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European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (repealed)

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(1)(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[(1)],

b Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States on veterinary medicinal products[(2)],

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[(3)],

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[(4)],

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[(5)],

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[(6)],

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[(7)],

h Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[(8)],

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[(9)], 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[(10)] and European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners[(11)],

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[(12)],

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[(13)],

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[(14)],

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[(15)],

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[(16)],

o Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[(17)], Council Directive 82/471/EEC of 30 June 1982 on certain products used in animal nutrition[(18)] and Council Directive 77/101/EEC of 23 November 1976 on the marketing of straight feedingstuffs[(19)],

p Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[(20)],

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[(21)],

r Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[(22)]**[**[F1]**,]**

[[F2]s Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[(23)]**.]**

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[(24)],

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[(25)],

c Council Regulation (EEC) No 2455/92 of 23 July 1992 concerning the export and import of certain dangerous chemicals[(26)],

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[(27)], 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[(28)] 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[(29)].

4 Article 20 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

Textual Amendments

F1 Substituted by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (Text with EEA relevance).

F2 Inserted by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (Text with EEA relevance).

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 I A 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 on 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[(30)], 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[(31)].

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 (l) 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(1)(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 1(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[(32)], 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[(33)] 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[(34)].

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(1)(b), (c) and (d),

and no other Member State, on the basis of the summary it receives, makes legitimate objection, in accordance with Article 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[35] 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[36], 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[(37)].

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

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

4 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 78/631/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)[38] 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

[[F3]1 The Commission shall be assisted by a Standing Committee on Biocidal Products (hereinafter referred to as 'the Committee').

The Standing Committee shall adopt its rules of procedure.

2 For matters referred to the Standing Committee by virtue of Articles 4, 11(3), 15, 17, 18, 19, 27(1)(b), 29 and 33 and for the compilation of specific data by product type referred to in Annex V, to be drawn from Annexes III A and III B and, as appropriate, from Annexes IV A and IV B, Articles 4 and 7 of Decision 1999/468/EC[(39)] shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.**]**

[[F3]3 For matters referred to the Standing Committee by virtue of Articles 10, 11(4), 16, 27(1)(a) and (2), and 32, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.**]**

Textual Amendments

F3 Substituted by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty.

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.

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

(**2**) 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).

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

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

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

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

(**7**) 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).

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

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

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

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

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

(**13**) 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).

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

(**15**) 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).

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

(**17**) 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).

(**18**) 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).

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

(**20**) 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).

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

(**22**) 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).

(**23**) **[**[F2]OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).**]**

(**24**) 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).

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

(**26**) 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).

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

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

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

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

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

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

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

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

(**35**) 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).

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

(**37**) 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).

(**38**) 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).

(**39**) **[**[F3]Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).**]**

Textual Amendments

F2 Inserted by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (Text with EEA relevance).

F3 Substituted by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty.