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European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (repealed)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concerning the placing of biocidal products on the market (repealed)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

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[(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]**[**[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[33]**.]**

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[34],

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[35],

c Council Regulation (EEC) No 2455/92 of 23 July 1992 concerning the export and import of certain dangerous chemicals[36],

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[37], 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[38] 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[39].

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 *U.K.*

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[(40)], 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[(41)].

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 U.K.

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 U.K.

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 *U.K.*

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 U.K.

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 U.K.

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 *U.K.*

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[(42)], 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[(43)] 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[(44)].

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 U.K.

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 U.K.

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.

[[F3]The assessment shall be circulated in accordance with Article 11(2) for a decision to be adopted by the Commission in accordance with the procedure laid down in Article 27. That decision, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4).**]**

(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. **[**[F3]the complete data dossiers of the evaluation serving or having served for entry in Annexes I, IA or IB shall be put at the disposal of the committee referred to in Article 28(1).**]**

(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.

Textual Amendments

F3 Substituted by Directive 2008/31/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 98/8/EC concerning the placing of biocidal products on the market, as regards the implementing powers conferred on the Commission.

Article 11 U.K.

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.

[[F3]4 On receipt of the evaluation, the Commission shall, in accordance with Article 27, prepare a proposal without undue delay for a decision to be taken at the latest 12 months after the receipt of the evaluation referred to in paragraph 2. That decision, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4).**]**

Textual Amendments

F3 Substituted by Directive 2008/31/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 98/8/EC concerning the placing of biocidal products on the market, as regards the implementing powers conferred on the Commission.

Article 12 U.K.

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) **[**F4until 14 May 2014 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, but not beyond 14 May 2014 or, if applicable, not beyond the date to which the transitional period referred to in Article 16(1) is extended in accordance with Article 16(2);**]**

(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) **[**F4until 14 May 2014 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, but not

beyond 14 May 2014 or, if applicable, not beyond the date to which the transitional period referred to in Article 16(1) is extended in accordance with Article 16(2);**]**

(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.

Textual Amendments

F4 Substituted by Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods (Text with EEA relevance).

Article 13 U.K.

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 U.K.

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 U.K.

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 *U.K.*

Transitional measures

[[F4]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 of this Article, a Member State may, until 14 May 2014, continue to apply its current system or practice of placing biocidal products on the market. If a decision to include an active substance in Annex I or IA sets a later date for compliance with Article 16(3) than 14 May 2014, this derogation shall continue to apply for products including that active substance until the date set in that decision. A Member State may, in particular, in accordance with 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).**]**

[[F3]**[**[F4]2 Following the adoption of this Directive, the Commission shall commence a 14-year work programme 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). Regulations shall provide for the establishment and implementation of the programme, including the setting of priorities for the evaluation of the different active substances and a timetable. Those regulations, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4). Not later

than two years before completion of the work programme, the Commission shall forward to the European Parliament and to the Council a report on progress achieved with the programme. Depending upon the conclusions of the report, it may be decided to extend the transitional period referred to in paragraph 1 and the 14-year period of the work programme for a period of no more than two years. That measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4).**]**

[[F4]During that 14-year period**]** and from the date referred to in Article 34(1), it may be decided that an active substance will 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 will not be included in Annexes I, IA or IB. Such measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4).**]**

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[(45)] shall continue to apply during the transitional period referred to in paragraph 2.

Textual Amendments

F3 Substituted by Directive 2008/31/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 98/8/EC concerning the placing of biocidal products on the market, as regards the implementing powers conferred on the Commission.

F4 Substituted by Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods (Text with EEA relevance).

Article 17 *U.K.*

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.

[[F3]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 order to permit an assessment in accordance with paragraph 2, shall be adopted. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4).**]**

Textual Amendments

F3 Substituted by Directive 2008/31/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 98/8/EC concerning the placing of biocidal products on the market, as regards the implementing powers conferred on the Commission.

Article 18 U.K.

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 *U.K.*

Confidentiality

1 Without prejudice to Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment[(46)], 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 U.K.

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[(47)].

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)[(48)] 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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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.

[F3 2 At the end of the period for comment, the Commission shall prepare a draft for a decision in accordance with the relevant procedure referred to in Article 28(2) or (4) on the basis of all the following elements:

a the documents received from the Member State evaluating the dossiers;

b any advice obtained from advisory scientific committees;

c comments received from other Member States and the applicants; and

d any other relevant information.**]**

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

Textual Amendments

F3 Substituted by Directive 2008/31/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 98/8/EC concerning the placing of biocidal products on the market, as regards the implementing powers conferred on the Commission.

Article 28 U.K.

Committees and procedures

[F3 1 The Commission shall be assisted by a Standing Committee on Biocidal Products.**]**

[F3 2 Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC 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 Where reference is made to this paragraph, 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.**]**

[F5 4 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.**]**

Textual Amendments

F3 Substituted by Directive 2008/31/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 98/8/EC concerning the placing of biocidal products on the market, as regards the implementing powers conferred on the Commission.

F5 Inserted by Directive 2008/31/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 98/8/EC concerning the placing of biocidal products on the market, as regards the implementing powers conferred on the Commission.

[F3 Article 29 U.K.

Adaptation to technical progress

Measures necessary to adapt Annexes IIA, IIB, IIIA, IIIB, IVA or IVB or the descriptions of product types in Annex V to technical progress or to specify data requirements for each of these product types shall be adopted. Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4).**]**

Textual Amendments

F3 Substituted by Directive 2008/31/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 98/8/EC concerning the placing of biocidal products on the market, as regards the implementing powers conferred on the Commission.

Article 30 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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

Article 36 U.K.

This Directive is addressed to the Member States.

ANNEX I U.K.

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

[F6[F8No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance[b]	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies[c]	Expiry date of inclusion	Product type	Specific provisions][a]
1	sulfuryl fluoride	sulfuryl difluoride EC No: 220-281-5 CAS No: 2699-79-8	> 994 g/kg	1 January 2009	31 December 2010	31 December 2018	8	Member States shall ensure that authorisations are subject to the following conditions: (1) the product may only be sold to and used by professionals trained to use it; (2) appropriate risk mitigation measures are

								included for operators and bystanders; (3) concentrations of sulfuryl fluoride in remote tropospheric air are monitored. Member States shall also ensure that reports of the monitoring referred to in point (3) are transmitted by authorisation holders directly to the Commission every fifth year starting from 1 January 2009.
[F11			994 g/kg	1 July 2011	30 June 2013	30 June 2021	18	Member States shall ensure that authorisations are subject to the

							following conditions: (1) Products shall only be sold to and used by professionals trained to use them. (2) Appropriate measures to protect fumigators and bystanders during fumigation and venting of treated buildings or other enclosures must be taken. (3) Labels and/or safety-data sheets of products shall indicate that, prior to fumigation of any enclosure,

								all food items must be removed.
							(4)	Concentrations of sulfuryl fluoride in remote tropospheric air are monitored.
							(5)	Member States shall also ensure that reports of the monitoring referred to in point (4) are transmitted by authorisation holders directly to the Commission every fifth year, starting at the latest five years after the authorisation. The

								limit of detection for the analysis shall be at least 0,5 ppt (equivalent to 2,1 ng sulfuryl fluoride/ m^3 of tropospheric air).]
[F12 2	dichlofluanid	N-(Dichlorofluoromethylthio)-N′,N′-dimethyl-N-phenylsulfamide EC No: 214-118-7 CAS No: 1085-98-9	> 96 % (w/w)	1 March 2009	28 February 2011	28 February 2019	8	Member States shall ensure that authorisations are subject to the following conditions: (1) Products authorised for industrial and/ or professional use must be used with appropriate personal protective equipment. (2) In view of

								the risks identified for the soil compartment appropriate risk mitigation measures must be taken to protect that compartment.
							(3)	Labels and/or safety-data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any

								losses must be collected for re-use or disposal.]
[F13 3	clothianidin	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine EC No: 433-460-1 CAS No: 210880-92-5	950 g/kg	1 February 2010	31 January 2012	31 January 2020	8	When assessing, in accordance with Article 5 and Annex VI, the application for authorisation of a product, Member States shall assess those use/ exposure scenarios and/or populations that have not been representatively addressed in the Community level risk assessment and that may be exposed to the product. When granting product authorisation,

							Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorisations are subject to the following conditions: In view of the risk identified

							for the soil, surface water and groundwater compartments, products cannot be authorised for the treatment of wood that will be used outdoors unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use indicate

								that freshly treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for reuse or disposal.]
[F14 4	Difethialone	3-[3-(4′-bromo[1,1′biphenyl]-4-yl)-1,2,3,4-tetrahydronaphth-1-yl]-4-hydroxy-2H-1-benzothiopyran-2-one EC No: n/a CAS No: 104653-34-1	976 g/kg	1 November 2009	31 October 2011	31 October 2014	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment

							in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 0,0025 % w/w and only ready-for-use baits shall

								be authorised.
							(2)	Products shall contain an aversive agent and, where appropriate, a dye.
							(3)	Products shall not be used as tracking powder.
							(4)	Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the

								restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.]
[F15 5	etofenprox	3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether EC No: 407-980-2 CAS No: 80844-07-1	970 g/kg	1 February 2010	31 January 2012	31 January 2020	8	When assessing, in accordance with Article 5 and Annex VI, the application for authorisation of a product, Member States shall access those use and/or exposure scenarios and/or populations that have

							not been representatively addressed in the Community level risk assessment and that may be exposed to the product. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to

								acceptable levels. Member States shall ensure that authorisations are subject to the following conditions: In view of the risk identified for workers, products cannot be used year round unless dermal absorption data is provided to demonstrate that there are no unacceptable risks from chronic exposure. In addition, products intended for industrial use must be used with appropriate personal protective equipment.]

[F16 6	tebuconazole	(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol EC No: 403-640-2 CAS No: 107534-96-3	950 g/kg	1 April 2010	31 March 2012	31 March 2020	8	Member States shall ensure that authorisations are subject to the following conditions: In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use indicate that freshly treated timber

							must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. In addition, products cannot be authorised for the *in situ* treatment of wood outdoors or for wood that will be in continuous

								contact with water unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.]
[F17 7	carbon dioxide	carbon dioxide EC No: 204-696-9 CAS No: 124-38-9	990 ml/l	1 November 2009	31 October 2011	31 October 2019	14	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when

							relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation

								can only be granted where the application demonstrates that risks can be reduced to acceptable levels.]
[F18			990 ml/l	1 November 2012	31 October 2014	31 October 2022	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively

							addressed in the European level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Member States shall ensure that authorisations are subject to the following conditions: (1) Product shall only be sold to and used by professionals

								trained to use them. (2) Appropriate measures to protect operators shall be taken to ensure minimum risk, including the availability of personal protective equipment if necessary. (3) Appropriate measures shall be taken to protect bystanders, such as exclusion from the treatment area during fumigation.]
[F19 8	propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole EC No: 262-104-4	930 g/kg	1 April 2010	31 March 2012	31 March 2020	8	Member States shall ensure that authorisations are subject to the

	CAS No: 60207-90-1						following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate

							risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. In addition, products cannot

								be authorised for the *in situ* treatment of wood outdoors or for wood that will be exposed to weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.**]**
[F209	Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin EC No: 259-978-4 CAS No: 56073-07-5	960 g/kg	1 April 2010	31 March 2012	31 March 2015	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very

							persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not

								exceed 75 mg/ kg and only ready-for-use products shall be authorised.
							(2)	Products shall contain an aversive agent and, where appropriate, a dye.
							(3)	Products shall not be used as tracking powder.
							(4)	Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all

								appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.]
[F21 10	K-HDO	Cyclohexylhydroxydiazene 1-oxide, potassium salt EC No: n/a CAS No: 66603-10-9 (This entry also covers the hydrated	977 g/kg	1 July 2010	30 June 2012	30 June 2020	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member

	forms of K-HDO)						States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: (1) in view of the possible risks for the environment and workers, products shall

not be used in other systems than industrial, fully automated and closed ones unless the application for product authorisation demonstrates that risks can be reduced to acceptable levels in accordance with Article 5 and Annex VI;

(2) in view of the assumptions made during the risk assessment, products must be used with appropriate personal

									protective equipment, unless the application for product authorisation demonstrates that risks to users can be reduced to acceptable levels by other means;
								(3)	in view of the risk identified for infants, products shall not be used for the treatment of wood that may enter in direct contact with infants.]
[F22 11	IPBC	3-iodo-2-propynyl butylcarbamate	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Member States shall ensure	

	EC No: 259-627-5 CAS No: 55406-53-6						that authorisations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/ or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/ or professional users can

							be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must

								be stored after treatment under shelter or on impermeable hardstanding to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.]
[F23 12	Chlorophacinone	Chlorophacinone EC No: 223-003-0 CAS No: 3691-35-8	978 g/kg	1 July 2011	30 June 2013	30 June 2016	14	In view of the identified risks for non-target animals, the active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article

							10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: (1) The nominal concentration of the active substance in products other than tracking powder shall not exceed 50 mg/kg and only ready-for use products shall be authorised. (2) Products to be used

as tracking powder shall only be placed on the market for use by trained professionals.

(3) Products shall contain an aversive agent and, where appropriate, a dye.

(4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures.

								These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.]
[F24 13	Thiabendazole	2-thiazol-4-yl-1H-benzoimidazole EC No: 205-725-8 CAS No: 148-79-8	985 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Member States shall ensure that authorisations are subject to the following conditions: in view of the assumptions made during the risk assessment, products

							authorised for industrial and/or professional use, with respect to the double-vacuum and dipping application tasks, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by

							others means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/ or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or

							on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. Products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the

								product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.]
[F25 14	thiamethoxam	thiamethoxam EC No: 428-650-4 CAS No: 153719-23-4	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Member States shall ensure that authorisations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use must be used with appropriate personal protective equipment,

							unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly

							treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. Products shall not be authorised for the *in situ* treatment of wood outdoors or for wood that will be exposed to weathering, unless data have been submitted to demonstrate that the product will meet the

								requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.]
[F26			980 g/kg	1 February 2015	31 January 2017	31 January 2025	18	The Union level risk assessment did not address all potential uses; certain uses, such as outdoor application and use by non-professionals, were excluded. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall

							assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products shall not be authorised for application by brushing, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application

							of appropriate risk mitigation measures. For products containing thiamethoxam that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded. Products applied in such a

							way that emission via a sewage treatment plant or directly to surface water cannot be prevented shall not be authorised, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Member States shall ensure that authorisations are subject to the following conditions: (1) Products authorised for professional

								use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by other means. (2) Where appropriate, measures shall be taken to protect honey bees.]
[F27 15	alphachloralose	(R)-1,2-O-(2.2,2-Trichloroethylidene)-α-D-glucofuranose	825 g/kg	1 July 2011	30 June 2013	30 June 2021	14	When assessing the application for authorisation of a

	EC No: 240-016-7 CAS No: 15879-93-3						product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures

							are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. In particular, products cannot be authorised for outdoor use unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the

							application of appropriate risk mitigation measures. Member States shall ensure that authorisations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 40 g/kg. (2) Products shall contain an aversive agent and a dye. (3) Only products for use in tamper resistant and securely closed bait

								boxes shall be authorised.]
[F28 16	brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-napthyl]-4-hydroxycoumarin EC No: 259-980-5 CAS No: 56073-10-0	950 g/kg	1 February 2012	31 January 2014	31 January 2017	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall

							ensure that authorisations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. (2) Products shall contain an aversive agent and, where appropriate, a dye. (3) Products shall not be used as tracking powder.

							(4)	Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant

								and secured bait boxes.]
[F29 17	bromadiolone	3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one EC No: 249-205-9 CAS No: 28772-56-7	969 g/kg	1 July 2011	30 June 2013	30 June 2016	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall

							ensure that authorisations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. (2) Products shall contain an aversive agent and, where appropriate, a dye. (3) Products shall not be used as tracking powder.

							(4)	Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant

								and secured bait boxes.]
[F30 18	Thiacloprid	(Z)-3-(6-chloro-3-pyridylmethyl)-1,3-thiazolidin-2-ylidenecyanamide EC No: n/a CAS No: 111988-49-9	975 g/kg	1 January 2010	n/a	31 December 2019	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product

							authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorisations are subject to the following conditions: (1) In view of

							the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means.

							(2)	In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on

impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

(3) Products shall not be authorised for the *in situ* treatment of wooden structures near water, where direct losses to the aquatic compartment cannot be prevented, or for wood that will be

								in contact with surface water, unless data have been submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.**]**
[[F31]19	Indoxacarb (enantiomeric reaction mass S:R 75:25)	Reaction mass of methyl (S)- and methyl(R)-7-chloro-2.3,4a,5-tetrahydro-2-[methoxycarbonyl-(4-trifluoromethoxyphenyl) carbamoyl]indeno[1,2-e] [1.3,4]oxadiazine-4a-carboxylate (This entry covers	796 g/kg	1 January 2010	n/a	31 December 2019	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States

	the 75:25 reaction mass of the S and R enantiomers) EC No: n/a CAS No: S-enantiomer: 173584-44-6 and R-enantiomer: 185608-75-7)						shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the

							identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorisations are subject to the following conditions: Appropriate risk mitigation measures must be taken to minimise the potential exposure of humans, of non-target species and of the aquatic environment. In particular, labels and/or safety-

								data sheets of products authorised shall indicate that: (1) Products shall not be placed in areas accessible to infants, children and companion animals. (2) Products shall be positioned away from external drains. (3) Unused products shall be disposed of properly and not washed down the drain. For amateur uses, only ready-to-use products shall be authorised.]

[F32]20	aluminium phosphide releasing phosphine	aluminium phosphide EC No: 244-088-0 CAS No: 20859-73-8	830 g/kg	1 September 2011	31 August 2013	31 August 2021	14	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess

							the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. In particular, products cannot be authorised for indoor use unless data is submitted to demonstrate that the product will meet the requirements

							of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Member States shall ensure that authorisations are subject to the following conditions: (1) Products shall only be sold to and used by specifically trained professionals. (2) In view of the risks identified for operators, appropriate risk mitigation measures must be applied. These include,

amongst others, the use of appropriate personal protective equipment, the use of applicators and the presentation of the product in a form designed to reduce operator exposure to an acceptable level.

(3) In view of the risks identified for terrestrial non-target species, appropriate risk reduction measures must be applied. These include, amongst others,

								the non-treatment of areas where other burrowing mammals than the target species are present.]
[F33			830 g/kg	1 February 2012	31 January 2014	31 January 2022	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been

							representatively addressed in the Union level risk assessment. In particular, where relevant, Member States shall assess outdoor use. When granting product authorisation, Member States shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Member States shall ensure that

							authorisations are subject to the following conditions: (1) Products shall only be supplied to and used by specifically trained professionals in the form of ready-for-use products. (2) In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and

							respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the

									protection of bystanders against leaking of gas.
								(3)	For products containing aluminium phosphide that may lead to residues in food or feed, labels and/or safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article

								18 of Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).]
[F34 21	fenpropimorph	(+/-)-cis-4-[3-(p-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine EC No: 266-719-9 CAS No: 67564-91-4	930 g/kg	1 July 2011	30 June 2013	30 June 2021	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the

							use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to

							acceptable levels. Member States shall ensure that authorisations are subject to the following conditions: (1) In view of the assumptions made during the risk assessment, products authorised for industrial use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial users can

								be reduced to an acceptable level by other means.
							(2)	In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must

								be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.]
[F35 22	boric acid	boric acid EC No: 233-139-2 CAS No: 10043-35-3	990 g/kg	1 September 2011	31 August 2013	31 August 2021	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant

							for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can

							only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorisations are subject to the following conditions: (1) Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to

									industrial and/ or professional users can be reduced to an acceptable level by other means.
								(2)	In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted

							to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/

								or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.]
[F36 23	boric oxide	Diboron trioxide EC No: 215-125-8 CAS No: 1303-86-2	975 g/kg	1 September 2011	31 August 2013	31 August 2021	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be

							exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that

							risks can be reduced to acceptable levels. Member States shall ensure that authorisations are subject to the following conditions: (1) Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be

								reduced to an acceptable level by other means.
							(2)	In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet

								the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent

								direct losses to soil or water and that any losses must be collected for reuse or disposal.]
[F37 24	disodium tetraborate	[F38 disodium tetraborate EC No: 215-540-4 CAS No (anhydrous): 1330-43-4 CAS No (pentahydrate): 12179-04-3 CAS No (decahydrate): 1303-96-4]	990 g/kg	1 September 2011	31 August 2013	31 August 2021	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios

							that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.

							Member States shall ensure that authorisations are subject to the following conditions: (1) Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by

								other means.
							(2)	In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and

							Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water

								and that any losses must be collected for reuse or disposal.]
[F39 25	disodium octaborate tetrahydrate	disodium octaborate tetrahydrate EC No: 234-541-0 CAS No: 12280-03-4	975 g/kg	1 September 2011	31 August 2013	31 August 2021	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the

							Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorisations are

								subject to the following conditions: (1) Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. (2) In view of the risks

							identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application

								of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected

								for reuse or disposal.]
[F40 26	Magnesium phosphide releasing phosphine	Trimagnesium diphosphide EC No: 235-023-7 CAS No: 12057-74-8	880 g/kg	1 February 2012	31 January 2014	31 January 2022	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the Union level risk assessment. In particular, where relevant,

							Member States shall assess outdoor use. When granting product authorisation, Member States shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Member States shall ensure that authorisations are subject to the following conditions: (1) Products shall only be supplied

									to and used by specifically trained professionals in the form of ready-for-use products.
								(2)	In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product

								in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas.
							(3)	For products containing magnesium phosphide that

							may lead to residues in food or feed, labels and/or safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/2005 of the European Parliament and of the Council

								(OJ L 70, 16.3.2005, p. 1).]
[F41 27	Nitrogen	Nitrogen EC No: 231-783-9 CAS No: 7727-37-9	999 g/kg	1 September 2011	31 August 2013	31 August 2021	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment.

							When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorisations are subject to the following conditions:

								(1)	Products may only be sold to and used by professionals trained to use them.
								(2)	Safe working practices and safe systems of work must be in place to ensure minimum risk, including the availability of personal protective equipment if necessary.]
[F42 28	Coumatetralyl	Coumatetralyl EC No: 227-424-0 CAS No: 5836-29-3	980 g/kg	1 July 2011	30 June 2013	30 June 2016	14		In view of the identified risks for non-target animals, the active substance shall be subject to a

							comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: (1) The nominal concentration of the active substance in products other than tracking powder shall not exceed 375 mg/kg and only ready-

								for use products shall be authorised.
							(2)	Products shall contain an aversive agent and, where appropriate, a dye.
							(3)	Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use

								only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.]
[F43 29	tolylfluanid	Dichloro-N-[(dimethylamino)sulphonyl]fluoro-N-(p-tolyl)methanesulphenamide EC No: 211-986-9 CAS No: 731-27-1	960 g/kg	1 October 2011	30 September 2013	30 September 2021	8	Products shall not be authorised for the *in situ* treatment of wood outdoors or for wood that will be exposed to weathering. Member States shall ensure that authorisations are subject to the following conditions: (1) In view of the

								assumptions made during the risk assessment, products authorised for industrial or professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means.
							(2)	In view of the

							risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial or professional use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard

								standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.]
[F44 30	Acrolein	Acrylaldehyde EC No: 203-453-4 CAS No: 107-02-8	0,18 g/kg	1 September 2010	Not applicable	31 August 2020	12	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, the populations that may be exposed to the product and the

							use or exposure scenarios that have not been representatively addressed at the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: (1) Waste waters containing acrolein shall be monitored prior to discharge, unless it can be demonstrated that risks for the environment can be reduced by other means. Where necessary in

									view of the risks to marine environment, waste waters shall be held in suitable tanks or reservoirs or appropriately treated before discharge.
								(2)	Products authorised for industrial and/ or professional use shall be used with appropriate personal protective equipment, and safe operational procedures shall be established, unless it can be demonstrated in the application

								for product authorisation that risks to industrial and/ or professional users can be reduced to an acceptable level by others means.]
[F45 31	Flocoumafen	4-hydroxy-3-[(1*RS*,3*RS*;1*RS*,3*RS*)-2,3,4-tetrahydro-3-[4-(4-trifluoromethylbenzyloxy)phenyl]-1-naphthyl]coumarin EC No 421-960-0 CAS No 90035-08-8	955 g/kg	1 October 2013	30 September 2013	30 September 2016	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the

							second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: (1) The nominal concentration of the active substance in products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. (2) Products shall contain an

								aversive agent and, where appropriate, a dye.
							(3)	Products shall not be used as tracking powder.
							(4)	Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. Those include, amongst others, the restriction to professional use only, setting

								an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.]
[F46 32	Warfarin	(RS)-4-hydroxy-3-(3-oxo-1-phenylbutyl)coumarin EC No: 201-377-6 CAS No: 81-81-2	990 g/kg	1 February 2012	31 January 2014	31 January 2017	14	The active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are

							subject to the following conditions: (1) the nominal concentration of the active substance shall not exceed 790 mg/kg and only ready-for-use products shall be authorised; (2) products shall contain an aversive agent and, where appropriate, a dye; (3) primary and secondary exposure of humans, non-target animals and the environment are minimised, by considering

								and applying all appropriate and available risk mitigation measures. These include, amongst others, the possibility of restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.]
[F47 33	Warfarin sodium	Sodium 2-oxo-3-(3-oxo-1-phenylbutyl)chromen-4-olate EC No: 204-929-4 CAS No: 129-06-6	910 g/kg	1 February 2012	31 January 2014	31 January 2017	14	The active substance shall be subject to a comparative risk assessment in accordance

							with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: (1) the nominal concentration of the active substance shall not exceed 790 mg/kg and only ready-for-use products shall be authorised; (2) products shall contain an aversive

									agent and, where appropriate, a dye;
								(3)	primary and secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the possibility of restriction to professional use only, setting an upper limit to the package size and laying

								down obligations to use tamper resistant and secured bait boxes.]
[F48 34	Dazomet	Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione EC No: 208-576-7 CAS No: 533-74-4	975 g/kg	1 August 2012	31 July 2014	31 July 2022	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the EU level risk

							assessment. In particular, where relevant, Member States shall assess any other use than professional use outdoors for the remedial treatment of wooden poles by insertion of granules. Member States shall ensure that authorisations are subject to the following condition: Products authorised for industrial and/or professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application

								for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by others means.]
[F49 35	N,N-diethyl-meta-toluamide	N,N-diethyl-m-toluamide EC No: 205-149-7 CAS No: 134-62-3	970 g/kg	1 August 2012	31 July 2014	31 July 2022	19	Member States shall ensure that authorisations are subject to the following conditions: (1) primary exposure of humans shall be minimized by considering and applying appropriate risk mitigation measures, including, where applicable, instructions for the amount and frequency of

									application of the product on human skin;
								(2)	labels on products intended for application on human skin, hair or clothing shall indicate that the product is intended only for restricted use on children between two and twelve years old, and that it is not intended for use on children less than two years old,

								unless it can be demonstrated in the application for product authorisation that the product will meet the requirements of Article 5 and Annex VI without such measures; (3) products must contain deterrents for ingestion.]
[F50 36	Metofluthrin	RTZ isomer: (1R,3R)-2,2-dimethyl-3-(Z)-(prop-1-enyl)cyclopropanecarboxylic acid (2,3,5,6-tetrafluoro-4-methoxymethylbenzyl) ester EC No: n.a. CAS No: 240494-71-7 Sum of all isomers: (1R,3R)-2,2-dimethyl-3-(Z)-(prop-1-enyl)cyclopropanecarboxylic acid (2,3,5,6-tetrafluoro-4-methoxymethylbenzyl) ester	1 May 2011	Not applicable	30 April 2021	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess,

			all isomers: 2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl (EZ)-(1RS,3RS;1SR,3SR)-2,2-dimethyl-3-prop-1-enylcyclopropanecarboxylate EC No: n.a. CAS No: 240494-70-6	930 g/kg				when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the European level risk assessment.**]**
[[F51]37	Spinosad	EC No: 434-300-1 CAS No: 168316-95-8 Spinosad is a mixture of 50-95 % spinosyn A and 5-50 % spinosyn D. **Spinosyn A** (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-[(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-	850 g/kg	1 November 2012	31 October 2014	31 October 2022	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure

	pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione CAS No: 131929-60-7 **Spinosyn D** (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-[(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione CAS No: 131929-63-0						scenarios and those risks to compartments and populations that have not been representatively addressed in the EU level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: — Authorisations shall be subject to appropriate risk mitigation measures. In particular, products authorised for professional use by spraying shall be used with appropriate personal protective equipment,

								unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by others means.
								— For products containing spinosad that may lead to residues in food or feed, Member States shall verify the need to set new and/or amended existing maximum

								residue levels (MRLs) according to Regulation (EC) No 470/2009 and/ or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.]
[F52 38	Bifenthrin	IUPAC name: 2-methylbiphenyl-3-ylmethyl (1RS)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate EC No: n.a. CAS No: 82657-04-3	911 g/kg	1 February 2013	31 January 2015	31 January 2023	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the

							particular product, those uses or exposure scenarios and those risks to environmental compartments and populations that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: — Products shall be authorised only for industrial or professional use, unless it is demonstrated in the application for product

								authorisation that risks to non-professional users can be reduced to acceptable levels in accordance with Article 5 and Annex VI.
								— Products authorised for industrial or professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional

								users can be reduced to an acceptable level by other means.
								— Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable

								hardstanding, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.
								— Products shall not be authorised for the *in situ* treatment of wood outdoors, or for treatment of wood that will be either continually exposed to

								the weather or protected from the weather but subject to frequent wetting, unless data have been submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.]
[F53 39	(Z,E)-tetradeca-9,12-dienyl acetate	(9Z,12E)-tetradeca-9,12-dien-1-yl acetate EC No: n.a. CAS No: 30507-70-1	977 g/kg	1 February 2013	31 January 2015	31 January 2023	19	When assessing the application for authorisation of a product in accordance with

							Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to environmental compartments and populations that have not been representatively addressed in Union level risk assessment. Member States shall ensure that authorisations are subject to the following condition: — Labels for biocidal products containing (Z,E)-tetradeca-9,12-dienyl acetate

								shall indicate that those products shall not be used in spaces where un-packaged food or feed is kept.]
[F54 40	Fenoxycarb		1000 g/kg name: Ethyl [2-(4-phenoxyphenoxy)ethyl]carbamate EC No: 276-696-7 CAS No: 72490-01-8	1 February 2013	31 January 2015	31 January 2023	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to environmental compartments

							and populations that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: — Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety data sheets of products authorised shall indicate that freshly

								treated timber shall be stored after treatment under shelter or on impermeable hardstanding under roof, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.
								— Products shall not be authorised for treatment of wood that will

								be used in outdoor constructions near or above water, unless data is submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.]
[F55 41	Nonanoic acid, Pelargonic acid		IUPAC name: Nonanoic acid EC No: 203-931-2 CAS No: 112-05-0	1 February 2013	31 January 2015	31 January 2023	19	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI,

								Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to environmental compartments and populations that have not been representatively addressed in Union level risk assessment.**]**
[[F56]				1 October 2014	30 September 2016	30 September 2024	2	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular

							product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations of products for non-professional use are subject to the packaging being designed to minimise user exposure, unless it can be demonstrated in the application for product authorisation that risks for

								human health can be reduced to acceptable levels by other means.]
[F57 42	imidacloprid	(2E)-1-[(6-chloropyridin-3-yl)methyl]-N-nitroimidazolidin-2-imine EC No: 428-040-8 CAS No: 138261-41-3	970 g/kg	1 July 2013	30 June 2015	30 June 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union

							level risk assessment. Products shall not be authorised for uses in animal housings where emission to a sewage treatment plant or direct emission to surface water cannot be prevented, unless data is submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Authorisations shall be subject to appropriate risk

								mitigation measures. In particular, appropriate risk mitigation measures shall be taken to minimise the potential exposure of infants and children. For products containing imidacloprid that may lead to residues in food or feed, Member States shall verify the need to set new or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk

								mitigation measures ensuring that the applicable MRLs are not exceeded.]
[F58 43	Abamectin	Abamectin is a mixture of avermectin B_{1a} and avermectin B_{1b}	The active substance shall comply with all the following purities: *Abamectin:* minimum 900 g/kg *Avermectin B_{1a}:* minimum 800 g/kg *Avermectin B_{1b}:* minimum 20 g/kg	1 July 2013	30 June 2015	30 June 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level
			Abamectin: IUPAC name: n.a. CAS No: n.a. *Avermectin B_{1a}:* IUPAC name: (10E,14E,16E,22Z)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-6-[(S)-sec-butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.1^{4,8}.0^{20,24}]pentacosa-10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-					

			L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabinohexopyranoside EC No: 265-610-3 CAS No: 65195-55-3				risk assessment. Products applied in such a way that emission to a sewage treatment plant cannot be prevented shall not be authorised for those application areas for which the Union level risk assessment showed unacceptable risks, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Authorisations shall be
		Avermectin B_{1b}:	IUPAC name: (10E,14E,16E,22Z)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.$1^{4,8}$.$0^{20,24}$]pentacosa-10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabinohexopyranoside EC No: 265-611-9				

				CAS No: 65195-56-4				subject to appropriate risk mitigation measures. In particular, appropriate risk mitigation measures shall be taken to minimise the potential exposure of infants and children.]
[F59 44	4,5-Dichloro-2-octyl-2H-isothiazol-3-one	4,5-Dichloro-2-octylisothiazol-3(2*H*)-one EC No: 264-843-8 CAS No: 64359-81-5	950 g/kg	1 July 2013	30 June 2015	30 June 2023	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those

							risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products shall not be authorised for treatment of wood that will be continually exposed to the weather, protected from the weather but subject to frequent wetting or in contact with fresh water, unless data have been submitted demonstrating that the product will meet the requirements

							of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Member States shall ensure that authorisations are subject to the following conditions: (1) for products authorised for industrial or professional use, safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment unless it can be demonstrated

									in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means;
								(2)	labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing under roof,

								or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.]
[F10 45	Creosote	Creosote EC No: 232-287-5 CAS No: 8001-58-9	Grade B or Grade C creosote as specified in European Standard EN 13991:2003	1 May 2013	30 April 2015	30 April 2018	8	Biocidal products containing creosote may only be authorised for uses where the authorising Member State, based on an analysis regarding the technical and economic feasibility of substitution which

							it shall request from the applicant, as well as on any other information available to it, concludes that no appropriate alternatives are available. Those Member States authorising such products in their territory shall no later than 31 July 2016 submit a report to the Commission justifying their conclusion that there are no appropriate alternatives and indicating how the development of alternatives is promoted. The Commission will

							make these reports publicly available. The active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) before its inclusion in this Annex is renewed. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those

							uses or exposure scenarios and those risks to environmental compartments and populations that have not been representatively addressed at the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: (1) Creosote may only be used under the conditions mentioned in point 2 of the second column of entry No 31 in Annex

								XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as

									Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[d].
								(2)	Creosote shall not be used for the treatment of wood intended for those uses referred to in point 3 of the second column of entry No 31 in Annex XVII to Regulation (EC) No 1907/2006.
								(3)	Appropriate risk

							mitigation measures shall be taken to protect workers, including down-stream users, from exposure during treatment and handling of treated wood in compliance with Regulation (EC) No 1907/2006 and Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related

								to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/ EEC)[e].
							(4)	Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated

								timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.]
[F60 46	*Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52	Not applicable	No relevant impurities	1 October 2013	30 September 2015	30 September 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall

							assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products authorised for professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced

							to an acceptable level by other means. For products containing *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable

								MRLs are not exceeded.]
[F61 47	fipronil	(±)-5-amino-1-(2,6-dichloro-α,α,α,-trifluoro-p-tolyl)-4-trifluoromethylsulfinylpyrazole-3-carbonitrile (1:1) EC No: 424-610-5 CAS No: 120068-37-3	950 g/kg	1 October 2013	30 September 2015	30 September 2023	18	Only professional use indoors by application in locations normally inaccessible after application to man and domestic animals has been addressed in the Union level risk assessment. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or

								exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.]
[F62 48	lambda-cyhalothrin	Reaction mass of (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate (1:1) CAS-No: 91465-08-6 EC No: 415-130-7	900 g/kg	1 October 2013	30 September 2015	30 September 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human

							populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products applied in such a way that emission to a sewage treatment plant cannot be prevented shall not be authorised, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Products authorised

							for professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by other means. For products containing lambda-cyhalothrin that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according

								to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.]
[F6349	deltamethrin	(S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate CAS-No: 52918-63-5 EC No: 258-256-6	985 g/kg	1 October 2013	30 September 2015	30 September 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human

							populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products shall not be authorised for indoor treatments resulting in sewage treatment plant emissions of the scale for which the Union level risk assessment showed unacceptable risks, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary

								by the application of appropriate risk mitigation measures.]
[F6450	Copper hydroxide	Copper (II) hydroxide EC No: 243-815-9 CAS No: 20427-59-2	965 g/kg	1 February 2014	31 January 2016	31 January 2024	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level

							risk assessment. Member States shall ensure that authorisations are subject to the following conditions: (1) Products shall not be authorised for application by dipping, unless data have been submitted in the application for product authorisation demonstrating that that application meets the requirements of Article 5 and Annex VI, if necessary by the application of appropriate

								risk mitigation measures.
							(2)	For products authorised for industrial use, safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial users can be reduced to an acceptable level by other means.
							(3)	Labels and,

							where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

								(4)	Products shall not be authorised for treatment of wood that will be used in outdoor constructions near or above water, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate mitigation measures.
51	Copper (II) oxide	Copper (II) oxide	976 g/kg	1 February 2014	31 January 2016	31 January 2024	8	When assessing the application	

	EC No: 215-269-1 CAS No: 1317-38-0						for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions:

							(1)	For products authorised for industrial use, safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial users can be reduced to an acceptable level by other means.
							(2)	Labels and, where provided, safety

								data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.
							(3)	Products shall not

								be authorised for treatment of wood that will be used in outdoor constructions near or above water or for the treatment of wood in contact with fresh water, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of

								appropriate mitigation measures.
52	Basic copper carbonate	Copper(II) carbonate-copper(II) hydroxide (1:1) EC No: 235-113-6 CAS No: 12069-69-1	957 g/kg	1 February 2014	31 January 2016	31 January 2024	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Member States shall

							ensure that authorisations are subject to the following conditions: (1) Products shall not be authorised for application by dipping, unless data have been submitted in the application for product authorisation demonstrating that that application meets the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. (2) For products

								authorised for industrial use, safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial users can be reduced to an acceptable level by other means.
							(3)	Labels and, where provided, safety data sheets

								of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.
							(4)	Products shall not be authorised

							for treatment of wood that will be used in outdoor constructions near or above water, or for the treatment of wood in direct contact with fresh water, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate

								mitigation measures.]
[F65 53	*bendiocarb*	2,2-dimethyl-1,3-benzodioxol-4-yl methylcarbamate CAS-No: 22781-23-3 EC No: 245-216-8	970 g/kg	1 February 2014	31 January 2016	31 January 2024	18	The Union level risk assessment did not address all potential uses, but concerned, for example, application by professionals only, and excluded contact with feed or food and direct application on soil. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product,

							those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: Products shall not be used for the treatment of surfaces that are prone to frequent wet cleaning, other than crack

							and crevice or spot treatment, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Products authorised for industrial or professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated

								in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. Where relevant, measures shall be taken to prevent foraging bees from gaining access to treated nests by removing the combs or blocking the nest entrances.]
[F66 54	methyl nonyl ketone	Undecan-2-one	975 g/kg	1 May 2014	30 April 2016	30 April 2024	19	The Union level risk

	CAS No: 112-12-9 EC No: 203-937-5						assessment was based on indoor use by non-professional users. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level

								risk assessment.]
[F6755	*margosa extract*	IUPAC name: Not applicable CAS-No: 84696-25-3 EC No: 283-644-7 Description: margosa extract from the kernels of *Azadirachta indica* extracted with water and further processed with organic solvents	1 000 g/kg	1 May 2014	30 April 2016	30 April 2024	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Member States shall ensure

								that authorisations are subject to appropriate risk mitigation measures for the protection of surface water, sediment and non-target arthropods.]
[F68 56	Hydrochloric acid	Hydrochloric acid CAS No: not applicable EC No: 231-595-7	929 g/kg	1 May 2014	30 April 2016	30 April 2024	2	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to

								environmental compartments that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations of products for non-professional use are subject to the packaging being designed to minimise user exposure, unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means.]

[F69]57	flufenoxuron	1-[4-(2-chloro-alpha,alpha,alpha-trifluoro-para-tolyloxy)-2-fluorophenyl]-3-(2,6-difluorobenzoyl)urea EC No: 417-680-3 CAS No: 101463-69-8	960 g/kg	1 February 2014	31 January 2016	31 January 2017	8	Flufenoxuron shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. The Union level risk assessment addressed treatment of wood which will not be used in animal housing or come into contact with food or feed. Products shall not be authorised for uses or exposure scenarios that

							have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: (1) Products shall only be used for treatment of wood intended for indoor use. (2) For products authorised for industrial or professional use safe operational procedures shall be established, and products shall be used with

								appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means.
							(3)	Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety

								data sheets of authorised products shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.]

[F70 58	DDACarbonate	Reaction mass of N,N-Didecyl-N,N-dimethylammonium Carbonate and N,N-Didecyl-N,N-dimethylammonium Bicarbonate EC No: 451-900-9 CAS No: 894406-76-9	Dry weight: 740 g/kg	1 February 2013	Not applicable	31 January 2023	8	The Union level risk assessment did not address all potential uses; certain uses, such as use by non-professionals, were excluded. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental

							compartments that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: (1) for industrial users safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that

								risks can be reduced to an acceptable level by other means;
							(2)	labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on

								impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal;
							(3)	products shall not be authorised for treatment of wood that will be in contact with fresh water or used for outdoor constructions near

								or above water, or for treatment by dipping of wood that will be continually exposed to the weather or subject to frequent wetting, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate mitigation measures.**]**

[F71]59	*cis*-tricos-9-ene (Muscalure)	*cis*-Tricos-9-ene; (Z)-Tricos-9-ene EC No: 248-505-7 CAS No: 27519-02-4	801 g/kg	1 October 2014	30 September 2016	30 September 2024	19	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as outdoor use and exposure of food or feed, were excluded. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and

							those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. For products containing *cis*-tricos-9-ene that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any

								appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.]
[F72 60	hydrogen cyanide	hydrogen cyanide EC No: 200-821-6 CAS No: 74-90-8	976 g/kg	1 October 2014	30 September 2016	30 September 2024	8, 14 and 18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the

							Union level risk assessment. Member States shall ensure that authorisations of products for use as a fumigant are subject to the following conditions: (1) product shall only be supplied to and used by professionals adequately trained to use them; (2) safe operational procedures during fumigation and venting shall be established for operators and bystanders; (3) products shall be used

									with adequate personal protective equipment including, where appropriate, self-contained breathing apparatus and gas-tight clothing;
								(4)	re-entry into fumigated spaces shall be prohibited until the air concentration has reached safe levels for operators and bystanders by ventilation;
								(5)	exposure during and after ventilation shall be prevented from exceeding safe levels for operators and

									bystanders by the establishment of a supervised exclusion zone;
								(6)	prior to fumigation, any food and any porous material with a potential to absorb the active substance, except wood intended to be treated, shall either be removed from the space to be fumigated or protected from absorption by adequate means, and the space to

								be fumigated shall be protected against accidental ignition.]
[F73 61	Didecyldimethylammonium Chloride; DDAC	N-Didecyl-N,N-dimethylammonium Chloride EC No: 230-525-2 CAS No: 7173-51-5	Dry weight: 870 g/kg	1 February 2015	31 January 2017	31 January 2025	8	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as use by non-professionals and exposure of food or feed, were excluded. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall

							assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: (1) For industrial or professional users safe operational procedures shall be established, and products shall

								be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means.
							(2)	Products shall not be used for treatment of wood with which children may enter in direct contact, unless it can be demonstrated in

								the application for product authorisation that risks can be reduced to an acceptable level.
							(3)	Labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored

								after treatment on impermeable hard standing to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.
							(4)	Products shall not be authorised for treatment of wood that will be in contact with fresh water or used for outdoor constructions

								near or above water, continually exposed to the weather or subject to frequent wetting, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate mitigation measures.]
[F74 62	pyriproxyfen	4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether EC No: 429-800-1	970 g/kg	1 February 2015	31 January 2017	31 January 2025	18	The Union level risk assessment did not address all potential uses and

	CAS No: 95737-68-1						exposure scenarios; certain uses and exposure scenarios, such as use by non-professionals, were excluded. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed

							in the Union level risk assessment. For products containing pyriproxyfen that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded. Member States shall

							ensure that authorisations are subject to the following conditions: (1) Products authorised for professionals shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means. (2) Products shall not be authorised for direct use on surface

									water, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level.
								(3)	Products intended to be used in waste treatment facilities shall be subject to appropriate risk mitigation measures to avoid contamination of the area outside the waste treatment site.]
[F75 63	diflubenzuron	1-(4-chlorophenyl)-3-	960 g/kg	1 February 2015	31 January 2017	31 January 2025	18	The Union level	

	(2,6-difluorobenzoyl)urea EC No: 252-529-3 CAS No: 35367-38-5						risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as outdoor use, use by non-professionals, and exposure of livestock were excluded. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and

							those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. For products containing diflubenzuron that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, with special consideration

							to the *in vivo* genotoxic metabolite PCA, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded. Member States shall ensure that authorisations are subject to the following conditions unless it can be demonstrated in the application for product authorisation that the risks can be reduced to an acceptable level: (1) Professional users shall wear appropriate personal protective equipment. (2) Product information

								shall include the requirement that products shall only be used on dry manure, and that the manure must undergo complete aerobic composting by professionals prior to application on arable land. (3) Products shall not be used in water systems.]
[F76 64	Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride; C_{12-16}-ADBAC	IUPAC name: Not applicable EC No: 270-325-2 CAS No: 68424-85-1	Dry weight: 940 g/kg	1 February 2015	31 January 2017	31 January 2025	8	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and

							exposure scenarios, such as use by non-professionals and exposure of food or feed, were excluded. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed

							in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: (1) For industrial or professional users safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced

								to an acceptable level by other means.
							(2)	Products shall not be used for treatment of wood with which children may enter in direct contact, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level.
							(3)	Labels and, where provided, safety data sheets of products

								authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment on impermeable hard standing to prevent direct losses to soil or water, and that any losses from the application of the

									product shall be collected for reuse or disposal.
								(4)	Products shall not be authorised for treatment of wood that will be in contact with fresh water or used for outdoor constructions near or above water, continually exposed to the weather or subject to frequentwetting, unless data is submitted to demonstrate that the product will

									meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate mitigation measures.]

a	[F7][F8For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm]
b	[F9The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 11. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated substance.
c	For products containing more than one active substance covered by Article 16(2), the deadline for compliance with Article 16(3) is that of the last of its active substances to be included in this Annex. For products for which the first authorisation has been granted later than 120 days before the deadline for compliance with Article 16(3) and a complete application has been submitted for mutual recognition in accordance with Article 4(1) within 60 days of the granting of the first authorisation, the deadline for compliance with Article 16(3) in relation to that application is extended to 120 days after the date of reception of the complete application for mutual recognition. For products for which a Member State has proposed to derogate from mutual recognition in accordance with Article 4(4), the deadline for compliance with Article 16(3) is extended to 30 days after the date of the Commission Decision adopted in accordance with the second subparagraph of Article 4(4).]
d	[F10OJ L 396, 30.12.2006, p. 1.
e	OJ L 158, 30.4.2004, p. 50.]]]

Textual Amendments

F6 Inserted by Commission Directive 2006/140/EC of 20 December 2006 amending Directive 98/8/EC of the European Parliament and of the Council to include sulfuryl fluoride as an active substance in Annex I thereto (Text with EEA relevance).

F7 Substituted by Commission Directive 2007/69/EC of 29 November 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include difethialone as an active substance in Annex I thereto (Text with EEA relevance).

F8 Substituted by Commission Directive 2012/43/EU of 26 November 2012 amending certain headings of Annex I to Directive 98/8/EC of the European Parliament and of the Council (Text with EEA relevance).

F9 Inserted by Commission Directive 2012/43/EU of 26 November 2012 amending certain headings of Annex I to Directive 98/8/EC of the European Parliament and of the Council (Text with EEA relevance).

F10 Inserted by Commission Directive 2011/71/EU of 26 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include creosote as an active substance in Annex I thereto (Text with EEA relevance).

F11 Inserted by Commission Directive 2009/84/EC of 28 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include sulfuryl fluoride as an active substance in Annex I thereto (Text with EEA relevance).

F12 Inserted by Commission Directive 2007/20/EC of 3 April 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include dichlofluanid as an active substance in Annex I thereto (Text with EEA relevance).

F13 Inserted by Commission Directive 2008/15/EC of 15 February 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include clothianidin as an active substance in Annex I thereto (Text with EEA relevance).

F14 Inserted by Commission Directive 2007/69/EC of 29 November 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include difethialone as an active substance in Annex I thereto (Text with EEA relevance).

F15 Inserted by Commission Directive 2008/16/EC of 15 February 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include etofenprox as an active substance in Annex I thereto (Text with EEA relevance).

F16 Inserted by Commission Directive 2008/86/EC of 5 September 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include tebuconazole as an active substance in Annex I thereto (Text with EEA relevance).

F17 Inserted by Commission Directive 2008/75/EC of 24 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include carbon dioxide as an active substance in Annex I thereto (Text with EEA relevance).

F18 Inserted by Commission Directive 2010/74/EU of 9 November 2010 amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance carbon dioxide to product type 18 (Text with EEA relevance).

F19 Inserted by Commission Directive 2008/78/EC of 25 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include propiconazole as an active substance in Annex I thereto (Text with EEA relevance).

F20 Inserted by Commission Directive 2008/81/EC of 29 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include difenacoum as an active substance in Annex I thereto (Text with EEA relevance).

F21 Inserted by Commission Directive 2008/80/EC of 28 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include cyclohexylhydroxydiazene 1-oxide, potassium salt (K-HDO) as an active substance in Annex I thereto (Text with EEA relevance).

F22 Inserted by Commission Directive 2008/79/EC of 28 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include IPBC as an active substance in Annex I thereto (Text with EEA relevance).

F23 Inserted by Commission Directive 2009/99/EC of 4 August 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include chlorophacinone as an active substance in Annex I thereto (Text with EEA relevance).

F24 Inserted by Commission Directive 2008/85/EC of 5 September 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include thiabendazole as an active substance in Annex I thereto (Text with EEA relevance).

F25 Inserted by Commission Directive 2008/77/EC of 25 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include thiamethoxam as an active substance in Annex I thereto (Text with EEA relevance).

F26 Inserted by Commission Directive 2013/3/EU of 14 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance thiamethoxam to product-type 18 (Text with EEA relevance).

F27 Inserted by Commission Directive 2009/93/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include alphachloralose as an active substance in Annex I thereto (Text with EEA relevance).

F28 Inserted by Commission Directive 2010/10/EU of 9 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include brodifacoum as an active substance in Annex I thereto (Text with EEA relevance).

F29 Inserted by Commission Directive 2009/92/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include bromadiolone as an active substance in Annex I thereto (Text with EEA relevance).

F30 Inserted by Commission Directive 2009/88/EC of 30 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include thiacloprid as an active substance in Annex I thereto (Text with EEA relevance).

F31 Inserted by Commission Directive 2009/87/EC of 29 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include indoxacarb as an active substance in Annex I thereto (Text with EEA relevance).

F32 Inserted by Commission Directive 2009/95/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include aluminium phosphide releasing phosphine as an active substance in Annex I thereto (Text with EEA relevance).

F33 Inserted by Commission Directive 2010/9/EU of 9 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance aluminium phosphide releasing phosphine to product type 18 as defined in Annex V thereto (Text with EEA relevance).

F34 Inserted by Commission Directive 2009/86/EC of 29 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include fenpropimorph as an active substance in Annex I thereto (Text with EEA relevance).

F35 Inserted by Commission Directive 2009/94/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include boric acid as an active substance in Annex I thereto (Text with EEA relevance).

F36 Inserted by Commission Directive 2009/98/EC of 4 August 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include boric oxide as an active substance in Annex I thereto (Text with EEA relevance).

F37 Inserted by Commission Directive 2009/91/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include disodium tetraborate as an active substance in Annex I thereto (Text with EEA relevance).

F38 Substituted by Commission Directive 2012/40/EU of 26 November 2012 correcting Annex I to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (Text with EEA relevance).

F39 Inserted by Commission Directive 2009/96/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include disodium octaborate tetrahydrate as an active substance in Annex I thereto (Text with EEA relevance).

F40 Inserted by Commission Directive 2010/7/EU of 9 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include magnesium phosphide releasing phosphine as an active substance in Annex I thereto (Text with EEA relevance).

F41 Inserted by Commission Directive 2009/89/EC of 30 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include nitrogen as an active substance in Annex I thereto (Text with EEA relevance).

F42 Inserted by Commission Directive 2009/85/EC of 29 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include coumatetralyl as an active substance in Annex I thereto (Text with EEA relevance).

F43 Inserted by Commission Directive 2009/151/EC of 27 November 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include tolylfluanid as an active substance in Annex I thereto (Text with EEA relevance).

F44 Inserted by Commission Directive 2010/5/EU of 8 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include acrolein as an active substance in Annex I thereto (Text with EEA relevance).

F45 Inserted by Commission Directive 2009/150/EC of 27 November 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include flocoumafen as an active substance in Annex I thereto (Text with EEA relevance).

F46 Inserted by Commission Directive 2010/11/EU of 9 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include warfarin as an active substance in Annex I thereto (Text with EEA relevance).

F47 Inserted by Commission Directive 2010/8/EU of 9 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include warfarin sodium as an active substance in Annex I thereto (Text with EEA relevance).

F48 Inserted by Commission Directive 2010/50/EU of 10 August 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include dazomet as an active substance in Annex I thereto (Text with EEA relevance).

F49 Inserted by Commission Directive 2010/51/EU of 11 August 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include N,N-diethyl-meta-toluamide as an active substance in Annex I thereto (Text with EEA relevance).

F50 Inserted by Commission Directive 2010/71/EU of 4 November 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include metofluthrin as an active substance in Annex I thereto (Text with EEA relevance).

F51 Inserted by Commission Directive 2010/72/EU of 4 November 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include spinosad as an active substance in Annex I thereto (Text with EEA relevance).

F52 Inserted by Commission Directive 2011/10/EU of 8 February 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include bifenthrin as an active substance in Annex I thereto (Text with EEA relevance).

F53 Inserted by Commission Directive 2011/11/EU of 8 February 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include (Z,E)-tetradeca-9,12-dienyl acetate as an active substance in Annexes I and IA thereto (Text with EEA relevance).

F54 Inserted by Commission Directive 2011/12/EU of 8 February 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include fenoxycarb as an active substance in Annex I thereto (Text with EEA relevance).

F55 Inserted by Commission Directive 2011/13/EU of 8 February 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include nonanoic acid as an active substance in Annex I thereto (Text with EEA relevance).

F56 Inserted by Commission Directive 2012/41/EU of 26 November 2012 amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance nonanoic acid to product type 2 (Text with EEA relevance).

F57 Inserted by Commission Directive 2011/69/EU of 1 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include imidacloprid as an active substance in Annex I thereto (Text with EEA relevance).

F58 Inserted by Commission Directive 2011/67/EU of 1 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include abamectin as an active substance in Annex I thereto (Text with EEA relevance).

F59 Inserted by Commission Directive 2011/66/EU of 1 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include 4,5-Dichloro-2-octyl-2H-isothiazol-3-one as an active substance in Annex I thereto (Text with EEA relevance).

F60 Inserted by Commission Directive 2011/78/EU of 20 September 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include Bacillus thuringiensis subsp. israelensis Serotype H14, Strain AM65-52 as an active substance in Annex I thereto (Text with EEA relevance).

F61 Inserted by Commission Directive 2011/79/EU of 20 September 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include fipronil as an active substance in Annex I thereto (Text with EEA relevance).

F62 Inserted by Commission Directive 2011/80/EU of 20 September 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include lambda-cyhalothrin as an active substance in Annex I thereto (Text with EEA relevance).

F63 Inserted by Commission Directive 2011/81/EU of 20 September 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include deltamethrin as an active substance in Annex I thereto (Text with EEA relevance).

F64 Inserted by Commission Directive 2012/2/EU of 9 February 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include copper (II) oxide, copper (II) hydroxide and basic copper carbonate as active substances in Annex I thereto (Text with EEA relevance).

F65 Inserted by Commission Directive 2012/3/EU of 9 February 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include bendiocarb as an active substance in Annex I thereto (Text with EEA relevance).

F66 Inserted by Commission Directive 2012/14/EU of 8 May 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include methyl nonyl ketone as an active substance in Annex I thereto (Text with EEA relevance).

F67 Inserted by Commission Directive 2012/15/EU of 8 May 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include margosa extract as an active substance in Annex I thereto (Text with EEA relevance).

F68 Inserted by Commission Directive 2012/16/EU of 10 May 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include hydrochloric acid as an active substance in Annex I thereto (Text with EEA relevance).

F69 Inserted by Commission Directive 2012/20/EU of 6 July 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include flufenoxuron as an active substance for product-type 8 in Annex I thereto (Text with EEA relevance).

F70 Inserted by Commission Directive 2012/22/EU of 22 August 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include DDACarbonate as an active substance in Annex I thereto (Text with EEA relevance).

F71 Inserted by Commission Directive 2012/38/EU of 23 November 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include cis-Tricos-9-ene as an active substance in Annex I thereto (Text with EEA relevance).

F72 Inserted by Commission Directive 2012/42/EU of 26 November 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include hydrogen cyanide as an active substance in Annex I thereto (Text with EEA relevance).

F73 Inserted by Commission Directive 2013/4/EU of 14 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to include Didecyldimethylammonium Chloride as an active substance in Annex I thereto (Text with EEA relevance).

F74 Inserted by Commission Directive 2013/5/EU of 14 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to include pyriproxyfen as an active substance in Annex I thereto (Text with EEA relevance).

F75 Inserted by Commission Directive 2013/6/EU of 20 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to include diflubenzuron as an active substance in Annex I thereto (Text with EEA relevance).

F76 Inserted by Commission Directive 2013/7/EU of 21 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to include Alkyl (C12-16) dimethylbenzyl ammonium chloride as an active substance in Annex I thereto (Text with EEA relevance).

ANNEX IA U.K.

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

[F77No	Common name	IUPAC name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3)(except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions
1	Carbon dioxide	Carbon dioxide EC No: 204-696-9 CAS No: 124-38-9	990 ml/l	1 November 2009	31 October 2011	31 October 2019	14	Only for use in ready-for-use gas canisters functioning together with a

*Note:*For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm**]**

								trapping device.
[F532	(Z,E)-tetradeca-9,12-dienyl acetate	(9Z,12E)-tetradeca-9,12-dien-1-yl acetate EC No: n.a. CAS No: 30507-70-1	977 g/kg	1 February 2013	31 January 2015	31 January 2023	19	Member States shall ensure that registrations are subject to the following conditions: — Only for traps containing a maximum of 2 mg of (Z,E)-Tetradeca-9,12-dienyl acetate for indoor use, — Labels for biocidal products containing (Z,E)-tetradeca-9,12-dienyl acetate shall indicate that those products shall only be used indoors, and

*Note:*For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm]

									shall not be used in spaces where un-packaged food or feed is kept.]

*Note:*For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm]

Textual Amendments

F77 Inserted by Commission Directive 2007/70/EC of 29 November 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include carbon dioxide as an active substance in Annex IA thereto (Text with EEA relevance).

ANNEX IB U.K.

LIST OF BASIC SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL

ANNEX IIA U.K.

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 U.K.

1.1. Name and address, etc.

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

II. IDENTITY U.K.

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/l, 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/l, as appropriate

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

2.10. Exposure data in conformity with Annex VIIA to Directive 92/32/EEC[(49)].

III. PHYSICAL AND CHEMICAL PROPERTIES U.K.

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 U.K.

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[(50)] 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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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
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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

— 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

Notes

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

ANNEX IIIA U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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[(51)]

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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

[F78ANNEX IVA U.K.

DATA SET FOR ACTIVE SUBSTANCES MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI

Textual Amendments

F78 Substituted by Commission Directive 2006/50/EC of 29 May 2006 amending Annexes IVA and IVB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (Text with EEA relevance).

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

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

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

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

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

Dossier requirements

SECTIONS:

I. Identity of the micro-organism

II. Biological properties of the micro-organism

III. Further information on the micro-organism

IV. Analytical methods

V. Effects on human health

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

VII. Fate and behaviour in the environment

VIII. Effects on non-target organisms

IX. Classification and labelling

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

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

I. IDENTITY OF THE MICRO-ORGANISM U.K.

1.1. Applicant

1.2. Manufacturer

1.3. Name and species description, strain characterisation

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

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

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

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

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

1.4.1. Content of the micro-organism

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

1.4.3. Analytical profile of batches

II. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM U.K.

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

2.1.1. Historical background

2.1.2. Origin and natural occurrence

2.2. Information on target organism(s)

2.2.1. Description of the target organism(s)

2.2.2. Mode of action

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

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

2.5. Infectiveness, dispersal and colonisation ability

2.6. Relationships to known plant or animal or human pathogens

2.7. Genetic stability and factors affecting it

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

2.9. Antibiotics and other anti-microbial agents

2.10. Robustness to environmental factors

2.11. Effects on materials, substances and products

III. FURTHER INFORMATION ON THE MICRO-ORGANISM U.K.

3.1. Function

3.2. Field of use envisaged

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

3.4. Method of production and quality control

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

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

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

3.8. Procedures for destruction or decontamination

3.9. Measures in case of an accident

3.10. Procedures for waste management

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

IV. ANALYTICAL METHODS U.K.

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

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

V. EFFECTS ON HUMAN HEALTH U.K.

TIER I

5.1. Basic information

5.1.1. Medical data

5.1.2. Medical surveillance on manufacturing plant personnel

5.1.3. Sensitisation/allergenicity observations

5.1.4. Direct observation, e.g. clinical cases

5.2. Basic studies

5.2.1. Sensitisation

5.2.2. Acute toxicity, pathogenicity, and infectiveness

5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness

5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness

5.2.2.3. Intraperitoneal/subcutaneous single dose

5.2.3. *In vitro* genotoxicity testing

5.2.4. Cell culture study

5.2.5. Information on short-term toxicity and pathogenicity

5.2.5.1. Health effects after repeated inhalatory exposure

5.2.6. Proposed treatment: first aid measures, medical treatment

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

TIER II

5.3. Specific toxicity, pathogenicity and infectiveness studies

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

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

END OF TIER II

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

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

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

6.2. Further information required

6.2.1. Non-viable residues

6.2.2. Viable residues

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

VII. FATE AND BEHAVIOUR IN THE ENVIRONMENT U.K.

7.1. Persistence and multiplication

7.1.1. Soil

7.1.2. Water

7.1.3. Air

7.2. Mobility

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

VIII. EFFECTS ON NON-TARGET ORGANISMS U.K.

8.1. Effects on birds

8.2. Effects on aquatic organisms

8.2.1. Effects on fish

8.2.2. Effects on freshwater invertebrates

8.2.3. Effects on algae growth

8.2.4. Effects on plants other than algae

8.3. Effects on bees

8.4. Effects on arthropods other than bees

8.5. Effects on earthworms

8.6. Effects on soil micro-organisms

8.7. Further studies

8.7.1. Terrestrial plants

8.7.2. Mammals

8.7.3. Other relevant species and processes

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

IX. CLASSIFICATION AND LABELLING U.K.

The dossier shall be accompanied by a reasoned proposals for allocating an active substance which is a micro-organism to one of the risk groups specified in Article 2 of Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work[52] together with indications on the need for products to carry the biohazard sign specified in Annex II to that Directive.

ANNEX IVB U.K.

DATA SET FOR BIOCIDAL PRODUCTS MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI

1. For the purposes of this Annex, the term micro-organisms shall be understood as including also viruses and fungi. This Annex provides data requirements for the authorisation of a biocidal product based on preparations of micro-organisms. For all

biocidal products based on preparations containing micro-organisms that are subject to application, all available relevant knowledge and information in literature should be provided. The information related to the identification and characterisation of all components in a biocidal product is particularly important and must be entered in sections I to IV and provides the basis for an assessment of possible impacts on human health and the environment.

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

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[(53)] shall be used wherever possible to minimise animal testing.

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

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

Dossier requirements

SECTIONS:

I. Identity of the biocidal product

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

III. Data on application

IV. Further information on the biocidal product

V. Analytical methods

VI. Efficacy data

VII. Effects on human health

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

IX. Fate and behaviour in the environment

X. Effects on non-target organisms

XI. Classification, packaging and labelling of the biocidal product

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

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

I. IDENTITY OF THE BIOCIDAL PRODUCTS U.K.

1.1. Applicant

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

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

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

1.5. Physical state and nature of the biocidal product

1.6. Function

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

2.1. Appearance (colour and odour)

2.2. Storage stability and shelf-life

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

2.2.2. Other factors affecting stability

2.3. Explosivity and oxidising properties

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

2.5. Acidity, alkalinity and pH value

2.6. Viscosity and surface tension

2.7. Technical characteristics of the biocidal product

2.7.1. Wettability

2.7.2. Persistent foaming

2.7.3. Suspensibility and suspension stability

2.7.4. Dry sieve test and wet sieve test

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

2.7.6. Emulsifiability, re-emulsifiability, emulsion stability

2.7.7. Flowability, pourability (rinsability) and dustability

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

2.8.1. Physical compatibility

2.8.2. Chemical compatibility

2.8.3. Biological compatibility

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

III. DATA ON APPLICATION U.K.

3.1. Field of use envisaged

3.2. Mode of action

3.3. Details of intended use

3.4. Application rate

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

3.6. Method of application

3.7. Number and timing of applications and duration of protection

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

3.9. Proposed instructions for use

3.10. Category of users

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

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

IV. FURTHER INFORMATION ON THE BIOCIDAL PRODUCT U.K.

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

4.2. Procedures for cleaning application equipment

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

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

4.5. Measures in the case of an accident

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

4.6.1. Controlled incineration

4.6.2. Others

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

V. ANALYTICAL METHODS U.K.

5.1. Methods for the analysis of the biocidal product

5.2. Methods to determine and quantify residues

VII. EFFECTS ON HUMAN HEALTH U.K.

7.1. Basic acute toxicity studies

7.1.1. Acute oral toxicity

7.1.2. Acute inhalation toxicity

7.1.3. Acute percutaneous toxicity

7.2. Additional acute toxicity studies

7.2.1. Skin irritation

7.2.2. Eye irritation

7.2.3. Skin sensitisation

7.3. Data on exposure

7.4. Available toxicological data relating to non-active substances

7.5. Supplementary studies for combinations of biocidal products

7.6. Summary and evaluation of effects on human health

X. EFFECTS ON NON-TARGET ORGANISMS U.K.

10.1. Effects on birds

10.2. Effects on aquatic organisms

10.3. Effects on bees

10.4. Effects on arthropods other than bees

10.5. Effects on earthworms

10.6. Effects on soil micro-organisms

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

10.7.1. Terrestrial plants

10.7.2. Mammals

10.7.3. Other relevant species and processes

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

XI. CLASSIFICATION, PACKAGING AND LABELLING OF THE BIOCIDAL PRODUCT U.K.

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

necessary, specimens of proposed packaging shall be submitted to the competent authority of a Member State.

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

ANNEX V U.K.

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-type 7: Film preservatives

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-type 8: Wood preservatives

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

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-type 10: Masonry preservatives

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

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-type 12: Slimicides

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-type 13: Metalworking-fluid preservatives

Products used for the preservation of metalworking fluids by the control of microbial deterioration.
MAIN GROUP 3: Pest control
Product-type 14: Rodenticides

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 18: Insecticides, acaricides and products to control other arthropods

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans).
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 U.K.

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

CONTENTS

DEFINITIONS

(a) Hazard identification U.K.

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

(b) Dose (concentration) — response (effect) assessment U.K.

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 U.K.

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 U.K.

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 U.K.

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 makea 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 riskcharacterisation 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[(54)].

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[(55)],
  — 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**) **[**[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).**]**

(**34**) 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).

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

(**36**) 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).

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

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

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

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

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

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

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

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

(**45**) 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).

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

(**47**) 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).

(**48**) 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).

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

(**50**) 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).

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

(**52**) **[**[F78]OJ L 262, 17.10.2000, p. 21.

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

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

(**55**) 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).

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).

F78 Substituted by Commission Directive 2006/50/EC of 29 May 2006 amending Annexes IVA and IVB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (Text with EEA relevance).