described in Annex V to Directive 67/548/EEC. In the event of a method being inappropriate or not described, other methods used should, whenever possible, be internationally recognised and must be justified. Where appropriate, tests must be conducted in accordance with the provisions laid down in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[42] and Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions

relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances[(43)].

9 Where test data exist that have been generated before the adoption of this Directive by methods other than those laid down in Annex V to Directive 67/548/EEC, the adequacy of such data for the purposes of this Directive and the need to conduct new tests according to Annex V must be decided on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrate animals.

10 Competent authorities as referred to within the meaning of Article 26 shall ensure that a file is compiled 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. On request, Member States shall 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 paragraph 2.

11 Member States my require that samples of the preparation and of its ingredients be provided.

12 Member States may require that applications for authorisation be submitted in their national or official languages or one of these languages.

Article 9

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 referred to in Article 34(1), a dossier has been forwarded to a Member State, which satisfies the requirements of Article 11(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 pursuant to Article 17;

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

Article 10

Inclusion of an active substance in Annexes I, IA or IB

1 In the light of current scientific and technical knowledge, an active substance shall be included in Annex I, Annex IA or IB for an initial period not exceeding 10 years if it may be expected that

— biocidal products containing the active substance,

— low-risk biocidal products complying with the definition in Article 2(1)(b),

— commodity substances complying with the definition in Article 2(1)(c),

will fulfil the conditions laid down in Article 5(1)(b), (c) and (d), taking into account, where relevant, cumulation effects from the use of biocidal products containing the same active substances.

An active substance cannot be included in Annex IA if it is classified according to Directive 67/548/EEC as:

— carcinogenic,

— mutagenic,

— toxic for reproduction,

— sensitising, or

— is bioaccumulative and does not readily degrade.

Where appropriate, the entry of an active substance in Annex IA shall refer to the concentration ranges between which the substance can be used.

2 Inclusion of an active substance in Annexes I, IA or IB 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 and area 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 which has been made available in the context of this Directive;

(ii) the establishment of the following:

(a) acceptable operator exposure level (AOEL), if necessary,

(b) where relevant, an acceptable daily intake for man (ADI) and a maximum residue limit (MRL),

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

3 The inclusion in Annex I, IA or IB of an active substance shall be restricted to those product types in Annex V for which relevant data have been submitted in accordance with Article 8.

4 The inclusion of an active substance in Annex I, IA or IB 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 are indications that any of the requirements referred to in paragraph 1 are not longer satisfied. Renewal may, where necessary, be granted only for the minimum 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 further information requested in accordance with Article 11(2).

5

(i) An entry of an active substance in Annex I and,

— where relevant, IA or IB may be refused or removed,

if the evaluation of the active substance in accordance with Article 11(2) shows that, under normal conditions under which it may be used in

authorised biocidal products, risks to health or the environment still give rise to concern, and

— if there is another active substance on Annex I for the same product type which, in the light of scientific or technical knowledge, presents significantly less risk to health or to the environment.

When such a refusal or removal is considered, an assessment of an alternative active substance or substances shall take place to demonstrate that it can be used with similar effect on the target organism without significant economic and practical disadvantages for the user and without an increased risk for health or for the environment.

The assessment shall be circulated in accordance with the procedures in Article 11(2) for decision in accordance with the procedures laid down in Articles 27 and 28(3).

(ii) The refusal or removal of an Annex I and, where relevant, IA or IB entry shall be carried out under the following conditions:

1. the chemical diversity of the active substances should be adequate to minimise occurrence of resistance in the target organism;

2. it should be applied only to active substances which, when used under normal conditions in authorised biocidal products, present a significantly different level of risk;

3. it should be applied only to active substances used in products of the same product type;

4. it should be applied only after allowing the possibility, where necessary, of acquiring experience from use in practice, if it is not already available;

5. the complete data dossiers of the evaluation serving or having served for entry in Annex I, IA or IB shall be put at the disposal of the Committee referred to in Article 28(3).

(iii) A decision to remove an Annex I entry shall not have immediate effect but shall be delayed for a period of up to a maximum of four years from the date of that decision.

Article 11

Procedure for inclusion of an active substance in Annex I, IA or IB

1 Inclusion, or subsequent changes to the inclusion, of an active substance in Annex I, IA or IB shall 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 IVA or the requirements of Annex IIA and, where specified, the relevant parts of Annex IIIA;

(ii) a dossier for at least one biocidal product containing the active substance satisfying the requirements of Article 8, with the exception of paragraph 3 thereof;

b the receiving competent authority has verified the dossiers and believes them to satisfy the requirements of Annex IVA and Annex IVB or the requirements of Annex IIA and Annex IIB and, where relevant, Annexes IIIA and IIIB, 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 12 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, IA or IB.

If, when the dossiers are evaluated, 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 12-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 when it informs the applicant.

3 To avoid dossiers being evaluated by only a few Member States, the evaluation can be carried out by Member States other than the receiving one. A request for this shall be given when the dossiers are accepted, and the decision shall be taken in accordance with the procedure laid down in Article 28(2). The decision shall be taken at the latest one month after receipt by the Commission of the request.

4 On receipt of the evaluation, the Commission shall, in accordance with the procedure in Article 27, prepare a proposal without undue delay for decision in accordance with the procedure laid down in Article 28(3). The decision shall be taken at the latest 12 months after the receipt by the Commission of the evaluation referred to in paragraph 2.

Article 12

Use of data held by competent authorities for other applicants

1 Member States shall not make use of the information referred to in Article 8 for the benefit of a second or subsequent applicant:

a unless the second or subsequent applicant has the written agreement in the form of a letter of access 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 referred to in Article 34(1), for a period of 15 years from the date of first inclusion in Annex I or IA, or

c in the case of an active substance already on the market on the date referred to in Article 34(1):

(i) for a period of 10 years from the date referred to in Article 34(1) 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 referred to in Article 34(1);

(ii) for a period of 10 years from the date of entry of an active substance onto Annex I or IA for information submitted for the first time in support of the first inclusion in Annex I or IA 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 requirements of the entry on Annex I or IA;

(ii) maintenance of the entry of Annex I or. IA

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 paragraphs 1(b) and (c), in which case the period of five years shall be extended so as to expire on the same date as those periods.

2 Member States shall not make use of the information referred to in Article 8, for the benefit of a second or subsequent applicant:

a unless the second or subsequent applicant has the written agreement in the form of a letter of access 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 referred to in Article 34(1) for a period of 10 years from the date of first authorisation in any Member State, or;

c in the case of a biocidal product containing an active substance already on the market on the date referred to in Article 34(1);

(i) for a period of 10 years from the date referred to in Article 34(1) 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 referred to in Article 34(1);

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

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

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 paragraphs (b) and (c), in which case the period of five years shall be extended so as to expire on the same date as those periods.

3 For decisions to be taken in accordance with Article 10(5), the information referred to in paragraphs 1 and 2 can be used by the Commission, the Scientific Committees as referred to in Article 27 and the Member States.

Article 13

Cooperation in the use of data for second and subsequent applications for authorisation

1 In the case of a biocidal product which has already been authorised in accordance with Articles 3 and 5, and without prejudice to the obligations imposed pursuant to Article 12, the competent authority may agree that a second or subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the second or subsequent applicant can provide

evidence that the biocidal product is similar and its active substances are the same as the one formerly authorised, including degree of purity and nature of impurities.

2 Notwithstanding Article 8(2):

a an applicant for authorisation of biocidal products shall, before carrying out experiments involving vertebrate animals, enquire of the competent authority of the Member State to which he intends making application:

— whether the biocidal product for which an application is to be made is similar to a biocidal product for which authorisation has been granted, and

— as to the name and address of the holder or holders of the authorisation or authorisations.

The enquiry shall be supported by evidence that the prospective applicant intends to apply for authorisation on his own behalf and that the other information specified in Article 8(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 former relevant authorisations and shall at the time inform the holders of the authorisations of the name and address of the applicant.

The holder or holders of former authorisations and the applicant shall take all reasonable steps to reach agreement on the sharing of information, so as to avoid, if possible, the duplication of testing on vertebrate animals.

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

Article 14

New information

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

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

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

— changes in composition of a biocidal product,

— development of resistance,

— changes of an administrative nature or other aspects, such as the nature of the packaging.

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

Article 15

Derogation from the requirements

1 By way of derogating from Articles 3 and 5, a Member State may authorise 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 28(2), whether, and, if so, under what 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 5(1)(a) and until an active substance is listed in Annex I or IA, a Member State may authorise provisionally, for a period not exceeding three years, the placing on the market of a biocidal product containing an active substance not listed in Annex I or IA and not yet available on the market on the date referred to in Article 34(1) for purposes other than those defined in Article 2(2)(c) and (d). Such an authorisation may be issued only if, after dossiers have been evaluated in accordance with Article 11, the Member State believes that:

— the active substance satisfies the requirements of Article 10 and,

— the biocidal product may be expected to satisfy the conditions of Articles 5(l)(b), (c) and (d),

and no other Member State, on the basis of the summary it receives, makes legitimate objection, in accordance with Article 18(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 procedure laid down in Article 28(2) without undue delay.

If, following the procedures laid down in Articles 27 and 28(2), it is decided that the active substance does not satisfy the requirements specified in Article 10, the Member State shall ensure that the provisional authorisation is cancelled.

In cases where evaluation of dossiers for the purposes of inclusion of an active substance in Annex I or IA is not completed when the period of three years expires, the competent authority may further provisionally authorise 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 10. Member States shall inform other Member States and the Commission of such action.

Article 16

Transitional measures

1 By way of further derogating from Articles 3(1), 5(1), 8(2) and 8(4), and without prejudice to paragraphs 2 and 3, a Member State may, for a period of 10 years from the date referred to in Article 34(1), continue to apply its current system or practice of placing biocidal

products on the market. It may, in particular, according to its national rules, authorise the placing on the market in its territory of a biocidal product containing active substances not listed in Annex I or IA for that product type. Such active substances must be on the market on the date referred to in Article 34(1) as active substances of a biocidal product for purposes other than those defined in Article 2(2)(c) and (d).

2 Following the adoption of this Directive, the Commission shall commence at 10-year programme of work for the systematic examination of all active substances already on the market on the date referred to in Article 34(1) as active substances of a biocidal product for purposes other than those defined in Article 2(2)(c) and (d). A Regulation, adopted according to the procedure laid down in Article 28(3), will provide for all provisions necessary for the establishment and implementation of the programme including the setting of priorities for the evaluation of the different active substances and a timetable. No later than two years before completion of the work programme, the Commission shall forward to the European Parliament and the Council a report on the progress achieved with the programme.

During that 10-year period and from the date referred to in Article 34(1), it may be decided pursuant to the procedure laid down in Article 28(3) that an active substance shall be included in Annexes I, IA or IB and under which conditions, or, in cases where the requirements of Article 10 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, IA or IB.

3 Following such a decision to include or not to include an active substance in Annex I, IA or IB, Member States shall ensure that authorisations or, where relevant, registrations for biocidal products containing the active substances and complying with the provisions of this Directive are granted, modified or cancelled as appropriate.

4 Where, following a review of an active substance, it is concluded that the substance does not meet the requirements of Article 10 and consequently cannot be included in Annex I, IA or IB, the Commission shall bring forward proposals for restricting the marketing and use of that substance in accordance with Directive 76/769/EEC.

5 The provisions of Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and Regulations[44] shall continue to apply during the transitional period referred to in paragraph 2.

Article 17

Research and development

1 By way of derogation from Article 3, Member States shall prescribe that any experiment or test for the purposes of research or development involving the 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 biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance and compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. This information shall, if requested, be made available to the competent authority,

b in the case of process-oriented 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 unauthorised biocidal product or an active substance for exclusive use in a biocidal product may not be placed on the market for the purpose of any experiment or test which may involve, or result in, release into the environment unless the competent authority has assessed the available data and issued an authorisation for this purpose which limits the quantities to be used and the areas to be treated and may impose further conditions.

3 Where any experiment or test takes place in a Member State other than the Member State where placing on the market occurs, the applicant shall obtain experiments or tests authorisation from the competent authority of the Member State in the territory of which the experiments or tests are to be conducted.

If the proposed experiments or tests referred to in paragraphs 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 allow 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 28(2).

Article 18

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 authorised or registered within their territory or for which an authorisation or registration has been refused, modified, renewed or cancelled, indicating at least:

a the name or business name of the applicant for, or the holder of, the authorisation or registration;

b the trade name of the biocidal product;

c the name and amount of each active substance which it contains, as well as the name and amount of each dangerous substance in the meaning of Article 2(2) of Directive 67/548/EEC and their classification;

d the product-type and the use or uses for which it is authorised;

e the type of formulation;

f any proposed limits on residues which have been established;

g conditions of the authorisation and where relevant, the reasons for the modification or cancellation of an authorisation;

h an indication of whether the product is of a special type (e.g. within a frame-formulation, low-risk biocidal product).

2 Where a Member State receives a summary of the dossiers in accordance with Articles 11 (1)(b) and 15(2) 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 without undue delay inform the Commission and other Member States of its concerns.

3 Each Member State shall draw up an annual list of the biocidal products authorised or registered 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 28(2), a standardised information system shall be set up to facilitate the application of paragraphs 1 and 2.

5 The Commission shall draw up a report on the implementation of this Directive and, in particular, on the functioning of the simplified procedures (frame-formulations, low-risk biocidal products and commodity substances) seven years after the date mentioned in Article 34(1). The Commission shall submit the report to the Council, accompanied by proposals if necessary.

Article 19

Confidentiality

1 Without prejudice to Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment[45], 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. Without prejudice to the information referred to in paragraph 3 and the provisions of Directives 67/548/EEC and 88/379/EEC, Member States shall take the necessary steps to ensure the confidentiality of the full composition of product formulations if requested by the applicant.

2 The competent authority receiving the application shall decide, on the basis of documentary evidence produced by the applicant, 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 After the authorisation has been granted, confidentiality shall not in any case apply to:

a the name and address of the applicant;

b the name and address of the biocidal product manufacturer;

c the name and address of the active substance manufacturer;

d the names and content of the active substance or substances in the biocidal product and the name of the biocidal product;

e the names of other substances which are regarded as dangerous within the meaning of Directive 67/548/EEC and contribute to the classification of the product;

f physical and chemical data concerning 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 pursuant to Article 8 to establish the substance's or product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;

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

j safety data sheets;

k methods of analysis referred to in Article 5(1)(c);

l methods of disposal of the product and of its packaging;

m procedures to be followed and measures to be taken in the case of spillage or leakage;

n first aid and medical advice 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 and for implementing this Article shall be decided in accordance with the procedures set out in Article 28(2).

Article 20

Classification, packaging and labelling of biocidal products

1 Biocidal products shall be classified in accordance with the provisions relating to classification in Directive 88/379/EEC.

2 Biocidal products shall be packaged in accordance with Article 6 of Directive 88/379/EEC. In addition:

a products which may be mistaken for food, drink or feedingstuff 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, drink or feedingstuff shall contain components to discourage their consumption.

3 Biocidal products shall be labelled in accordance with the provisions relating to labelling in Directive 88/379/EEC. Labels shall not be misleading or give an exaggerated impression of the product and, in any case, not mention the indications ‘low-risk biocidal product’, ‘non-toxic’, ‘harmless’ or similar indications. In addition, the label must show clearly and indelibly the following:

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

b the authorisation 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 authorised (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 authorisation;

f particulars of likely direct 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 reuse of packaging;

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

j the period of time needed for the biocidal effect, 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, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use, storage and transport (e.g. personal protective clothing and equipment, measures for protection against fire, covering of furniture, removal of food and feedingstuff and directions to prevent animals from being exposed);

and where applicable:

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

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

m for microbiological biocidal products, labelling requirements according to Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work[46].

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 (1) 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 Where a biocidal product identified as insecticide, acaricide, rodenticide, avicide or molluscicide is authorised pursuant to this Directive and is also subject to classification, packaging and labelling according to Council Directive 78/63 I/EEC of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides)[47] 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 in so far as they do not conflict with the conditions of an authorisation issued under this Directive.

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

6 Member States shall make the placing of biocidal products on the market in their territories subject to them being labelled in their national language or languages.

Article 21

Safety-data sheets

Member States shall take the necessary measures to ensure that a system of specific information is established to enable professional and industrial users and, as appropriate, other users of biocidal products to take the necessary measures for the. protection of the environment and health as well as health and safety at the workplace. This shall be done in the form of a safety-data sheet provided by those responsible for the placing on the market of the product.

The safety-data sheets shall be prepared:

— for biocidal products classified as dangerous and in accordance with Article 10 of Directive 88/379/EEC,

— for active substancess used exclusively in biocidal products in accordance with the requirements of Article 27 of Directive 67/548/EEC.

Article 22

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, for example wood preservatives, disinfectants, surface biocides, anti-fouling products, etc.

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

Under no circumstances may the advertising of a biocidal product mention ‘low-risk biocidal product’, ‘non-toxic’, ‘harmless’ or any similar indications.

Article 23

Poison control

Member States shall appoint a 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 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 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 on the date referred to in Article 34(1), Member States shall take measures to comply with this Article within three years of the date referred to Article 34(1).

Article 24

Compliance with requirements

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

Every three years after the date referred to in Article 34(1), Member States shall forward to the Commission by 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 25

Charges

Member States shall establish systems obliging those having placed or seeking to place biocidal products on the market and those supporting entries for active substances on Annexes I, IA or IB to pay charges, corresponding as far as possible to their costs in carrying out all the different procedures associated with the provisions of this Directive.

Article 26

Competent authorities

1 Member States shall designate a competent authority or competent authorities responsible for carrying out the duties imposed on Member States pursuant to this Directive.

2 Member States shall inform the Commission of the identity of their competent authority or competent authorities, not later than the date referred to in Article 34(1).

Article 27

Commission procedures

1 When the Commission receives from a Member State either:

a an evaluation and recommendations concerning an active substance in accordance with Article 11(2) and/or an assessment according to Article 10(5), or

b a proposal to refuse an authorisation or a registration and an explanatory document in accordance with Article 4(4),

it shall allow a period of 90 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 scientific committees,

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

— any other relevant information,

prepare a draft for decision in accordance with the relevant procedures laid down in Article 28(2) or 28(3).

3 The Commission shall ask the applicant and/or his authorised representative to submit remarks to it, unless a favourable decision is envisaged.

Article 28

Committees and procedures

1 The Commission shall be assisted by a Standing Committee on Biocidal Products (the Standing Committee). 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 4, 11(3), 15, 17, 18, 19, 27(l)(b), 29 and 33 and the elaboration of specific data by product type referred to in Annex V, to be drawn from Annexes IIIA and IIIB and, as appropriate, from Annexes IVA and IVB, 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 which shall apply immediately. However, if these measures are not in accordance with the opinion of the Committee, they shall be communicated by the Commission to the Council forthwith. In that event:

The Commission shall defer application of the measures which it has decided for a period of three months from the date of communication.

The Council, acting by a qualified majority, may take a different decision within the time limit referred to in the previous subparagraph.

3 For matters referred to the Standing Committee by virtue of Articles 10, 11(4), 16, 27(l)(a) and (2), and 32, 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 three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 29

Adaptation to technical progress

The amendments necessary for adapting Annexes IIA, IIB, IIIA, IIIB, IVA and IVB, the descriptions of the product-types in Annex V to technical progress and for specifying data requirements for each of these product types, shall be adopted in accordance with the procedure laid down in Article 28(2).

Article 30

Modification or adaptation of Annexes V and VI

Acting on a proposal from the Commission, the Council and the European Parliament shall, in accordance with the procedures laid down in the Treaty, modify or adapt to technical progress the titles of the product-types of Annex V and the provisions of Annex VI.

Article 31

Civil and criminal liability

The granting of authorisation 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 32

Safeguard clause

Where a Member State has valid reasons to consider that a biocidal product which it has authorised, registered or is bound to authorise or register pursuant to Articles 3 or 4, 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 28(3).

Article 33

Technical notes for guidance

The Commission, in accordance with the procedure laid down in Article 28(2), shall draw up technical notes for guidance to facilitate the day-to-day implementation of this Directive.

These technical notes shall be published in the ‘C’ series of the *Official Journal of the European Communities.*

Article 34

Implementation of the Directive

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 24 months after its entry into force. 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.

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

Article 35

This Directive shall enter into force on the 20th day following its publication.

Article 36

This Directive is addressed to the Member States.

Done at Brussels, 16 February 1998.

For the European Parliament

The President

J. M. GIL-ROBLES

For the Council

The President

J. CUNNINGHAM

ANNEX I

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

ANNEX IA

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

ANNEX IB

LIST OF BASIC SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL

ANNEX IIA

COMMON CORE DATA SET FOR ACTIVE SUBSTANCES 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. The dossier requirements must be in line with technical development.

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. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

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

II. IDENTITY

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 EC numbers (if available)

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

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

2.7. Specification of purity of the active substance in g/kg or g/1, as appropriate

2.8. Identity of impurities and additives (e.g. stabilisers), together with the structural formula and the possible range expressed as g/kg or g/1, 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

2.10. Exposure data in conformity with Annex VIIA to Directive 92/32/EEC[(48)].

III. PHYSICAL AND CHEMICAL PROPERTIES

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

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

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

3.4. Absorption spectra (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. Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature([1])

3.7. Thermal stability, identity of relevant breakdown products

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

3.9. Flash-point

3.10. Surface tension

3.11. Explosive properties

3.12. Oxidising properties

3.13. Reactivity towards container material

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. stabilisers)

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 to Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption[49] can be estimated with adequate reliability at the MAC specified in that Directive for individual pesticides

(d) Animal and human body fluids and tissues

V. EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES

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

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

5.3. Effects on target organisms, and likely concentration at which the active substance will be used

5.4. Mode of action (including time delay)

5.5. Field of use envisaged

5.6. User: industrial, professional, general public (non-professional)

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

VI. TOXICOLOGICAL AND METABOLIC STUDIES

6.1. Acute toxicity

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

6.1.1. Oral

6.1.2. Dermal

6.1.3. Inhalation

6.1.4. Skin and eye irritation (^{3})

6.1.5. Skin sensitisation

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

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

6.3. 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. Subchronic toxicity

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

6.5. Chronic toxicity ([4])

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 cells

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

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

6.6.5. If negative in 6.6.4 but positive *in-vitro* tests then undertake a second *in-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 6.6.4 then a test to assess possible germ cell effects may be required

6.7. Carcinogenicity study ([4])

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

6.8. Reproductive toxicity ([5])

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. Medical data in anonymous form

6.9.1. Medical surveillance data on manufacturing plant personnel if available

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

6.9.3. Health records, both from industry and any other available sources

6.9.4. Epidemiological studies on the general population, if available

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

6.9.6. Sensitisation/allergenicity observations, if available

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

6.9.8. Prognosis following poisoning

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

VII. ECOTOXICOLOGICAL STUDIES

7.1. Acute toxicity to fish

7.2. Acute toxicity to *Daphnia magna*

7.3. Growth inhibition test on algae

7.4. Inhibition to microbiological activity

7.5. Bioconcentration

Fate and behaviour in the environment

7.6. Degradation

7.6.1. Biotic

7.6.1.1. Ready biodegradability

7.6.1.2. Inherent biodegradability, where appropriate

7.6.2. Abiotic

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

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

7.7. Adsorption/desorption screening test

Where the results of this test indicate the need to do so, the test described in Annex IIIA Part XII.1 paragraph 1.2 shall be required, and/or the test described in Annex IIIA Part XII.2 paragraph 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.

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

8.5.1. Possibility of reuse or recycling

8.5.2. Possibility of neutralisation of effects

8.5.3. Conditions for controlled discharge including leachate qualities on disposal

8.5.4. Conditions for controlled incineration

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

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 SECTIONS II TO IX

Notes

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

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

([3]) Eye irritation test shall not be necessary where the active substance has been shown to have potential corrosive properties.

([4]) The long-term toxicity and carcinogenicity of an active substance may not be required where a full justification demonstrates that these tests are not necessary.

([5]) If, in exceptional circumstances, it is claimed that such testing is unnecessary, that claim must be fully justified.

ANNEX IIB

COMMON CORE DATA SET FOR BIOCIDAL PRODUCTS CHEMICAL PRODUCTS

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. The dossier requirements must be in line with technical development.

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. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 88/379/EEC should be used wherever possible to minimise animal testing.

Dossier requirements

I. Applicant

II. Identity of the biocidal product

III. Physical and chemical properties of the biocidal product

IV. Methods for identification and analysis of the biocidal product

V. Intended uses of the biocidal product and efficacy for these uses

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

VII. Ecotoxicology data for the biocidal product (additional to that for the active substance)

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

IX. Classification, packaging and labelling

X. Summary and evaluation of Sections 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. Formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))

II. IDENTITY

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 biocidal product, e.g. active substance(s), impurities, adjutants, inert components

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

III. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES

3.1. Appearance (physical state, colour)

3.2. Explosive properties

3.3. Oxidising properties

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

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

3.6. Relative density

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

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

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

IV. METHODS OF IDENTIFICATION AND ANALYSIS

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

4.2. In so far as not covered by Annex IIA, paragraph 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. Product type and field of use envisaged

5.2. Method of application including description of system used

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

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

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

5.7. Effects on target organisms

5.8. Mode of action (including time delay) in so far as not covered by Annex IIA, paragraph 5.4

5.9. User: industrial, professsional, general public (non-professional)

Efficacy data

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

5.11. Any other known limitations on efficacy including resistance

VI. TOXICOLOGICAL STUDIES

6.1. Acute toxicity

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

6.1.1. Oral

6.1.2. Dermal

6.1.3. Inhalation

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

6.2. Skin and eye irritation([1])

6.3. Skin sensitisation

6.4. Information on dermal absorption

6.5. Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)

6.6. Information related to the exposure of the biocidal product to man and the operator

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

VII. ECOTOXICOLOGICAL STUDIES

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

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

7.3. Available ecotoxicological information relating to exotoxicological relevant non-active substances (i.e. substances of concern), such as information from safety data sheets

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. Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment; in so far as not covered by Annex IIA, paragraph 8.3

8.3. Procedures, if any, for cleaning application equipment

8.4. Identity of relevant combustion products in cases of fire

8.5. Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public (non-professional users), e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration

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

(a) Air

(b) Water, including drinking water

(c) Soil

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

8.8. Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms

IX. CLASSIFICATION, PACKAGING AND LABELLING

— Proposals for packaging and labelling

— Proposals for safety-data sheets, where appropriate

— Justification for the classification and labelling according to the principles of Article 20 of this Directive

  — Hazard symbol(s)

  — Indications of danger

  — Risk phrases

  — Safety phrases

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

X. SUMMARY AND EVALUATION OF SECTIONS II TO IX

Notes

([1]) Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

ANNEX IIIA

ADDITIONAL DATA SET FOR ACTIVE SUBSTANCES 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. The dossier requirements must be in line with technical development.

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. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

III. PHYSICAL AND CHEMICAL PROPERTIES

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

2. Stability in organic solvents used in biocidal products and identity of relevant breakdown products ([2])

IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

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

VI. TOXICOLOGICAL AND METABOLIC STUDIES

1. Neurotoxicity study

If the active substance is an organophosphorus compound or if there are any other indications that the active substance may have neurotoxic properties then neurotoxicity studies will be required. The test species is the adult hen unless another test 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

2. Toxic effects on livestock and pets

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

4. 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 Section XI, part 1 shall be required

5. If any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, are considered necessary, then the test(s) referred to in Section XI, part 2 shall be required

6. 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

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

VII. ECOTOXICOLOGICAL STUDIES

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

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 Sections XII and XIII shall be required

3. If the result of the test in paragraph 7.6.1.2 of Annex IIA is negative and if the likely route of disposal of the active substance is by sewage treatment then the test described in Section XIII, part 4.1 shall be required

4. Any other biodegradability tests that are relevant from the results in paragraphs 7.6.1.1 and 7.6.1.2 of Annex IIA

5. Phototransformation in air (estimation method), including identification of breakdown products ([1])

6. If the results from paragraphs 7.6.1.2 in Annex IIA or from paragraph 4, above, indicate the need to do so, or the active substance has an overall low or absent abiotic degradation, then the tests described in Section XII, part 1.1, part 2.1 and, where appropriate, part 3 shall be required

VIII. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

1. Identification of any 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[(50)]

Notes

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

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

XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. Food and feedingstuffs studies

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

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

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

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

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

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

1.7. Proposed acceptable residues and the justification of their acceptability

1.8. Any other available information that is relevant

1.9. Summary and evaluation of data submitted under 1.1 to 1.8

2. Other test(s) related to the exposure to humans

Suitable test(s) and a reasoned case will be required

XII. FURTHER STUDIES ON FATE AND BEHAVIOUR 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. Absorption and desorption in at least three soil types and, where relevant, absorption 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 IIA, paragraph 7.6) including identification of metabolites and degradation products

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

3. Fate and behaviour in air

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 Section VII, part 5

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

XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. Effects on birds

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

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

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 Section VII, part 1

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, 3 and 4

ANNEX IIIB

ADDITIONAL DATA SET FOR BIOCIDAL PRODUCTS
CHEMICAL PRODUCTS

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. The dossier requirements must be in line with technical development.

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. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 88/379/EEC should be used wherever possible to minimise animal testing.

XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. Food and feedingstuffs studies

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

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

2. Other test(s) related to the exposure to humans

Suitable test(s) and a reasoned case will be required for the biocidal product

XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1. Where relevant all the information required in Annex IIIA, Section XII

2. Testing for distribution and dissipation in the following:

(a) Soil

(b) Water

(c) Air

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

XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. Effects on birds

1.1. Acute oral toxicity, if not already done in accordance with Annex IIB, Section VII

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 IIIA, Section XIII, parts 2.1, 2.2, 2.3 and 2.4 may be required for relevant components of the biocidal product

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

3. Effects on other non-target organisms

3.1. Toxicity to terrestrial vertebrates other than birds

3.2. Acute toxicity to honeybees

3.3. Effects on beneficial arthropods other than bees

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

3.5. Effects on soil non-target micro-organisms

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

3.7. If the biocidal product is in the form of bait or granules

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

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

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

ANNEX IVA

DATA SET FOR ACTIVE SUBSTANCES 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. The dossier requirements must be in line with technical development.

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. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

Dossier requirements

I. Applicant details

II. Identity of the 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 organisms and the environment

X. Classification and labelling

XI. Summary and evaluation of Sections 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 the microbiological purity of the final product and showing that contaminants have been controlled to an acceptable level, the results obtained and information on variability

4.4. Methods used to show that there are no human or other mammalian pathogens as contaminants in the active agent, including in the case of protozoa and fungi, the effects of temperature (35 ^{o}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 toxins 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, and transmissibility

5.6. Transmissibility to other non-target organisms

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

5.8. Infectivity and physical stability when properly used

5.9. Genetic stability under environmental conditions of proposed use

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

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

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 product, 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 sensitisation and, where necessary, respiratory sensitisation 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 viroids test for infectivity carried out by bio assay or on a suitable cell culture at least seven days after administration to test animals

7.3. Chronic toxicity

Two species, rodent and one other mammal, oral administration unless another route is more appropriate

7.4. Carcinogenicity study

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

7.5. Mutagenicity studies

As specified in Annex IIA, Section VI, part 6.6

7.6. Reproductive toxicity

Teratogenicity test — rabbit and one rodent species. Fertility study — one species, minimum of two generations, male and female

7.7. Metabolism studies

Basic toxicokinetics, absorption (including dermal absorption) distribution and excretion in mammals including elucidation of metabolic pathways

7.8. Neurotoxicity studies: required where there is any indication of anticholinerterase activity or other neurotoxic effects. 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 algae 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. In cases where toxins are produced, data as outlined in Annex IIA, Section VII, parts 7.1 to 7.5 should be produced

Fate and behaviour in the environment

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

8.10. In cases where toxins are produced, data as outlined in Annex IIA, Section VII, parts 7.6 to 7.8

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

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

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

9.3. The possibility of rendering the active organism non-infective 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/EEC with justifications for the proposal together with indications on the need for products to carry the biohazard sign specified in Annex II to Directive 90/679/EEC

ANNEX IVB

DATA SET FOR BIOCIDAL PRODUCTS 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. The dossier requirements must be in line with technical development.

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. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 88/379/EEC should be used wherever possible to minimise animal testing.

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 humans, non-target organisms and the environment

IX. Classification, packaging and labelling of the biocidal product

X. Summary of Sections 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 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 biocidal product

3.4.1. Wettability

3.4.2. Persistent foaming

3.4.3. Suspensibility and suspension stability

3.4.4. Wet sieve test and dry sieve test

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

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

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

3.4.8. Emulsifiability, re-emulsifiability, emulsion stability

3.4.9. Flowability, pourability and dustability

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

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

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 standardisation

V. INTENDED USES AND EFFICACY FOR THESE USES

5.1. Use

Product-type (e.g. wood preservative, insecticide, etc.)

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

5.3. Application rate

5.4. 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 sensitisation

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

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 biocidal product with proposed packaging materials

9.3. Specimens of proposed packaging

ANNEX V

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN ARTICLE 2(1)(a) OF THIS DIRECTIVE

These product-types exclude products where they are covered by the Directives mentioned in Article 1(2) of this Directive for the purposes of these Directives and their subsequent modifications.

MAIN GROUP 1: Disinfectants and general biocidal products

These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Product-type 1: Human hygiene biocidal products

Products in this group are biocidal products used for human hygiene purposes.

Product-type 2: Private area and public health area disinfectants and other biocidal products

Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals, as well as products used as algaecides.

Usage areas include, *inter alia,* swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil or other substrates (in playgrounds).

Product-type 3: Veterinary hygiene biocidal products

Products in this group are biocidal products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.

Product-type 4: Food and feed area disinfectants

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.

Product-type 5: Drinking water disinfectants

Products used for the disinfection of drinking water (for both humans and animals).

MAIN GROUP 2: Preservatives

Product-type 6: In-can preservatives

Products used for the preservation of manufactured products, other than foodstuffs or feedingstuffs, in containers by the control of microbial deterioration to ensure their shelf life.

Product- Film preservatives
type 7:

Products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.

Product- Wood preservatives
type 8:

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

This product type includes both preventive and curative products.

Product- Fibre, leather, rubber and polymerised materials preservatives
type 9:

Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.

Product- Masonry preservatives
type 10:

Products used for preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack.

Product- Preservatives for liquid-cooling and processing systems
type 11:

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

Products used for the preservation of drinking water are not included in this product type.

Product- Slimicides
type 12:

Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

Product- Metalworking-fluid preservatives
type 13:

Products used for the preservation of metalworking fluids by the control of microbial deterioration.

MAIN GROUP 3: Pest control

Product- Rodenticides
type 14:

Products used for the control of mice, rats or other rodents.

Product-type 15: Avicides

Products used for the control of birds.

Product-type 16: Molluscicides

Products used for the control of molluscs.

Product-type 17: Piscicides

Products used for the control of fish; these products exclude products for the treatment of fish diseases.

Product-type 19: Repellents and attractants

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.

MAIN GROUP 4: Other biocidal products

Product-type 20: Preservatives for food or feedstocks

Products used for the preservation of food or feedstocks by the control of harmful organisms.

Product-type 21: Antifouling products

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

Product-type 22: Embalming and taxidermist fluids

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

Product-type 23: Control of other vertebrates

Products used for the control of vermin.

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

CONTENTS

Introduction

Evaluation

— General principles
— Effects on humans
— Effects on animals
— Effects on the environment
— Unacceptable effects
— Efficacy
— Summary

Decision-making

— General principles
— Effects on humans
— Effects on animals
— Effects on the environment
— Unacceptable effects
— Efficacy
— Summary

Overall integration of conclusions

DEFINITIONS

(a) *Hazard identification*

This is the identification of the adverse effects which a biocidal product has an inherent capacity to cause.

(b) *Dose (concentration) — response (effect) assessment*

This is the estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

(c) *Exposure assessment*

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

(d) *Risk characterisation*

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

(e) *Environment*

Water, including sediment, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms.

INTRODUCTION

1. This Annex lays down principles to ensure that evaluations made and decisions taken by a Member State concerning the authorisation of a biocidal product providing it is a chemical preparation results in a harmonised high level of protection for humans, animals and the environment in accordance with Article 5(1)(b) of this Directive.

2. In order to ensure a high and harmonised level of protection of human and animal health and of the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this a risk assessment shall be carried out to determine the acceptability or otherwise of any risks identified during the proposed normal use of the biocidal product. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product.

3. A risk assessment on the active substance or substances present in the biocidal product is always required. This will already have been carried out for the purpose of Annexes I, IA or IB. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.

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

5. In order to carry out a risk assessment data are required. These data are detailed in Annexes II, III and IV and, recognising that there are a wide variety of product types, are flexible according to the product type and associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. Member States should take due consideration of the requirements of Articles 12 and 13 of this Directive in order to avoid duplication of data submissions. The minimum set of data required for an active substance in any biocidal product type, however, shall be that detailed in Annex VIIA to Directive 67/548/EEC; these data will already have been submitted and assessed as part of the risk assessment required for entry of the active substance into Annex I, IA or IB to this Directive. Data may also be required on a substance of concern present in a biocidal product.

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

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

(a) take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues;

(b) evaluate, where relevant, justifications submitted by the applicant for not supplying certain data.

8. The Member State shall comply with the requirements of mutual recognition as stated in Articles 4(1), (2) and (6) of this Directive.

9. It is known that many biocidal products present only minor differences in composition and this should be taken into account when evaluating dossiers. The concept of ‘frame-formulations’ is relevant here.

10. It is known that certain biocidal products are considered as posing only a low risk, these biocidal products, while complying with the requirements of this Annex, are subject to a simplified procedure as detailed in Article 3 of this Directive.

11. The application of these common principles shall lead to the Member State deciding whether or not a biocidal product can be authorised, such authorisation may include restrictions on use or other conditions. In certain cases the Member State may conclude that more data are required before an authorisation decision can be made.

12. During the process of evaluation and decision-making, Member States and applicants shall cooperate in order to resolve any questions on the data requirements quickly or to identify at an early stage any additional studies required, or to amend any proposed conditions for the use of the biocidal product or to modify its nature or its composition in order to ensure full compliance with the requirements of this Annex or of this Directive. The administrative burden, especially for small and medium-sized enterprises (SMEs), shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.

13. The judgments made by the Member State during the evaluation and decision-making process must be based on scientific principles, preferably recognised at international level, and be made with the benefit of expert advice.

EVALUATION

General principles

14. The data submitted in support of an application for authorisation of a biocidal product shall be examined for completeness and overall scientific value by the receiving Member State. After acceptance of these data the Member State shall utilise them by carrying out a risk assessment based on the proposed use of the biocidal product.

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

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

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

18. The risk assessment shall determine:

(a) the risk to humans and animals,

(b) the risk to the environment,

(c) the measures necessary to protect humans, animals and the general environment during both the proposed normal use of the biocidal product and in a realistic worst-case situation.

19. In certain cases it may be concluded that further data are required before a risk assessment can be finalised. Any such additional data requested shall be the minimum necessary to complete such a risk assessment.

Effects on humans

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

21. The effects previously mentioned result from the properties of the active substance and any substance of concern present. They are:

— acute and chronic toxicity,
— irritation,
— corrosivity,
— sensitisation,
— repeated dose toxicity,
— mutagenicity,
— carcinogenicity,
— reproduction toxicity,
— neurotoxicity,
— any other special properties of the active substance or substance of concern,
— other effects due to physico-chemical properties.

22. The populations previously mentioned are:

— professional users,
— non-professional users,
— humans exposed indirectly via the environment.

23. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of Article 20 of this Directive then dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation shall be required.

24. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not lead to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern, e.g. adverse environmental effects or unacceptable residues.

25. The Member State shall apply paragraphs 26 to 29 when carrying out a dose (concentration) — response (effect) assessment on an active substance or a substance of concern present in a biocidal product.

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

27. For acute toxicity, corrosivity and irritation, it is not usually possible to derive a NOAEL or LOAEL on the basis of tests conducted in accordance with the requirements of this Directive. For acute toxicity, the LD50 (median lethal dose) or LC50 (median lethal concentration) value or, where the fixed dose procedure has been used, the discriminating dose shall be derived. For the other effects it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the product.

28. For mutagenicity and carcinogenicity it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product. However, if it can be demonstrated that an active substance or a substance of concern identified as a carcinogen is non-genotoxic, it will be appropriate to identify a N(L)OAEL as described in paragraph 26.

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

30. Where toxicity data derived from observations of human exposure, e.g. information gained from manufacture, from poison centres or epidemiology surveys, are available special consideration shall be given to those data when carrying out the risk assessment.

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

32. The exposure assessment shall be based on the information in the technical dossier provided in conformity with Article 8 of this Directive and on any other available and relevant information. Particular account shall be taken, as appropriate, of:

— adequately measured exposure data,
— the form in which the product is marketed,
— the type of biocidal product,
— the application method and application rate,
— the physico-chemical properties of the product,
— the likely routes of exposure and potential for absorption,
— the frequency and duration of exposure,
— the type and size of specific exposed populations where such information is available.

33. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied.

These models shall:

— make a best possible estimation of all relevant processes taking into account realistic parameters and assumptions,
— be subjected to an analysis taking into account possible elements of uncertainty,

— be reliably validated with measurements carried out under circumstances relevant for the use of the model,
— be relevant to the conditions in the area of use.

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

34. Where, for any of the effects set out in paragraph 21 a NOAEL or LOAEL had been identified, the risk characterisation shall entail comparison of the NOAEL or LOAEL with the evaluation of the dose/concentration to which the population will be exposed. Where a NOAEL or LOAEL cannot be established a qualitative comparison shall be made.

Effects on animals

35. Using the same relevant principles as described in the section dealing with effects on humans, the Member State shall consider the risks posed to animals from the biocidal product.

Effects on the environment

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

37. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of this Directive then dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation shall be required.

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

— any indications of bioaccumulation potential,
— the persistence characteristics,
— the shape of the toxicity/time curve in ecotoxicity testing,
— indications of other adverse effects on the basis of toxicity studies (e.g. classification as a mutagen),
— data on structurally analogous substances,
— endocrine effects.

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

40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Article 8 of this Directive.

It shall be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g. LD50 (median lethal dose), LC50 (median lethal concentration), EC50 (median effective concentration), IC50 (concentration causing 50 % inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)).

41. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor.

The specifications for the assessment factors shall be elaborated in the notes for technical guidance which, to this end, shall be based particularly on the indications given in Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and environment from substances notified in accordance with Council Directive 67/548/EEC[(51)].

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

43. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions including any relevant contribution from material treated with biocidal products are known or are reasonably foreseeable.

44. The PEC, or qualitative estimation of exposure, shall be determined taking account of, in particular, and if appropriate:

— adequately measured exposure data,
— the form in which the product is marketed,
— the type of biocidal product,
— the application method and application rate,
— the physico-chemical properties,
— breakdown/transformation products,
— likely pathways to environmental compartments and potential for adsorption/desorption and degradation,
— the frequency and duration of exposure.

45. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in paragraph 33. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.

46. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.

47. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under

the current conditions of exposure or will occur under the expected conditions of exposure.

Unacceptable effects

48. Data shall be submitted to and evaluated by the Member State to assess whether the biocidal product does not cause unnecessary suffering in its effect on target vertebrates. This shall include an evaluation of the mechanism by which the effect is obtained and the observed effects on the behaviour and health of the target vertebrates; where the intended effect is to kill the target vertebrate the time necessary to obtain the death of the target vertebrate and the conditions under which death occurs shall be evaluated.

49. The Member State shall, where relevant, evaluate the possibility of the development of resistance to an active substance in the biocidal product by the target organism.

50. If there are indications that any other unacceptable effects may occur the Member State shall evaluate the possibility of such effects occurring. An example of such an unacceptable effect would be an adverse reaction to fastenings and fittings used in wood following the application of a wood preservative.

Efficacy

51. Data shall be submitted and evaluated to ascertain if the efficacy claims of the biocidal product can be substantiated. Data submitted by the applicant or held by the Member State must be able to demonstrate the efficacy of the biocidal product against the target organism when used normally in accordance with the conditions of authorisation.

52. Testing should be carried out according to Community guidelines if these are available and applicable. Where appropriate, other methods can be used as shown in the list below. If relevant acceptable field data exist, these can be used.

— ISO, CEN or other international standard method
— national standard method
— industry standard method (accepted by Member State)
— individual producer standard method (accepted by Member State)
— data from the actual development of the biocidal product (accepted by Member State).

Summary

53. In each of the areas where risk assessments have been carried out, i.e. effects on man, animals, and the environment, the Member State shall combine the results for the active substance together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This should take account of any likely synergistic effects of the active substance(s) and substances of concern in the biocidal product.

54. For biocidal products containing more than one active substance any adverse effects shall also be combined to produce an overall effect for the biocidal product itself.

DECISION MAKING

General principles

55. Subject to paragraph 96, the Member State shall come to a decision regarding the authorisation for use of a biocidal product as a result of the integration of the risks arising from each active substance together with the risks from each substance of concern present in the biocidal product. The risk assessments shall cover normal use of the biocidal product together with a realistic worst-case scenario including any relevant disposal issue either of the biocidal product itself or any material treated with it.

56. In making a decision concerning authorisation, the Member State shall arrive at one of the following conclusions for each product type and for each area of use of the biocidal product for which application has been made:

1. the biocidal product cannot be authorised;

2. the biocidal product can be authorised subject to specific conditions/restrictions;

3. more data is required before a decision on authorisation can be made.

57. If the conclusion arrived at by the Member State is that additional information or data are required before an authorisation decision can be made, then the need for any such information or data shall be justified. This additional information or data shall be the minimum necessary to carry out a further appropriate risk assessment.

58. The Member State shall comply with the principles of mutual recognition as detailed in Article 4 of this Directive.

59. The Member State shall apply the rules concerning the concept of 'frame formulations' when making an authorisation decision on a biocidal product.

60. The Member State shall apply the rules concerning the concept of 'low risk' products when making an authorisation decision on such a biocidal product.

61. The Member State shall only grant authorisation to those biocidal products which, when used according to their conditions of authorisation, do not present an unacceptable risk to humans, animals or the environment, are efficacious and which contain active substances permitted at Community level to be used in such biocidal products.

62. The Member State shall impose, where appropriate, conditions or restrictions when giving authorisations. The nature and severity of these shall be selected on the basis of, and be appropriate to, the nature and extent of the expected advantages and the risks likely to arise from the use of the biocidal product.

63. In the decision-making process the Member State shall take into consideration the following:

— the results of the risk assessment, in particular the relationship between exposure and effect,
— the nature and severity of the effect,
— the risk management which can be applied,
— the field of use of the biocidal product,
— the efficacy of the biocidal product,
— the physical properties of the biocidal product,
— the benefits of using the biocidal product.

64. The Member State shall, when taking a decision concerning the authorisation of a biocidal product, take into account the uncertainty arising from the variability in the data used in the evaluation and decision-making process.

65. The Member State shall prescribe that biocidal products shall be used properly. Proper use shall include application at an efficacious dose and minimisation of use of biocidal products where possible.

66. The Member State shall take the necessary measures to ensure that the applicant proposes a label, and, where relevant, the safety-data sheet, for the biocidal product which:

— fulfils the requirements of Articles 20 and 21 of this Directive,

— contains the information on the protection of users required by Community legislation on worker protection,

— specifies in particular the conditions or restrictions under which the biocidal product may or may not be used.

Before issuing an authorisation the Member State shall confirm that these requirements must be satisfied.

67. The Member State shall take the necessary measures to ensure that the applicant proposes packaging and, where appropriate, the procedures for destruction or decontamination of the biocidal product and its packaging or any other relevant material associated with the biocidal product, which conforms to the relevant regulatory provisions.

Effects on humans

68. The Member State shall not authorise a biocidal product if the risk assessment confirms that, in foreseeable application including a realistic worst possible scenario, the product presents an unacceptable risk to humans.

69. The Member State shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environment when making a decision on the authorisation of a biocidal product.

70. The Member State shall examine the relationship between the exposure and the effect, and use this in the decision-making process. A number of factors need to be considered when examining this relationship and one of the most important is the nature of the adverse effect of the substance. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, reproduction toxicity together with physico-chemical properties, and any other adverse properties of the active substance or substance of concern.

71. The Member State shall, where possible, compare the results obtained with those obtained from previous risk assessments for an identical or similar adverse effect and decide on an appropriate margin of safety (MOS) when making an authorisation decision.

An appropriate MOS is typically 100 but an MOS higher or lower than this may be appropriate depending on, among other things, the nature of the critical toxicological effect.

72. The Member State shall, if appropriate, impose, as a condition of authorisation, the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles in order to reduce exposure for professional operators. Such equipment must be readily available to them.

73. If for non-professional users the wearing of personal protective equipment would be the only possible method for reducing exposure, the product shall not normally be authorised.

74. If the relationship between the exposure and the effect cannot be reduced to an acceptable level then no authorisation can be given by the Member State for the biocidal product.

75. No biocidal product classified according to Article 20(1) of this Directive as toxic, very toxic or as a category 1 or 2 carcinogen, or as a category 1 or 2 mutagen, or classified as toxic for reproduction category 1 or 2, shall be authorised for use by the general public.

Effects on animals

76. The Member State shall not authorise a biocidal product if the risk assessment confirms that, in normal use, the biocidal product presents an unacceptable risk to non-target animals.

77. Using the same relevant criteria as described in the section dealing with effects on humans, the Member State shall consider the risks posed to animals from the biocidal product when making an authorisation decision.

Effects on the environment

78. The Member State shall not authorise a biocidal product if the risk assessment confirms that the active substance, or any substance of concern, or any degradation, or reaction product presents an unacceptable risk in any of the environmental compartments, water (including sediment), soil and air. This shall include the assessment of risks to non-target organisms in these compartments.

In considering whether there is an unacceptable risk Member States shall, when coming to a final decision in accordance with paragraph 96, take into account the criteria in paragraphs 81 to 91.

79. The basic tool used in the decision making is the PEC/PNEC ratio or, if this is not available, a qualitative estimation. Due consideration shall be given to the accuracy of this ratio due to variability in the data used both in measurements of concentration and of estimation.

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

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

If the PEC/PNEC ratio is greater than 1 the Member State shall judge, on the basis of the size of that ratio and on other relevant factors, if further information and/or testing are required to clarify the concern or if risk reduction measures are necessary or if the product cannot be given an authorisation at all. Relevant factors to be considered are those previously mentioned in paragraph 38.

Water

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

82. The Member State shall not authorise a biocidal product if, under the proposed conditions of use, the foreseeable concentration of the active substance or of any other

substance of concern or of relevant metabolites or breakdown or reaction products in groundwater exceeds the lower of the following concentrations:

(a) the maximum permissible concentration laid down by Directive 80/778/EEC, or

(b) the maximum concentration as laid down following the procedure for including the active substance in Annex I, IA or IB to this Directive, on the basis of appropriate data, in particular toxicological data

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

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

— exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by
  — Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States[(52)],
  — Directive 80/778/EEC or
— has an impact deemed unacceptable on non-target species

unless it is scientifically demonstrated that under relevant field conditions this concentration is not exceeded.

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

Soil

85. Where unacceptable contamination of soil is likely to occur, the Member State shall not authorise a biocidal product if the active substance or substance of concern contained in it, after use of the biocidal product:

— during tests in the field, persists in soil for more than one year, or
— during laboratory tests, forms non-extractable residues in amounts exceeding 70 % of the initial dose after 100 days with a mineralisation rate of less than 5 % in 100 days,
— has unacceptable consequences or effects on non-target organisms,

unless it is scientifically demonstrated that under field conditions there is no unacceptable accumulation in soil.

Air

86. The Member State shall not authorise a biocidal product where there is a foreseeable possibility of unacceptable effects on the air compartment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Effects on non-target organisms

87. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of non-target organisms being exposed to the biocidal product if for any active substance or substance of concern:

— the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur after use of the biocidal product according to the proposed conditions of use, or

— the bioconcentration factor (BCF) related to fat tissues in non-target vertebrates is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur, either directly or indirectly, after use of the product according to the proposed conditions of use.

88. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of aquatic organisms including marine and estuarine organisms being exposed to the biocidal product if for any active substance or substance of concern in it:

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

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

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

89. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of micro-organisms in sewage treatment plants being exposed to the biocidal product if for any active substance, substance of concern, relevant metabolite, breakdown or reaction product the PEC/PNEC ratio is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of such micro-organisms.

Unacceptable effects

90. If the development of resistance to the active substance in the biocidal product is likely the Member State shall take steps to minimise the consequences of this resistance. This may involve modification of the conditions of authorisation or even refusal of any authorisation.

91. An authorisation for a biocidal product intended to control vertebrates shall not be given unless:

— death is synchronous with the extinction of consciousness, or,

— death occurs immediately, or,

— vital functions are reduced gradually without signs of obvious suffering.

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

Efficacy

92. Member States shall not authorise a biocidal product which does not possess acceptable efficacy when used in accordance with the conditions specified on the proposed label or with other conditions of authorisation.

93. The level, consistency and duration of protection, control or other intended effects must, as a minimum, be similar to those resulting from suitable reference products, where such products exist, or to other means of control. Where no reference products exist, the biocidal product must give a defined level of protection or control in the areas of proposed use. Conclusions as to the performance of the biocidal product must be valid for all areas of proposed use and for all areas in the Member State except where the proposed label prescribes that the biocidal product is intended for use in specific circumstances. Member States shall evaluate dose response data generated in trials (which must include an untreated control) involving dose rates lower than the recommended rate, in order to assess if the recommended dose is the minimum necessary to achieve the desired effect.

Summary

94. In each of the areas where risk assessments have been carried out, i.e. effects on humans, animals, and the environment, the Member State shall combine the conclusions arrived at for the active substance and the substances of concern to produce an overall conclusion for the biocidal product itself. A summary should also be made of the efficacy assessment and of the unacceptable effects.

The result shall be:

— a summary of the effects of the biocidal product on humans,

— a summary of the effects of the biocidal product on animals,

— a summary of the effects of the biocidal product on the environment,

— a summary of the efficacy assessment,

— a summary of the unacceptable effects.

OVERALL INTEGRATION OF CONCLUSIONS

95. The Member State shall combine the individual conclusions arrived at with regard to effects of the biocidal product on the three sectors namely, humans, animals and the environment to arrive at an overall conclusion for the global effect of the biocidal product.

96. The Member State shall then take due consideration of any relevant unacceptable effects, the efficacy of the biocidal product and the benefits of using the biocidal product before taking an authorisation decision on the biocidal product.

97. The Member State shall ultimately decide whether or not the biocidal product can be authorised and whether this authorisation shall be subject to any restrictions or conditions in conformity with this Annex and this Directive.

(**1**) OJ C 239, 3.9.1993, p. 3, OJ C 261, 6.10.1995, p. 5 and OJ C 241, 20.8.1996, p. 8.

(**2**) OJ C 195, 18.7.1994, p. 70 and OJ C 174, 17.6.1996, p. 32.

(**3**) Opinion of the European Parliament of 18 April 1996 (OJ C 141, 13.5.1996, p. 191), Council common position of 20 December 1996 (OJ C 69, 5.3.1997, p. 13) and Decision of the European Parliament of 13 May 1997 (OJ C 167, 2.6.1997, p. 24). Council Decision of 18 December 1997. Decision of the European Parliament of 14 January 1998.

(**4**) OJ C 138, 17.5.1993, p. 1.

(**5**) OJ L 398, 30.12.1989, p. 19.

(**6**) OJ L 262, 27.9.1976, p. 201. Directive as last amended by Directive 97/16/EC (OJ L 116, 6.5.1997, p. 31).

(**7**) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Directive 96/68/EC (OJ L 277, 30.10.1996, p. 25).

(**8**) OJ L 154, 5.6.1992, p. 1.

(**9**) OJ L 84, 5.4.1993, p. 1.

(**10**) OJ C 102, 4.4.1996, p. 1.

(**11**) OJ 22, 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).

(**12**) OJ L 317, 6.11.1981, p. 1. Directive as last amended by Directive 93/40/EEC (OJ L 214, 24.8.1993, p. 31).

(**13**) OJ L 373, 31.12.1990, p. 26.

(**14**) OJ L 297, 13.10.1992, p. 8.

(**15**) OJ L 297, 13.10.1992, p. 12.

(**16**) OJ L 214, 24.8.1993, p. 1.

(**17**) OJ L 189, 20.7.1990, p. 17. Directive as last amended by Directive 93/68/EEC (OJ L 220, 31.8.1993, p. 1).

(**18**) OJ L 169, 12.7.1993, p. 1.

(**19**) OJ L 40, 11.2.1989, p. 27. Directive as amended by Directive 94/34/EC (OJ L 237, 10.9.1994, p. 1).

(**20**) OJ L 184, 15.7.1988, p. 61. Directive as amended by Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).

(**21**) OJ L 61, 18.3.1995, p. 1. Directive as amended by Directive 96/85/EC (OJ L 86, 28.3.1997, p. 4).

(**22**) OJ L 40, 11.2.1989, p. 38.

(**23**) OJ L 268, 14.9.1992, p. 1. Directive as last amended by Directive 94/71/EC (OJ L 368, 31.12.1994, p. 33).

(**24**) OJ L 212, 22.7.1989, p. 87. Directive as last amended by the 1994 Act of Accession.

(**25**) OJ L 268, 24.9.1991, p. 15. Directive as last amended by Directive 95/71/EC (OJ L 332, 30.12.1995, p. 40).

(**26**) OJ L 92, 7.4.1990, p. 42.

(**27**) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Directive 97/6/EC (OJ L 35, 5.2.1997, p. 11).

(**28**) OJ L 213, 21.7.1982, p. 8. Directive as last amended by Directive 96/25/EC (OJ L 125, 23.5.1996, p. 35).

(**29**) OJ L 32, 3.2.1977, p. 1. Directive as last amended by the 1994 Act of Accession.

(**30**) OJ L 262, 27.9.1976, p. 169. Directive as last amended by Directive 97/18/EC (OJ L 114, 11.5.1997, p. 43).

(**31**) OJ L 51, 8.3.1995, p. 12.

(**32**) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Directive 96/68/EC (OJ L 277, 30.10.1996, p. 25).

(**33**) OJ L 262, 27.9.1976, p. 201. Directive as last amended by Directive 97/16/EC (OJ L 116, 6.5.1997, p. 31).

(**34**) OJ L 33, 8.2.1979, p. 36. Directive as last amended by the 1994 Act of Accession.

(**35**) OJ L 251, 29.8.1992, p. 13. Regulation as last amended by Regulation (EC) No 1492/96 (OJ L 189, 30.7.1996, p. 19).

(**36**) OJ L 327, 3.12.1980, p. 8. Directive as last amended by the 1994 Act of Accession.

(**37**) OJ L 183, 29.6.1989, p. 1.

(**38**) OJ L 250, 19.9.1984, p. 17.

(**39**) OJ 196, 16.8.1967. Directive as last amended by Directive 94/69/EC (OJ L 381, 31.12.1994, p. 1).

(**40**) OJ L 187, 16.7.1988, p. 14).

(**41**) OJ L 187, 16.7.1988, p. 14. Directive as amended by Directive 93/18/EEC (OJ L 104, 29.4.1993, p. 46).

(**42**) OJ L 358, 18.12.1986, p. 1.

(**43**) OJ L 15, 17.1.1987, p. 29.

(**44**) OJ L 109, 26.4.1983, p. 8. Directive as last amended by Directive 94/10/EC (OJ L 100, 19.4.1994, p. 30).

(**45**) OJ L 158, 6.10.1990, p. 40.

(**46**) OJ L 374, 31.12.1990, p. 1. Directive as last amended by Directive 95/30/EC (OJ L 155, 6.7.1995, p. 5).

(**47**) OJ L 206, 29.7.1978, p. 13. Directive as last amended by Directive 92/32/EEC (OJ L 154, 5.6.1992, p. 1).

(**48**) OJ L 154, 5.6.1992, p. 1.

(**49**) OJ L 229, 30.8.1980, p. 11. Directive as last amended by Directive 91/692/EEC (OJ L 377, 31.12.1991, p. 48).

(**50**) OJ L 20, 26.1.1980, p. 43.

(**51**) OJ L 227, 8.9.1993, p. 9.

(**52**) OJ L 194, 25.7.1975, p. 26. Directive as last amended by Directive 91/692/EEC (OJ L 377, 31.12.1991, p. 48).