COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24.06.1996
COM(96) 312 final - COD 465

Amended proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

concerning the placing of biocidal products on the market

(presented by the Commission pursuant to Article 189 a (2)
of the EC-Treaty)

EXPLANATORY MEMORANDUM

Pursuant to Article 189(a) paragraph 2 of the EC treaty, the Commission submits an amended proposal for a European Parliament and Council Directive concerning the placing of biocidal products on the market. The amended proposal takes account of a number of amendments from the European Parliament, adopted at its plenary session on 18 April 1996[1].

A large number of amendments were proposed by Parliament, grouped essentially as follows: to limit the use of laboratory animals, to alter the scope, to clarify the text, to introduce simplified procedures, to modify the data requirements, to alter the operation in certain areas (eg labelling, treatment of anti-fouling products) and to introduce a system to charge fees.

Amendment 5 contains a proposal that a new recital, number 20a, be introduced stating that this directive assists in reducing the number of tests carried out on laboratory animals; the Commission agrees with this important addition.

As this proposal is designed to fill a gap in the existing European chemicals legislation the scope is critical - it needs to cover all relevant products not covered by other legislation but at the same time must avoid any duplication with existing legislation. The Commission agrees that reference needs to be made to additional relevant Community legislation, and accepts amendment number 2. The suggested text has, however, been added to recital 20 rather than recital 13 as this is a more logical place for it. Additions have also been made to article 1 as proposed in amendments 9, 10 and 11. Proposals to restrict the scope would leave gaps in the European legislation and so the Commission cannot accept amendment 12 which indirectly alters the scope by modifying an important definition, that of harmful organisms. Amendment 13 cannot be accepted as it would increase the scope unnecessarily by including products which are for export only; amendment 15 is unacceptable as it would bring treated materials under the scope of the proposal. The proposal is concerned with the placing of biocidal products on the European market and does not include the manufacturing stage of the biocidal products themselves nor the post treatment stage ie materials after they have been treated with biocides (eg treated wood).

Amendments 4, 7, 42 and 43 propose the setting up of action plans or other measures to reduce the usage of biocidal products. However, whilst these ideas are laudable and indeed are in line with the 5th Environmental Action Programme they cannot be incorporated into this proposal. The proposal is concerned with the assessment of individual active substances and biocidal products and not with the setting of an overall strategy for their use. For similar reasons the Commission cannot accept the part of amendment 38 which proposes that all product labels advise that the biocidal product should be used moderately.

The Commission recognizes that this is a very technical proposal and welcomes any relevant clarification. Amendments 3 and 92 (grouped together), which clarify certain basic principles,

---

[1] Reference- minutes of the session of 18 April 1996, provisional edition, PE 198.355.

have therefore been incorporated into recital 19 as suggested. A new recital, number 20b, has been introduced as proposed in amendment 6; this explains that a guidance document will be produced to assist in the implementation of annex VI (the common principles).

The Commission agrees with the introduction of the concept of "frame-formulations" in article 2, as suggested in amendment 14, as this will simplify certain procedures.

Another very useful clarification which has been accepted by the Commission is the principle of grouping all pertinent references to mutual recognition together in the manner suggested by amendments 19 and 20. This has resulted in a restructuring of the text in article 3 which is now split into two parts, a new article 3 which contains the general requirements for authorization and a new article 3a which contains the text dealing with mutual recognition. The rewording suggested in amendment 17 clarifies the time period stipulated for applications to be processed and this has been incorporated into the text of article 3.2. Amendment 18 has also been incorporated into the text in the new article 3 as the Commission agrees that biocidal products to which the concept of frame formulations has been applied should be processed within 60 days.

An addition to the text in article 14 has been made, as suggested in amendment 31 as this clarifies certain aspects of what happens in the transitional period. Amendment 57 has been accepted and the deletion of some text in paragraph 59 of annex VI clarifies the meaning.

The Commission cannot accept the proposal, contained in amendment 8, to delete the reference to the 5th Environmental Action Programme in recital 24 since the proposed directive underpins a key part of this Programme and so a reference to it is important.

A number of amendments were proposed which alter the data requirements; some of these have been incorporated into the text but others, which remove certain provisions for flexibility, are not acceptable. This flexibility is needed to ensure that only data which is really needed for the purposes of carrying out a risk assessment is submitted and evaluated; this flexibility does, of course, not result in a reduction in the level of protection afforded to humans or the environment. Amendments 23, 25, 27, 28, 44, 50, 51, 53 and 54 are therefore not acceptable. Other amendments propose adding to the data requirements regardless as to whether or not they are necessary for the purposes of the risk assessment eg requesting data on all degradation products of the active substances or decreasing the acceptable concentration limits in water. Amendment numbers 45, 46, 47, 48, 49, 52 and 60 fall into this category and are therefore unacceptable. The amendments relating to data requirements which have been incorporated into the modified text are numbers 79, 80, 81, and 83; these state that the dossier requirements must be in line with technical development.

Combining an alteration in the data requirements with a change in operation of the authorization conditions the Commission has incorporated amendments 21 and 24 into the text of article 4 and amendment 59 into paragraph 80 of annex VI; these now stipulate that effects on air and on surface water must be specifically considered and that application methods must be incorporated into the conditions of authorization. Amendment 56 states that only where appropriate should certain types of tests be used for efficacy purposes; this is a helpful amendment and the text in paragraph 51 of annex VI has been altered accordingly.

A number of amendments were concerned with labelling. Amendment 37 proposes that all biocides be labelled according to the Preparations Directive (88/379/EEC); the Commission agrees with this in principle but as Directive 88/379/EEC is currently being revised cannot implement this amendment yet. Amendment 37 will be acted upon once the modifications to Directive 88/379/EEC have been completed; article 18.4 has been amended slightly insofar as the reference to other Community provisions has been deleted. Amendment 36 also proposes modifications to the product label; the part which states that labels must not be misleading is acceptable but the request not to have claims on the label cannot be supported. Part of amendment 38 proposed that labelling should be clearly legible; this is not necessary as this point is already covered in Directive 88/379/EEC under which all biocidal products will be labelled. Directive 88/379/EEC also contains requirements as to when safety lids are required and so amendment 35 has not been accepted.
Part of amendments 29 & 95 (grouped together) clarifies that the principle of comparative assessment will not be applied to biocidal products, this helpful clarification has been incorporated into article 9.5. In contrast amendment 58 cannot be accepted as it implies that comparative assessment would be applied to biocidal products. The part of amendments 29 and 95 which is not acceptable relates to the request to have a 5 year phasing out period based on the procedure in article 10 of the proposal; this cannot be accepted as the reference to article 10 is not relevant and the 5 year period proposed is too long.

The requirement that the consultation between the applicant and the Commission be made mandatory, as proposed in amendment 39, is acceptable with the proviso that such consultation is not needed when a positive authorization decision is envisaged, article 24.3 has been reworded accordingly. However the suggestion that all requests for the composition of all product formulations be kept confidential automatically, as requested in amendment 34 is not acceptable as certain components of the formulation may have to be named on the product label if they are dangerous to humans or the environment.

A derogation for anti-fouling products used for specific purposes is proposed in amendment 96; this is acceptable to the Commission as it recognizes the special requirements of these products. Paragraph 86 of annex VI has been amended accordingly.

Amendments 1, 22 and 55 propose restricting the types of substance which can be included in biocidal products; these cannot be accepted as this would alter one of the fundamental principles of this proposal - that decisions are based on risk assessment (and not a hazard assessment). The proposal attempts to balance the decisions made at Member States level and at Community level by, as far as possible, leaving decisions on the biocidal product to Member States and taking decisions on the active substance at Community level. Amendment 33 is not acceptable as the Commission considers that the decision as to the completeness of a dossier on a biocidal product should be left to the Member State. Amendment 32 proposes an alteration in the committee procedure for the adoption of the Regulation which will deal with the review work; the Commission originally proposed, after careful consideration, an advisory committee for this work and sees no reason to change this.
Other proposed procedural changes which are not acceptable are numbers 41 and 63. Amendment 41 would automatically extend the application of the safety clause to all Member States following use by a single Member State and 63 is against the Commission rules in attempting to define the composition of the Standing Committee

Amendment 62 is not acceptable as it proposes that, in paragraph 92 of annex VI, only environmental and economic benefits should be considered rather than benefits in general - this would restrict the flexibility needed when deciding upon the authorization of a biocidal product.

Finally amendment 26 proposes that fees be charged for the authorization of biocidal products; this principle has been accepted by the Commission and a new article 7a introduced into the text.

ORIGINAL PROPOSAL	MODIFIED PROPOSAL
Recital 19	
Whereas Member States must be able to authorize biocidal products not complying with the above-mentioned conditions for a limited period of time, especially in case of an unforseen danger threatening man or the environment which cannot be contained by other means; whereas such authorization should be reviewed by the Commission in close cooperation with the Member States; whereas the Community procedure should not prevent Member States from authorizing for use in their territory for a limited period of time biocidal products containing an active substance not yet entered in the Community list, provided that a dossier meeting community requirements has been submitted and the Member States believes that the active substance and the biocidal products satisfy the Community conditions set in regard to them;	Whereas Member States must be able to authorize biocidal products not complying with the above-mentioned conditions for a limited period of time, especially in case of an unforseen danger threatening man or the environment which cannot be contained by other means; i.e. in cases where the requisite safety for humans and the environment cannot be achieved by other means or with the aid of the products listed in Annex V of this Directive; whereas such authorization must accord with principles laid down in Point 61 of Annex VI to this Directive and should be reviewed by the Commission in close cooperation with the Member States; whereas the Community procedure should not prevent Member States from authorizing for use in their territory for a limited period of time biocidal products containing an active substance not yet entered in the Community list, provided that a dossier meeting community requirements has been submitted and the Member States believes that the active substance and the biocidal products satisfy the Community conditions set in regard to them;

Recital 20

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

Recital 20a (new)

	Whereas it is essential that this Directive helps to reduce the number of tests on animals and that testing should be made dependant on the purpose and use of a product;

Recital 20b (new)

	Whereas the Commission is to draw up technical notes for guidance on the implementation of Annex VI;

Article 1(2)(aa) and (ab)(new) and (b)

	(aa) Council directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products;(1)
	(ab) Council Directive 90/677/EEC on 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 veterinary medicinal products;(2)
(b) Council Directives 70/524/EEC and 82/471/EEC on additives and substances for exclusive use in animal feedingstuffs;	(b) Council Directives 70/524/EEC and 82/471/EEC on additives and substances for exclusive use in animal feedingstuffs and Directive 77/101/EEC (3) on the marketing of straight feedingstuffs;
	(1) OJ L 317,6.11.1981, p.82. (2) OJ L 373, 31.12.1990 p.26 (3) OJ L 32, 3.2.1977 p.1

Article 1.2 (g) new

	(g) Council Directive 90/385/EEC on the approximation of the laws of the Member States on active implantable medicinal devices (1), (h) 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 (2) and subsequent follow-up Directives. (1) OJ L 189, 20.7.1990, p.17 (2)OJ L 40, 11.2.1989. P. 38

Article 1(3)(ea)(new)

	(ea) Council directive 84/450/EEC on the approximation of the laws, regulations or administrative provisions of the Member States relating to misleading advertising OJ L 250, 19.09.1984, p.17

Article 2 (1)(ea)(new)

(ea) Frame-Formulations

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 authorized 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 other presenting the same or a lower risk, and which do not decrease its efficacy.

Article 3 (2)

2. Every application for authorization shall be decided upon within a reasonable period.	2. Every application for authorization shall be decided upon without undue delay.

Article 3 (par 4,5,6,7,8)

3.A biocidal product that has already been authorized in one Member State shall be authorized, in another Member State within 60 days of an application being received by the other Member State, providing that the active substance of the biocidal product conforms to the entry in Annex 1.

deleted

4.If complying with Article 4 a Member State establishes that:
(a) unacceptable resistance of the target organism to the biocidal product is proven or
(b) the relevant circumstances of use, such as climate or breeding period of the target species, differ significantly from those in the Member State where biocidal product was first authorized, and an unchanged authorization may therefore present unacceptable risks to man or the environment;
the Member State may request that the directions for use and the dose rate referred to in Article 18(3)(e) are adjusted to the different circumstances, or, if the risk cannot be prevented in any other way, the Member State may request changes to be made to the biocidal product itself so that conditions for issue of an authorization provided for in article 4 are satisfied.

5. Notwithstanding paragraph 4 where a Member State believes a biocidal product cannot meet the conditions set out under article 4 and consequently proposes to refuse authorization, it shall notify the Commission, other Member States and the applicant and shall provide them with an explanatory document giving details of the product and setting out the grounds on which it proposes to refuse the authorization.

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

deleted

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

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

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

Article 3 par. 3,4,5,6 new

3.Without prejudice to Articles 7 and 11 and providing that the applicant has a right of access to it, when a subsequent application for authorization for a new biocidal product is based upon a frame-formulation, the competent authority shall take a decision with regard to this application within a period of 60 days.

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

5. Without prejudice to Article 6(1), authorizations shall be granted for a maximum period of 10 years from the date of first or renewed inclusion of the active substance onto Annex I for the product type, without exceeding the deadline specified for the active substance in Annex I, they may be renewed after verification that the conditions imposed in Article 4(1) and (2) are still satisfied. Renewal may, where necessary, be granted only for the period necessary to allow the competent authority of the Member States to make such verification, where an application for renewal has been made.

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

Article 3a (new)

1. Without prejudice to Article 11, a biocidal product that has already been authorized in one Member State shall be authorized in another Member States within 60 days of an application being received by the other Member State, provided that the active substance of the biocidal product is included in Annex I and conforms to the requirements thereof. The application shall include a summary of the dossier as required in Article 7(2)(a) and Annex IIB, Section X and a certified copy of the first authorization granted.
The authorization 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.

2.If, in accordance with Article 4, a Member State establishes that:

(aa) the target species can be assured not to occur on its territory.

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

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

the Member States may request that certain conditions referred to in Article 18(3)(e),(f),(h),(j) and (l) be adjusted to the different circumstances, so that conditions for issue of an authorization laid down in Article 4 are satisfied.

	3.Notwithstanding paragraph 2 where a Member State believes a biocidal product cannot meet the conditions set out under article 4 and consequently proposes to refuse or to restrict the authorization 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 authorization. The Commission shall prepare a proposal on these matters in accordance with Article 24 for a decision in accordance with the procedures laid down in Article 25(3).

Article 4(1)(b)(iii)and (iv)

(iii) has no harmful effects itself or as a result of its residues, on human or animal health, directly or indirectly (e.g. through drinking water, food or feed) or on groundwater;	(iii) has no harmful effects itself or as a result of its residues, on human or animal health, directly or indirectly (e.g. through air, drinking water, food or feed) or on groundwater and surface water;
(iv) has no unacceptable effect on the environment having particular regard to the following considerations: - its fate and distribution n the environment; particularly contamination of water including drinking water and groundwater, -its impact on non-target organisms;	(iv) has no unacceptable effect on the environment having particular regard to the following considerations: - its fate and distribution n the environment; particularly contamination of water including drinking water, groundwater and surface water, -its impact on non-target organisms;

Article 4.4

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

Article 7.a new

	Member States shall establish a system obliging those seeking to place or having placed biocidal products on the market and those supporting entries for active substances on Annexes I, Ia and Ib to pay charges, globally covering the costs of all different procedures associated with the provisions of this directive.

Article 9(5)

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

Article 14(3)

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

Article 18(3), introduction

3. Biocidal products shall be labelled according to the provisions of Directive 88/379/EEC concerning labelling. In addition the label must show clearly and indelibly the following:	3. Biocidal products shall be labelled according to the provisions of Directive 88/379/EEC concerning labelling. Labels shall not be misleading or give an exaggerated impression of the product. In addition the label must show clearly and indelibly the following:

Article 18 (4)

4.By way of derogation from paragraph 1 and 2 and the first sentence of paragraph 3 biocidal products authorised as insecticides, acaricides, rodenticides, avicides or molluscicides shall be classified, packaged and labelled in accordance with Directive 78/631/EEC on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides) (1) insofar as there is no other Community provision specifically covering these matters for such products. 1 OJ L 206, 29.7.1978, p. 13.	4.By way of derogation from paragraph 1 and 2 and the first sentence of paragraph 3 biocidal products authorised as insecticides, acaricides, rodenticides, avicides or molluscicides shall be classified, packaged and labelled in accordance with Directive 78/631/EEC on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides).(1) 1 OJ L 206, 29.7.1978, p. 13.

Article 24 (3)

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

Annex II (A) (1)

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.	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.

Annex II(B) (1)

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.	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 dossiers requirements must be in line with technical development.

Annex III(A) (1)

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.	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.

Annex III (B) (1)

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.	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.

Annex VI (51) introduction

51. Testing should be carried out according to European Union guide-lines if these are available and applicable. In the absence of these other methods can be used as shown in the list below which is in order of descending preference:	51. Testing should be carried out according to European Union guide-lines if these are available and applicable. Where appropriate other methods can be used as shown in the list below which is in order of descending preference:

Annex VI (59), 2nd subparagraph

In the case of active substances not on the market on the implementation date of the Directive only those substances listed in Annex I of the Directive can be used in biocidal products.	Deleted

Annex VI (80), introduction

80. The Member State shall not authorize 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 relevant metabolites or breakdown or reaction products in the groundwater exceeds the lower of the following concentrations:	80. The Member State shall not authorize 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 relevant metabolites or breakdown or reaction products in the surface water or groundwater exceeds the lower of the following concentrations:

Annex VI (86) new

86. The Member States shall not authorize a biocidal product where there is a reasonably foreseeable possibility of aquatic organisms being exposed to the biocidal product if for any active substance or substance of concern in it:	86. The Member States shall not authorize a biocidal product where there is a reasonably foreseeable possibility of aquatic organisms being exposed to the biocidal product if for any active substance or substance of concern in it:
- the PEC/PNEC> 1 unless it is clearly established in the risk assessment that under field conditions the viability of aquatic organisms is not threatened by the biocidal product according to the proposed conditions of use.	- the PEC/PNEC> 1 unless it is clearly established in the risk assessment that under field conditions the viability of aquatic organisms is not threatened by the biocidal product according to the proposed conditions of use.
- the bioconcentration factor (BCF) is greater than 1000 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 after use of the biocidal product according to the proposed conditions of use.	- the bioconcentration factor (BCF) is greater than 1000 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 after use of the biocidal product according to the proposed conditions of use. Member States may, however, authorize anti-fouling products used on sea going vessels of over 25 metres for a period of up to 10 years from the date on which this Directive enters into force. This provision shall lapse if appropriate IMO rules are adopted within that period.

ISSN 0254-1475

COM(96) 312 final

DOCUMENTS

EN 14 03 15

Catalogue number : CB-CO-96-320-EN-C

ISBN 92-78-05897-1

Office for Official Publications of the European Communities

L-2985 Luxembourg