



EUROPEAN PARLIAMENT

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Committee on the Environment, Public Health and Food Safety

2009/0076(COD)

1.2.2010

*****I**

DRAFT REPORT

on the proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products (COM(2009/0076(COD)) – C7-0036 – 2009/0076(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Christa Kläß

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- *** Assent procedure
*majority of Parliament's component Members except in cases
covered by Articles 105, 107, 161 and 300 of the EC Treaty and
Article 7 of the EU Treaty*
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on concerning the placing on the market and use of biocidal products (COM(2009/0076(COD)) – C7-0036 – 2009/0076(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2009)0267),
 - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C7-0036/2009),
 - having regard to the communication from the Commission to the European Parliament and the Council entitled: 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),
 - having regard to Article 294(3) and Article 114 of the Treaty on the Functioning of the EU,
 - having regard to the opinion of the Economic and Social Committee,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on the Internal Market and Consumer Protection and the Committee on Industry, Research and Energy (A7-0000/2010),
1. Adopts the position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, to the Commission and to the national parliaments.

Amendment 1

Proposal for a regulation Recital 21 a (new)

Text proposed by the Commission

Amendment

(21a) Given that the WHO Pesticide Evaluation Scheme (WHOPES) guarantees the effective testing and evaluation of the effects of insecticides on public health, compliance with the final recommendation recognised under such a scheme should be considered equivalent to product authorisation under this Regulation.

Or. de

Justification

To prevent unnecessary duplication of effort.

Amendment 2

Proposal for a regulation Recital 22

Text proposed by the Commission

Amendment

(22) To take account of the specific nature of some biocidal products and the low level of risk associated with their proposed use, and to encourage the development of biocidal products containing new active substances, it is appropriate to provide for a Community authorisation of those products.

deleted

Or. de

Justification

Consistency with the amendment to Article 33.

Amendment 3

Proposal for a regulation Recital 24

Text proposed by the Commission

(24) In order to facilitate access to the internal market and to avoid the additional costs and time involved in obtaining separate national authorisations in separate Member States, the Commission, **taking into account the experience with the provisions on Community authorisations, may decide to extend the scope of the Community authorisation procedure to other** biocidal products.

Amendment

(24) In order to facilitate access to the internal market and to avoid the additional costs and time involved in obtaining separate national authorisations in separate Member States, the Commission **has decided to introduce a** Community authorisation procedure **for all** biocidal products.

Or. de

Justification

Consistency with the amendment to Article 33.

Amendment 4

Proposal for a regulation Recital 48

Text proposed by the Commission

Applicants that have invested in supporting the inclusion of an active substance in Annex I or in the authorisation of a biocidal product in accordance with the provisions of this Regulation should be able to recover part of their investment by receiving equitable compensation whenever use of proprietary information which they submitted in support of such inclusions or authorisations is made for the benefit of subsequent applicants.

Amendment

Applicants that have invested in supporting the inclusion of an active substance in Annex I or in the authorisation of a biocidal product in accordance with the provisions of this Regulation **and/or in accordance with Directive 98/8/EC** should be able to recover part of their investment by receiving equitable compensation whenever use of proprietary information which they submitted in support of such inclusions or authorisations is made for the benefit of subsequent applicants.

Or. de

Justification

Applicants that have invested under the previous scheme should not be excluded.

Amendment 5

Proposal for a regulation

Recital 49

Text proposed by the Commission

(49) In view of ensuring that all proprietary information submitted in support of an inclusion of an active substance or an authorisation of a biocidal product is protected from the moment of its submission and to prevent situations where some information is without protection, the provision on information protection periods should also apply to information submitted for the purposes of Directive 98/8/EC.

Amendment

In view of ensuring that all proprietary information submitted in support of an inclusion of an active substance ***in Annex I*** or an authorisation of a biocidal product is protected from the moment of its submission and to prevent situations where some information is without protection, the provision on information protection periods should also apply to information submitted for the purposes of Directive 98/8/EC.

Or. de

Justification

Clarification.

Amendment 6

Proposal for a regulation

Recital 51

Text proposed by the Commission

(51) It is essential to minimise the number of tests on animals and to ensure that testing should be made dependent on the purpose and use of a product. Applicants should share, and not duplicate, vertebrate animal studies in exchange for equitable compensation. In absence of an agreement on sharing of vertebrate animal studies between the data owner and the prospective applicant, the Agency should allow the use of the studies by the

Amendment

(51) It is essential to minimise the number of tests on animals and to ensure that testing ***with biocidal products and/or active substances contained in biocidal products*** should be made dependent on the purpose and use of a product. Applicants should share, and not duplicate, vertebrate animal studies in exchange for equitable compensation. In absence of an agreement on sharing of vertebrate animal studies between the data owner and the

prospective applicant without prejudice to the decision on the compensation made by national courts. A Community register listing the contact details of the owners of such studies should be established and put at the disposal of all authorities to inform prospective applicants.

prospective applicant, the Agency should allow the use of the studies by the prospective applicant without prejudice to the decision on the compensation made by national courts. A Community register listing the contact details of the owners of such studies should be established and put at the disposal of all authorities to inform prospective applicants.

Or. de

Justification

To clarify that the exchange of data applies to data on active substances as well as products.

Amendment 7

Proposal for a regulation

Recital 61

Text proposed by the Commission

(61) In particular, the Commission should be empowered to adopt measures to decide on the application to include the active substance in Annex I or to renew or review the inclusion, to specify the procedures related to the renewal and review of an inclusion of an active substance in Annex I, ***to extend the provisions on Community authorisations to other categories of biocidal products***, to specify the criteria and procedures related to a cancellation of an authorisation or amendments of the terms and conditions of an authorisation, including a dispute settlement mechanism, to specify the overall applicable maximum quantities of active substances or biocidal products that may be released during experiments and the minimum data to be submitted, to establish a harmonised structure of fees and other rules concerning the payment of fees and charges to the competent authorities and the Agency, to adapt the Annexes to scientific and technical progress, to carry out the work

Amendment

(61) In particular, the Commission should be empowered to adopt measures to decide on the application to include the active substance in Annex I or to renew or review the inclusion, to specify the procedures related to the renewal and review of an inclusion of an active substance in Annex I, to specify the criteria and procedures related to a cancellation of an authorisation or amendments of the terms and conditions of an authorisation, including a dispute settlement mechanism, to specify the overall applicable maximum quantities of active substances or biocidal products that may be released during experiments and the minimum data to be submitted, to establish a harmonised structure of fees and other rules concerning the payment of fees and charges to the competent authorities and the Agency, to adapt the Annexes to scientific and technical progress, to carry out the work programme and to specify the related rights and obligations of the competent authorities

programme and to specify the related rights and obligations of the competent authorities and the participants in the programme and to extend the duration of the work programme for a determined period. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, inter alia, by supplementing this Regulation with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

and the participants in the programme and to extend the duration of the work programme for a determined period. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, inter alia, by supplementing this Regulation with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Or. de

Justification

Consistency with the amendment to Article 33.

Amendment 8

Proposal for a regulation

Recital 61 a (new)

Text proposed by the Commission

Amendment

(61a) The use of nanomaterials in biocidal products may increase with the further development of technology. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials at international level. The Union should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly. At present, there is inadequate information on the risks associated with nanomaterials. In order to better assess their safety the Scientific Committee for Consumer Safety (SCCS) should provide guidance in cooperation with relevant bodies on test methodologies

which take into account specific characteristics of nanomaterials. The Commission should regularly review the provisions on nanomaterials in the light of scientific progress.

Or. de

Amendment 9

Proposal for a regulation Recital 61 b (new)

Text proposed by the Commission

Amendment

(61b) In view of the environmental impact that anti-fouling products can have in the water, the Commission must take steps at international level to ensure that the AFS Convention (International Convention on the Control of Harmful Anti-Fouling Systems on Ships) is ratified worldwide and adapted to this Regulation.

Or. de

Amendment 10

Proposal for a regulation Article 1 - point 3 a (new)

Text proposed by the Commission

Amendment

(3a) The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market and use of biocidal products. The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans,

animals and the environment.

Or. de

Justification

The authorisation, marketing and use of biocidal products should be governed by the precautionary principle in order to ensure a high level of protection for human and animal health and to preserve living things.

Amendment 11

Proposal for a regulation

Article 2 - paragraph 2 - point k a (new)

Text proposed by the Commission

Amendment

(ka) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy;

Or. de

Amendment 12

Proposal for a regulation

Article 2 - paragraph 8 a (new)

Text proposed by the Commission

Amendment

(8a) Biocidal products covered by product type 18 manufactured in accordance with the final recommendation recognised under the WHO Pesticide Evaluation Scheme (WHOPES) shall be considered as authorised under Chapter VII of this Regulation. Articles 38 and 57 shall apply accordingly.

Or. de

Amendment 13

Proposal for a regulation

Article 3 - paragraph 1 - point a - subparagraph 1

Text proposed by the Commission

active substances or mixtures 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.

Amendment

active substances or mixtures containing one or more active substances, put up in the form in which they are supplied to the user, **primarily** 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.

Or. de

Justification

Clarification that treated materials and products with an external biocidal effect (e.g. treated mosquito nets) are biocidal products and must be authorised as such.

Amendment 14

Proposal for a regulation

Article 3 - paragraph 1 - point f

Text proposed by the Commission

(f) 'substance of concern' means 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 present risks of such an effect;

Amendment

(f) 'substance of concern' means 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 present risks of such an effect. ***Such a substance, unless there are other grounds for concern, would be normally a substance classified as dangerous according to Directive 67/548/EEC and present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Directive 1999/45/EC or Regulation (EC) No 1272/2008;***

Justification

This definition is already contained in Directive 98/8/EC and is inserted again for the sake of clarification.

Amendment 15**Proposal for a regulation****Article 3 - paragraph 1 - point k***Text proposed by the Commission*

(k) 'treated material or article' means any substance, mixture, material or article which was treated with or incorporates one or more biocidal products ***with the intention to protect the substance, mixture, material or article from deterioration caused by harmful organisms;***

Amendment

(k) 'treated material or article' means any substance, mixture, material or article which was treated with or incorporates one or more biocidal products;

Justification

The German translation of the English word 'article' is brought into line with Article 3(3) of the Reach Regulation No 1907/2006. The definition expands the scope of treated articles or materials to include articles with an external effect, such as mosquito nets, as well as products such as paint that are conserved in this way. The evaluation is made in relation to the chemical.

Amendment 16**Proposal for a regulation****Article 3 - paragraph 1 - point n***Text proposed by the Commission*

(n) 'authorisation' means national authorisation ***or*** Community authorisation;

Amendment

(n) 'authorisation' means national authorisation, Community authorisation, ***primary authorisation, duplicate authorisation or supplementary authorisation;***

Justification

The definitions need to be expanded in view of the new concepts 'primary authorisation', 'duplicate authorisation' and 'supplementary authorisation' introduced in Articles 18, 37(a) (new), 37(b) (new), 39, 40 and 41.

Amendment 17

Proposal for a regulation

Article 3 - paragraph 1 - point n a (new)

Text proposed by the Commission

Amendment

(na) 'primary authorisation' means an administrative act carried out in accordance with Article 23 or Article 35.

Or. de

Amendment 18

Proposal for a regulation

Article 3 - paragraph 1 - point n b (new)

Text proposed by the Commission

Amendment

(nb) 'duplicate authorisation' means an administrative act by which a Member State or the Commission authorises the placing on the market and the use of the same biocidal product under a different trade name for the benefit of the primary authorisation holder;

Or. de

Amendment 19

Proposal for a regulation

Article 3 - paragraph 1 - point n c (new)

Text proposed by the Commission

Amendment

(nc) 'supplementary authorisation' means

an administrative act by which a Member State or the Commission authorises the placing on the market and the use of a biocidal product under a different trade name on the basis of a primary authorisation and with the agreement of the primary authorisation holder;

Or. de

Amendment 20

Proposal for a regulation Article 3 - paragraph 1 - point p

Text proposed by the Commission

(p) 'frame formulation' means a group of biocidal products having similar uses and presenting **limited** variations in their composition with regard to a reference biocidal product belonging to that group which contains the same active substances of the same specifications where **such permitted variations do not adversely affect the level of risk or the efficacy of these products;**

Amendment

(p) 'frame formulation' means a group of biocidal products having similar uses and presenting variations in their composition with regard to a reference biocidal product belonging to that group which contains the same active substances of the same specifications where the risk **with regard to the reference biocidal product does not increase despite the variations and the stated efficacy in relation to the target organisms is guaranteed;**

Or. de

Justification

The deciding factor is that the risk with regard to the reference biocidal product does not increase and the stated efficacy in relation to the target organisms is still guaranteed.

Amendment 21

Proposal for a regulation Article 3 - paragraph 1 - point q

Text proposed by the Commission

(q) 'letter of access' means an original document, signed by the owner or owners of information, which states that the

Amendment

(q) 'letter of access' means an original document, signed by the owner or owners of information **or their authorised**

information may be used by the competent **authorities**, the European Chemicals Agency, or the Commission for the purpose of evaluating an active substance or granting an authorisation;

representative, which states that the information may be used by the **designated** competent **authority**, the European Chemicals Agency, or the Commission for the purpose of evaluating an active substance or granting an authorisation **for the benefit of a third party**;

Or. de

Justification

The definition of 'letter of access' in the Commission proposal is not sufficiently precise.

Amendment 22

Proposal for a regulation

Article 3 - paragraph 1 - point u a (new)

Text proposed by the Commission

Amendment

(ua) 'nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain at least one of the following properties that are characteristic to the nanoscale:
(i) properties related to the large specific surface area of the materials considered;
(ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material.

Or. de

Amendment 23

Proposal for a regulation

Article 3 - paragraph 1 - point u b (new)

Text proposed by the Commission

Amendment

(ub) 'manufacturer' means:

- in the case of an active substance produced within the Union and placed on the market, the manufacturer of that active substance or a person established within the Union designated by the manufacturer as his sole representative for the purposes of this Regulation,***
- in the case of an active substance produced outside the Union, the person established within the Union and designated by the manufacturer of that active substance as his sole representative for the purposes of this Regulation or, where no such person has been so designated, the importer into the Union of that active substance,***
- in the case of a biocidal product produced outside the Union, the person established within the Union and designated by the manufacturer of that biocidal product as his sole representative for the purposes of this Regulation or, where no such person has been so designated, the importer into the Union of that biocidal product;***

Or. de

Justification

The new wording of Article 83 means that a definition of 'manufacturer' is required. This definition is identical to Commission Regulation (EC) No 1896/2000 of 7 September 2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products.

Amendment 24

Proposal for a regulation

Article 3 - paragraph 1 - point u c (new)

Text proposed by the Commission

Amendment

(uc) 'professional user' means any natural or legal person who carries out the use of biocides in the framework of his professional activity.

Or. de

Amendment 25

Proposal for a regulation

Article 4 - paragraph 3 - introductory phrase

Text proposed by the Commission

Amendment

(3) An active substance shall, where appropriate, be included in Annex I together with any of the following conditions:

(3) An active substance and the definition of the reference source for the active substance for the purposes of determining technical equivalence as defined in Article 3(1)(u) shall, where appropriate, be included in Annex I together with any of the following conditions:

Or. de

Justification

It is important to establish a connection between the active substance described in Annex I and the data on the basis of which it was incorporated into that annex. Moreover, isomer composition is significant in order to distinguish its chemical identity.

Amendment 26

Proposal for a regulation

Article 4 - paragraph 3 - point e a (new)

Commission proposal

Amendment

(ea) characterisation of the chemical identity with regard to stereoisomers;

Justification

It is important to create a link between the active substance listed in Annex I and the data supporting its inclusion in Annex I. Furthermore, the isomer composition, as distinct from the chemical identity, is important.

Amendment 27**Proposal for a regulation
Article 5 - paragraph 1***Commission proposal*

(1) *Notwithstanding Article 4(1), active substances referred to in paragraph 2 shall be included in Annex I only if at least one of the following conditions is met:*

(a) *the exposure of humans to that active substance in a biocidal product, under normal conditions of use, is negligible, in particular where the product is used in closed systems or strictly controlled conditions;*

(b) *it is shown that the active substance is necessary to control a serious danger to public health;*

(c) *it is shown that not including the active substance in Annex I would cause disproportionate negative impacts when compared with the risk to human health or the environment arising from the use of the substance and that there are no suitable alternative substances or technologies.*

Amendment

(1) *The following active substances shall not be included in Annex I:*

(a) *active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogenic category 1A or 1B;*

(b) *active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagenic category 1A or 1B;*

(c) *active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;*

(d) *active substances identified under Article 57(f) of Regulation (EC) No 1907/2006 as having endocrine-disrupting properties. Until 30 June 2015, the Commission shall, by means of delegated acts in accordance with Articles XY, adopt measures on specific scientific criteria for*

determining endocrine-disrupting properties. Pending the adoption of these criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine-disrupting properties. In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.

*(e) active substances that are persistent, bio-accumulative and toxic;
(f) active substances that are very persistent and very bio-accumulative;
(g) persistent organic pollutants (POP) under Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants¹.*

Point (c) shall not apply to active substances for product types 4 and 14 to 19.

¹ OJ L 229, 29.6.2004, p. 5.

Or. de

(repositioning and amending Article 5(2))

Justification

The exclusion criteria should comply with the precautionary principle.

Amendment 28

Proposal for a regulation Article 5 - paragraph 2

Commission proposal

2. **The following** active substances **shall** be included in Annex I **where** at least one of the conditions **set out in paragraph 1** is met:

(a) **active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meets the criteria to be classified as, carcinogen category 1A or 1B;**

(b) **active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;**

(c) **active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;**

(d) **active substances identified under Article 57(f) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties.**

Amendment

2. **Notwithstanding Article 4(1)**, active substances **referred to in paragraph 2 may** be included in Annex I **if** at least one of the **following** conditions is met:

(a) **the exposure of humans or the environment to that active substance in a biocidal product, under normal conditions of use, is negligible, in particular where the product is used in closed systems or strictly controlled conditions;**

(b) **it is shown that the active substance is necessary to control a serious danger to public health or to the environment;**

(c) **it is shown that not including the active substance in Annex I would cause disproportionate negative impacts when compared with the risk to human health or the environment arising from the use of the substance and that there are no suitable alternative substances or technologies.**

Point (c) shall not apply to active substances for product types 4 and 14 to 19.

Or. de

(repositioning and amending Article 5(1))

Amendment 29

Proposal for a regulation Article 5 a (new)

Commission proposal

Amendment

- 1. Each prospective applicant for inclusion of an active substance in Annex I should ask the Agency whether:**
 - an application for inclusion in Annex I has already been submitted for the same active substance;**
 - the same active substance has been included in Annex I;**
 - the same substance is registered in accordance with Regulation (EC) No 1907/2006.**
- 2. Each potential applicant should provide the following information when making enquiries of the Agency:**
 - (a) information on the applicant's identity as laid down in section 1 of Annex VI to Regulation (EC) No 1907/2006, with the exception of 1.2 and 1.3;**
 - (b) information on the identity of the active substance, as laid down in section 2 of Annex VI to Regulation (EC) No 1907/2006;**
 - (c) what data requirements have been set for new vertebrate animal studies that it would have to carry out;**
 - (d) what data requirements have been set for other new studies that it would have to carry out.**
- 3. If the same active substance is not included in Annex I or not registered in accordance with Regulation (EC) No 1907/2006, the Agency shall inform the prospective applicant accordingly.**
- 4. If an application for inclusion for the same active substance in Annex I has already been submitted or if the same active substance has already been included in Annex I or registered in accordance with Regulation (EC) No 1907/2006, the Agency shall inform the prospective applicant immediately of the**

names and addresses of the former applicants and registrants and about the relevant study summaries or robust study summaries, if these have already been submitted.

5. At the same time, the Agency shall inform the former applicants or registrants of the names and addresses of the prospective applicant for an inclusion in Annex I. The available vertebrate animal studies shall be shared with the prospective applicant in accordance with Chapter XI of this Regulation.

Or. de

Justification

In order to avoid a repetition of vertebrate animal studies and to meet the data requirements of Annex II, a procedure of this kind is necessary. The 'requirement to ask' was taken from REACH, as the Agency will have the necessary technical conditions and the expertise to carry out this procedure.

Amendment 30

Proposal for a regulation
Article 6 - paragraph 1 - point a

Commission proposal

(a) a dossier for the active substance satisfying the requirements set out in Annex II;

Amendment

(a) a dossier, **or a letter of access to a dossier**, for the active substance satisfying the requirements set out in Annex II;

Or. de

Justification

It is possible that the applicants will not own the data required to support an application.

Amendment 31

Proposal for a regulation

Article 6 - paragraph 1- point b

Commission proposal

(b) a dossier for at least one representative biocidal product that contains the active substance satisfying the requirements set out in Annex III.

Amendment

(b) a dossier **or a letter of access** for at least one representative biocidal product that contains the active substance satisfying the requirements set out in Annex III.

Or. de

Justification

It is possible that the applicants will not own the data required to support an application.

Amendment 32

Proposal for a regulation

Article 7 - paragraph 1 a (new)

Commission proposal

Amendment

1a. The Agency shall provide a submission number to be used in all correspondence relating to the application until the active substance is included in Annex I, and a submission date, which shall be the date on which the application is received by the Agency.

Or. de

Justification

In addition to a reference to the name of the manufacturer in inclusions of active substances in Annex I, including individual information is another appropriate and effective means of avoiding free-riding and helps manufacturers to recoup their investments. It also contributes to transparency and facilitates data sharing.

Amendment 33

Proposal for a regulation

Article 7 - paragraph 3 - introduction

Commission proposal

3. Within **two months** after the receipt of an application, the Agency shall validate the application if it complies with the following requirements:

Amendment

3. Within **three weeks** after the receipt of an application, the Agency shall validate the application if it complies with the following requirements:

Or. de

Justification

The Agency should observe the same timeframes for the validation of applications as those introduced under REACH (Article 20). Extra time can be provided to enter all data in the Community register. This should not, however, delay the process of evaluating the application.

Amendment 34

Proposal for a regulation

Article 7 - paragraph 4 - subparagraph 2

Commission proposal

The Agency shall, within **two months** after the receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

Amendment

The Agency shall, within **three weeks** after the receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

Or. de

Justification

The Agency should observe the same timeframes for the validation of applications as those introduced under REACH (Article 20). Extra time can be provided to enter all data in the Community register. This should not, however, delay the process of evaluating the application.

Amendment 35

Proposal for a regulation

Article 7 - paragraph 4 - subparagraph 3 a (new)

Commission proposal

Amendment

3a. Within two months of receiving the application, the Agency shall assign a unique identification code to all the information in the dossier.

Or. de

Justification

The Agency should observe the same timeframes for the validation of applications as those introduced under REACH (Article 20). Extra time can be provided to enter all data in the Community register. This should not, however, delay the process of evaluating the application.

Amendment 36

Proposal for a regulation

Article 8 - paragraph 5

Commission proposal

Amendment

5. On receipt of the opinion of the Agency, the Commission shall adopt a decision on the application to include the active substance in Annex I. That decision, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).

5. On receipt of the opinion of the Agency, the Commission shall adopt a decision on the application to include the active substance in Annex I. That decision, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4). ***If the Commission decides to include the substance in Annex I, the names of the applicants shall be given.***

Or. de

Justification

A reference to the manufacturer's name in the inclusion of an active substance in Annex I is an appropriate and effective means of avoiding free-riding, as it allows for quick identification of the manufacturer that supported the active substance. Only those

manufacturers may produce letters of access to the dossier for the active substance.

Amendment 37

Proposal for a regulation

Article 8 - paragraph 5 a (new)

Commission proposal

Amendment

5a. When considering whether to include an active substance in Annex I, the Agency shall assign the active substance in question an inclusion number that is specific to the substance and to the applicant. The Agency shall inform the applicant in question of the inclusion number and the inclusion date immediately. The inclusion number shall be used for all subsequent correspondence concerning the active substance and for the product authorisation in accordance with Chapter IV of this Regulation.

Or. de

Justification

A reference to the manufacturer's name in the inclusion of an active substance in Annex I is an appropriate and effective means of avoiding free-riding, as it allows for quick identification of the manufacturer that supported the active substance. Only those manufacturers may produce letters of access to the dossier for the active substance.

Amendment 38

Proposal for a regulation

Article 12 - paragraph 5

Commission proposal

Amendment

5. At the end of the period referred to in paragraph 3 or on receipt of the opinion of the Agency, the Commission shall adopt a decision concerning a renewal of the inclusion of the active substance in Annex I. That decision, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in

5. At the end of the period referred to in paragraph 3 or on receipt of the opinion of the Agency, the Commission shall adopt a decision concerning a renewal of the inclusion of the active substance in Annex I. That decision, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in

accordance with the regulatory procedure with scrutiny referred to in Article 72(4).

accordance with the regulatory procedure with scrutiny referred to in Article 72(4). ***If the Commission decides to renew the inclusion of an active substance in Annex I, the name of the applicant shall be mentioned.***

Or. de

Justification

A reference to the manufacturer's name in the inclusion of an active substance in Annex I that is an appropriate and effective instrument for avoiding free-riding, as it allows for quick identification of the manufacturer that supported the active substance and reduces the administrative burden.

Amendment 39

Proposal for a regulation

Article 13 - paragraph 1 - subparagraph 1

Commission proposal

1. The Commission may review the inclusion of an active substance in Annex I at any time where there are serious indications that the requirements referred to in Article 4 are no longer complied with. Where those indications are confirmed, the Commission shall adopt a decision amending the inclusion of an active substance in Annex I or removing it from that Annex.

Amendment

1. The Commission may review the inclusion of an active substance in Annex I at any time where there are serious indications that the requirements referred to in Article 4 are no longer complied with. ***It shall review inclusion also in cases where there are indications that the objectives of Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy¹ may not be achieved.*** Where those indications are confirmed, the Commission shall adopt a decision amending the inclusion of an active substance in Annex I or removing it from that Annex.

¹ OJ L 327, 22.12.2000, p. 1.

Or. de

Justification

Reference to the Water Framework Directive.

Amendment 40

Proposal for a regulation Article 15 - paragraph 2 - subparagraph 2

Commission proposal

Amendment

Application for national authorisation in a Member State shall be submitted to the competent authority of that Member State (hereinafter referred to as 'the receiving competent authority').

deleted

Or. de

Justification

For consistency with the amendment to Article 33.

Amendment 41

Proposal for a regulation Article 15 - paragraph 2 - subparagraph 3

Commission proposal

Amendment

Application for Community authorisation shall be submitted to the Agency.

Application for Community authorisation shall be submitted to the Agency. ***The applicant may, with the prior agreement of a Member State, allow that Member State to carry out the review; in such cases it shall inform the Agency of the name of the evaluating competent authority as defined in Article 22.***

Or. de

Justification

For consistency with the amendment to Article 33.

Amendment 42

Proposal for a regulation

Article 16 - paragraph 1 - point a

Commission proposal

(a) the active substances included therein are listed in Annex I and any conditions included in that Annex together with those active substances are complied with;

Amendment

(a) the active substances included therein are listed in Annex I, ***an inclusion number has been assigned in accordance with Article 8(5a)***, and any conditions included in that Annex together with those active substances are complied with;

Or. de

Justification

For consistency with the evaluation procedure in Article 8(5a).

Amendment 43

Proposal for a regulation

Article 16 - paragraph 1 - point c

Commission proposal

(c) the ***nature***, the quantity and the technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant impurities and non-active substances, and its residues of toxicological or environmental significance, which result from uses to be authorised, can be determined according to the relevant requirements in Annexes II and III;

Amendment

(c) the ***chemical identity***, the quantity and the technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant impurities and non-active substances, and its residues of toxicological or environmental significance, which result from uses to be authorised, can be determined according to the relevant requirements in Annexes II and III;

Or. de

Justification

The word 'nature' is not defined clearly enough. 'Chemical identity' seems to describe the active substance better.

Amendment 44

Proposal for a regulation

Article 16 - paragraph 1 - point d a (new)

Commission proposal

Amendment

(da) when using nanomaterials in biocidal products, the risk to the environment and to health has been reviewed separately.

Or. de

Justification

Nanomaterials have different characteristics to the same substances in a non-nanomaterial form. The risks posed by biocides with nanomaterials must therefore be investigated separately.

Amendment 45

Proposal for a regulation

Article 16 - paragraph 2 a (new)

Commission proposal

Amendment

2a. When evaluating whether the criteria in paragraph 1(b) have been fulfilled, information should whenever possible be derived from information already available on the substance of concern contained in the biocidal product, in order to keep tests on animals to a minimum. In particular, the provisions of Directive 1999/45/EC or Regulation (EC) No 1272/2008 should wherever possible be applied for the purpose of ascertaining the adverse effects of the biocidal product and for the subsequent risk assessment.

Or. de

Justification

Avoidance of unnecessary tests on vertebrates. Adaptation to the rules on concentration limits for a chemical safety report.

Amendment 46

Proposal for a regulation

Article 16 - paragraph 2 - point 2 b (new)

Commission proposal

Amendment

2b. The evaluation of whether the biocidal product fulfils the criteria in paragraph 1(b) and (c) need not be carried out for a substance that is a component of the biocidal product if the concentration of the substance in the biocidal product is lower than the lowest value referred to in Article 14(2)(a) to (f) of Regulation (EC) No 1907/2006.

Or. de

Justification

Avoidance of unnecessary tests on vertebrates. Adaptation to the rules on concentration limits for a chemical safety report.

Amendment 47

Proposal for a regulation

Article 16 - paragraph 6

Commission proposal

Amendment

6. In the case of a frame formulation, a ***reduction in the percentage of the active substance in the reference biocidal product may be allowed, and/or an alteration in percentage composition of one or more non-active substances, and/or the replacement of one or more non-active substances by others presenting the same or lower risk.***

6. In the case of a frame formulation, ***the following variations in composition with regard to a reference biocidal product are possible:***

- (a) authorisation of an active substance in a reference biocidal product with at least two active substances;***
- (b) a reduction in the percentage of the active substances;***
- (c) authorisation of one or more non-active substances;***

*(d) alteration in percentage composition of one or more non-active substances;
(e) the replacement of one or more non-active substances.*

Or. de

Justification

A biocidal product may contain more than one active substance.

Amendment 48

**Proposal for a regulation
Article 16 - paragraph 6 a (new)**

Commission proposal

Amendment

6a. The Commission should, in accordance with the procedure set out in Article 72(2), provide technical and scientific guidance for product authorisation, with particular regard to harmonised data requirements, evaluation procedures and decisions by the Member States.

Or. de

Justification

This guarantees uniform implementation of the Regulation.

Amendment 49

**Proposal for a regulation
Article 18 - paragraph 1 - introduction**

Commission proposal

Amendment

1. The applicant for ***an*** authorisation shall submit the following documents together with the application:

1. The applicant for ***a primary*** authorisation shall submit the following documents together with the application:

Or. de

Justification

For consistency with the evaluation procedure in Article 8(5a). Low-risk products that are based on active substances included in Annex I or that are being evaluated with a view to inclusion in Annex I should require access to the data for the active substance. Property and data protection for active substances that have been included in Annex I should not be undermined.

Amendment 50

Proposal for a regulation

Article 18 - paragraph 1 - point c

Commission proposal

(c) for other than low-risk biocidal products, a dossier or a letter of access to a dossier satisfying the requirements set out in Annex II for each active substance in the biocidal product;

Amendment

(c) for other than low-risk biocidal products, a dossier or a letter of access to a dossier satisfying the requirements set out in Annex II for each active substance in the biocidal product ***and the inclusion number assigned in accordance with Article 8(5a)***;

Or. de

Justification

For consistency with the evaluation procedure in Article 8(5a). Low-risk products that are based on active substances included in Annex I or that are being evaluated with a view to inclusion in Annex I should require access to the data for the active substance. Property and data protection for active substances that have been included in Annex I should not be undermined.

Amendment 51

Proposal for a regulation

Article 18 - paragraph 1 - point d a (new)

Commission proposal

Amendment

(da) if the low-risk active substance contained in the biocidal product has been included in Annex I, it shall also be necessary to provide the relevant inclusion number. An access letter must be submitted if the appropriate periods of protection of information according to

Article 49 have not expired.

Or. de

Justification

For consistency with the evaluation procedure in Article 8(5a). Low-risk products that are based on active substances included in Annex I or that are being evaluated with a view to inclusion in Annex I should require access to the data for the active substance. Property and data protection for active substances that have been included in Annex I should not be undermined.

Amendment 52

**Proposal for a regulation
Article 18 - paragraph 2**

Commission proposal

2. The application for authorisation shall be accompanied by the fees payable under Article 70.

Amendment

2. The application for **primary** authorisation shall be accompanied by the fees payable under Article 70.

Or. de

Justification

The new terms ‘primary authorisation’, ‘duplicate authorisation’ and ‘supplementary application’ require a broadening of the definitions.

Amendment 53

**Proposal for a regulation
Article 18 - paragraph 3**

Commission proposal

3. The **receiving competent authority** may require that applications for a national authorisation be submitted in **one or more of the** official **languages** of the Member State where **that** competent authority is situated.

Amendment

3. The **Agency** may require that applications for a national authorisation be submitted in **an** official **language** of the Member State where **the** competent authority is situated.

Or. de

Justification

If all applications are submitted to and validated by the ECHA, the Agency will be the only receiving competent authority. One official language of the Member State should be sufficient. Any further references in the Commission proposal to the receiving competent authority should be replaced by references to the Agency.

Amendment 54

Proposal for a regulation Article 18 - paragraph 5

Commission proposal

5. The Commission, in accordance with the procedure referred to in Article 72(2), shall draw up technical notes for guidance to facilitate the implementation of point (d) of paragraph 1. The technical notes shall be published in the ‘C’ series of the Official Journal of the European Union.

Amendment

5. The Commission, in accordance with the procedure referred to in Article 72(2), shall draw up technical notes for guidance to facilitate the implementation of point (d) of paragraph 1. ***The Commission should, in accordance with the procedure set out in Article 72(2), provide technical and scientific guidance and tools, in particular to support applications for authorisation under Articles 18, 19 and 20, above all for SMEs.*** The technical notes shall be published in the ‘C’ series of the Official Journal of the European Union.

Or. de

Justification

This acknowledges the fact that advice and guidance for SMEs from the Commission are of particular value, as SMEs may not have the resources and expertise necessary to comply with this Regulation.

Amendment 55

Proposal for a regulation Article 20 - paragraph 2 - point e

Commission proposal

(e) qualitative and quantitative composition in terms of the active substances and non-active substances, ***knowledge of which is***

Amendment

(e) qualitative and quantitative composition in terms of the active substances and non-active substances, ***taking account of the***

essential for proper use of the biocidal product;

concentration limits in Article 16(2b) (new) and in so far as this information is required for proper use of the biocidal product;

Or. de

Justification

A restriction should help minimise the disclosure of confidential information.

Amendment 56

**Proposal for a regulation
Article 20 - paragraph 2 - point g**

Commission proposal

(g) manufacturers of the active substances (names and addresses including location of *manufacturing sites*);

Amendment

(g) manufacturers of the active substances (names and addresses including location of *the manufacturers*) *and the inclusion number of the substance in accordance with Article 8(5a)*;

Or. de

Justification

Provided the manufacturer of the active substance is authorised in accordance with the inclusion in Annex I, the location of manufacture should be confidential and not necessary as part of the authorisation of the biocidal product. For consistency with the evaluation procedure in Article 8(5a).

Amendment 57

**Proposal for a regulation
Article 22 - paragraph 1**

Commission proposal

1. *Within one month after the receipt of an application for a national authorisation referred to in Article 15, the receiving competent authority shall validate the application if it complies with the following requirements:*

Amendment

1. *The person responsible for the placing of a biocidal product on the market, or his representative, shall submit an application for a national or Community authorisation to the Agency and inform the Agency of the name of the competent*

(a) the information referred to in Article 18 has been submitted;

(b) it is accompanied by the fees payable under Article 70.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

authority of the Member State of his choice which shall be responsible for the evaluation of the application (hereinafter referred to as 'the evaluating competent authority'). The Agency shall, within three weeks after the receipt of the application, notify the evaluating competent authority that the application is available in the Agency database.

Or. de

Justification

The ECHA should carry out the initial validation of all applications throughout the Union, so that the evaluating competent authorities can concentrate on actual assessment of the applications. Currently, where the evaluating competent authorities consider both the administrative and the scientific aspects of applications, there have been inconsistencies in their approach. The Agency should observe the same timeframes for the validation of applications as those introduced under REACH (Article 20).

Amendment 58

Proposal for a regulation Article 22 – paragraph 2

Text proposed by the Commission

(2) If the receiving competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. The receiving competent authority shall, within one month from the receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application. The receiving competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and inform the applicant thereof.

Amendment

*(2) Within three weeks after the receipt of an application, the Agency shall validate the application if it complies with the following requirements:
(a) the information referred to in Article 18 has been submitted;
(b) it is accompanied by the fees payable under Article 70. The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.*

Justification

ECHA should carry out the initial validation of all applications throughout the Community, so that the evaluating competent authorities can concentrate on the actual evaluation of applications. Currently, where evaluating competent authorities consider both the administrative and the scientific aspects of applications, there have been inconsistencies in their approach. The Agency should observe the same timeframes for the validation of applications as those introduced under REACH (Article 20).

Amendment 59**Proposal for a regulation
Article 22 – paragraph 3***Text proposed by the Commission*

(3) If the receiving competent authority, on basis of the validation made pursuant to paragraph 1, considers that the application is complete, it shall without delay inform the applicant thereof.

Amendment

(3) If the Agency considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. The Agency shall, within three weeks after the receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application. The Agency shall reject the application if the applicant does not submit the required additional information on time, and shall notify the applicant and the evaluating competent authority of the rejection. In such cases, part of the fees payable to the Agency under Article 70 shall be reimbursed.

Justification

ECHA should carry out the initial validation of all applications throughout the Community, so that the evaluating competent authorities can concentrate on the actual evaluation of applications. Currently, where the evaluating competent authorities consider both the administrative and the scientific aspects of applications, there have been inconsistencies in

their approach. The Agency should observe the same timeframes for the validation of applications as those introduced under REACH (Article 20).

Amendment 60

Proposal for a regulation

Article 22 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

(3a) An appeal may be brought, in accordance with Article 67, against Agency decisions under the third subparagraph of paragraph 3.

Or. de

Justification

ECHA should carry out the initial validation of all applications throughout the Community, so that the evaluating competent authorities can concentrate on the actual evaluation of applications. Currently, where the evaluating competent authorities consider both the administrative and the scientific aspects of applications, there have been inconsistencies in their approach.

The Agency should observe the same timeframes for the validation of applications as those introduced under REACH (Article 20).

Amendment 61

Proposal for a regulation

Article 22 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

(3b) If the Agency, on the basis of the validation made pursuant to paragraph 2, considers that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

Or. de

Justification

ECHA should carry out the initial validation of all applications throughout the Community, so that the evaluating competent authorities can concentrate on the actual evaluation of

applications. Currently, where the evaluating competent authorities consider both the administrative and the scientific aspects of applications, there have been inconsistencies in their approach.

The Agency should observe the same timeframes for the validation of applications as those introduced under REACH (Article 20).

Amendment 62

Proposal for a regulation

Article 23 – paragraph 2a (new)

Text proposed by the Commission

Amendment

(2a) If a substance contained in a biocidal product has already been registered for use in a biocidal product in accordance with Regulation (EC) No 1907/2006, the evaluating competent authority shall not re-evaluate it.

Or. de

Justification

Avoidance of unnecessary duplication.

Amendment 63

Proposal for a regulation

Article 33 – paragraph 1

Text proposed by the Commission

Amendment

(1) The Community authorisation may be granted to ***the following categories of biocidal products:***

- (a) biocidal products containing one or more new active substances;***
- (b) low-risk biocidal products.***

(1) The Community authorisation may be granted to ***all biocidal products with substantially similar patterns and conditions of use.***

Or. de

Justification

It should be possible to obtain the Community authorisation for all types of product, i.e.

including products that contain only existing active substances. On the one hand, administrative expenditure by both applicants and Member States would be substantially reduced. On the other, extending the system in this way would not overburden it because the inclusion of active substances in Annex I is linked to the review programme.

Amendment 64

Proposal for a regulation Article 33 – paragraph 2

Text proposed by the Commission

Amendment

(2) Following the report of the Commission on the implementation of this Regulation referred to in Article 54(4) and in light of the experience gained with the Community authorisations, the Commission may add other categories of biocidal products in paragraph 1 of this Article.

deleted

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted according to the regulatory procedure with scrutiny referred to in Article 72(4).

Or. de

Justification

It should be possible to obtain the Community authorisation for all types of product, i.e. including products that contain only existing active substances. On the one hand, administrative expenditure by both applicants and Member States would be substantially reduced. On the other, extending the system in this way would not overburden it because the inclusion of active substances in Annex I is linked to the review programme.

Amendment 65

Proposal for a regulation Article 34

Text proposed by the Commission

Amendment

Article 34

deleted

Submission and validation of applications

(1) The person responsible for the placing of a biocidal product on the market, or his representative, shall submit an application for a Community authorisation to the Agency and inform the Agency of the name of the competent authority of the Member State of his choice which shall be responsible for the evaluation of the application (hereinafter referred to as 'the evaluating competent authority'). The Agency shall, within one month after the receipt of the application, notify the evaluating competent authority that the application is available in the Agency database.

(2) Within two months after the receipt of an application, the Agency shall validate the application if it complies with the following requirements: (a) the information referred to in Article 18 has been submitted; (b) it is accompanied by the fees payable under Article 70. The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

(3) If the Agency considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. The Agency shall, within two months from the receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application. The Agency shall reject the application if the applicant does not submit the required additional information on time, and shall notify the applicant and the evaluating competent authority of the rejection. In such cases, part of the fees payable to the Agency under Article 70 shall be reimbursed.

(4) An appeal may be brought, in

accordance with Article 67, against Agency decisions under the third subparagraph of paragraph 3.

(5) If the Agency, on basis of the validation made pursuant to paragraph 2, considers that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

Or. de

Justification

The new Article 22 provides that the same rules on submission and validation of applications shall apply to both national and Community authorisation. Article 34 of the proposal thus becomes redundant.

Amendment 66

Proposal for a regulation

Article 35 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

(1a) If a substance contained in a biocidal product has already been registered for use in a biocidal product in accordance with Regulation (EC) No 1907/2006, the evaluating competent authority shall not re-evaluate it.

Or. de

Justification

Avoidance of unnecessary duplication.

Amendment 67

Proposal for a regulation

Article 35 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Amendment

(3) Within **nine** months from the receipt of the conclusions of the evaluation, the

(3) Within **three** months from the receipt of the conclusions of the evaluation, the

Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product.

Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product.

Or. de

Justification

Nine months is much too long a time to allow for the Agency to prepare and submit an opinion, given that opinions are prepared on the basis of existing evaluations carried out by the evaluating authority. Three months would be a more suitable period.

Amendment 68

**Proposal for a regulation
Article 37 a (new)**

Text proposed by the Commission

Amendment

Article 37a

Duplicate authorisations

(1) Holders of a primary authorisation or applicants for a primary authorisation may apply to the Agency for a duplicate authorisation in respect of the same biocidal product.

2. Applicants for a duplicate authorisation shall submit the following information and documentation with the application:

(a) the authorisation number of the primary authorisation or, if primary authorisation is pending, the application number;

(b) the trade name of the biocidal product;

(c) the qualitative und quantitative composition including both active and inactive substances, taking account of the concentration limits in accordance with Article 16(2)(b)(new) and in so far as this information is of basic importance for proper use of the biocidal product;

(d) application doses and instructions for use;

(e) the categories of users.

3. The Agency shall validate the application in accordance with Article 22.

4. If the Agency considers, on the basis of a validation carried out in accordance with paragraph 3, that the application is complete, it shall, without delay, inform the applicant, the evaluating competent authority that issued the primary authorisation, or – where the application is for duplication of a Community authorisation – the Commission, to that effect.

5. In the case of an existing primary authorisation, the evaluating competent authority, or, in the case of duplication of a Community authorisation, the Commission shall take a decision on the application within one month after the validation. In the case of a pending primary authorisation, the evaluating competent authority, or, in the case of duplication of a Community authorisation, the Commission shall take a decision on the application within one month after the issue of the primary authorisation.

Or. de

Justification

In some EU Member States the generally current authorisation practice is to permit and facilitate marketing of the same products under different trade names and by different companies through a system of different types of authorisation. Because the nature of duplicate and supplementary authorisations is purely administrative and technical, there is no need for a re-evaluation of effects on human health or the environment.

Amendment 69

Proposal for a regulation

Article 37 b (new)

Text proposed by the Commission

Amendment

Article 37b

Supplementary authorisations

(1) A supplementary authorisation may be issued on the basis of a primary authorisation.

(2) When applying for a supplementary authorisation, the applicant shall submit the application to the Agency.

(3) Applicants for a supplementary authorisation shall submit the following information and documentation with their application:

(a) the authorisation number of the primary authorisation or, if primary authorisation is pending, the application number;

(b) the name and address of the applicant;

(c) the primary authorisation holder's agreement in writing;

(d) the qualitative and quantitative composition including both active and inactive substances, taking account of the concentration limits in accordance with Article 16(2)(b)(new) and in so far as this information is of basic importance for proper use of the biocidal product;

(e) application doses and instructions for use;

(f) the categories of users.

(4) The Agency shall validate the application in accordance with Article 22.

(5) If the Agency considers, on the basis of a validation carried out in accordance with paragraph 4, that the application is complete, it shall, without delay, inform the applicant, the evaluating competent authority that issued the primary authorisation, or – where the application is for an authorisation supplementary to a Community authorisation – the Commission, to that effect.

(6) In the case of an existing primary authorisation, the evaluating competent authority, or, in the case of an authorisation supplementary to a Community authorisation, the Commission shall take a decision on the application within one month after the validation. In the case of a pending primary authorisation, the evaluating competent authority, or, in the case of an authorisation supplementary to a

Community authorisation, the Commission shall take a decision on the application within one month after the issue of the primary authorisation.

(7) Should additional information prove necessary for evaluating the similarity of a biocidal product, the evaluating competent authority, or – in the case of an authorisation supplementary to a Community authorisation – the Commission, shall request the applicant to submit it. The time period of one month, referred to in paragraph 6, shall be suspended from the day on which the request is made until the day on which the information is received.

(8) As soon as the evaluating competent authority, or – in the case of an authorisation supplementary to a Community authorisation – the Commission, has approved the supplementary authorisation, it shall issue a separate authorisation number and shall record in the Community Register for Biocidal Products the administrative decisions taken in connection with the application.

(9) Without prejudice to the information supplied in accordance with paragraph 3, the conditions of the primary authorisation for placing on the market and use of the biocidal product shall also apply to the supplementary authorisation.

Or. de

Justification

In some EU Member States the generally current authorisation practice is to permit and facilitate marketing of the same products under different trade names and by different companies through a system of different types of authorisation. Because the nature of duplicate and supplementary authorisations is purely administrative and technical, there is no need for a re-evaluation of effects on human health or the environment.

Amendment 70

Proposal for a regulation

Article 38 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) changes in the source or composition of the active substance.

Or. de

Justification

A change in the source of an active substance used in a biocidal product needs to be reported because it could affect the product's safety.

Amendment 71

Proposal for a regulation

Article 40 – subparagraph 1

Text proposed by the Commission

Amendment

The competent authority that has granted the ***national*** authorisation, ***or in case of Community authorisation, the Commission***, shall cancel the authorisation at the request of its holder, who shall state the reasons for such request. If such a request concerns a Community authorisation, it shall be submitted to the Agency.

The competent authority that has granted the authorisation shall cancel the authorisation at the request of its holder, who shall state the reasons for such request. If such a request concerns a Community authorisation, ***a duplicate thereof or an authorisation supplementary to a Community authorisation***, it shall be submitted to the Agency.

Or. de

Amendment 72

Proposal for a regulation

Article 41 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(2a) A change in a primary authorisation made at the request of the primary authorisation holder shall also apply to

*duplicate and supplementary
authorisations based thereon.*

Or. de

Amendment 73

Proposal for a regulation Article 42 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

(1a) The criteria and procedures in accordance with paragraph 1 of this article should be based on the principle that different types of amendment procedure should be used according to the extent of the changes envisaged, whereby a simplified notification procedure shall apply in respect of:

- (a) administrative changes to an authorisation;*
- (b) changes to a biocidal product made within the scope of the permitted changes defined under an existing authorised frame formulation;*
- (c) the marketing of a new biocidal product that fits an existing authorised frame formulation;*
- (d) insignificant changes to a biocidal product that have no adverse effect on the risk level or the product's efficiency;*

Or. de

Justification

It needs to be made clear that different types of amendment procedure should be used depending on the level and significance of the changes to a biocidal product that are envisaged (be they relatively small or relatively major) – the point of comparison being the original authorisation.

Amendment 74

Proposal for a regulation

Article 47 – paragraph 2 – subparagraph 1 – introduction

Text proposed by the Commission

(2) Treated **articles or** materials shall be labelled with the following information:

Amendment

(2) Treated materials **or products** shall be labelled with the following information:

Or. de

Justification

To clarify the fact that treated materials and products which have external effects are subject to stricter labelling requirements.

Amendment 75

Proposal for a regulation

Article 47 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission

(a) the name of all active substances that were used to treat the **article or** materials or that were incorporated in the **articles or** materials;

Amendment

(a) the name of all active substances that were used to treat the materials **or products** or that were incorporated in the materials **or products**;

Or. de

Justification

To clarify the fact that treated materials and products which have external effects are subject to stricter labelling requirements.

Amendment 76

Proposal for a regulation

Article 47 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission

(b) **where relevant**, the biocidal property attributed to treated **articles or** materials;

Amendment

(b) the biocidal property attributed to treated materials **or products, if the biocidal product contained therein will come into direct contact with people or the**

environment;

Or. de

Justification

To clarify the fact that treated materials and products which have external effects are subject to stricter labelling requirements.

Amendment 77

Proposal for a regulation

Article 47 – paragraph 2 – subparagraph 1 – point d

Text proposed by the Commission

(d) any hazard statement or precautionary statement set out in the authorisation for the biocidal product.

Amendment

(d) any hazard statement or precautionary statement set out in the authorisation for the biocidal product, ***if the biocidal product will come into direct contact with people or the environment.***

Or. de

Justification

To clarify the fact that treated materials and products which have external effects are subject to stricter labelling requirements.

Amendment 78

Proposal for a regulation

Article 47 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The labelling shall be clearly visible, easily legible and appropriately durable. ***Where this is necessary because of the size or the function of the treated article or material, the labelling*** shall be printed on the packaging, on the instructions for use or on the warranty of the treated ***article or material***.

Amendment

The labelling shall be clearly visible, easily legible and appropriately durable ***and*** shall be printed on the ***material or product, on the*** packaging, on the instructions for use or on the warranty of the treated material ***or product.***

Or. de

Justification

To clarify the fact that treated materials and products which have external effects are subject to stricter labelling requirements.

Amendment 79

Proposal for a regulation

Article 48 – paragraph 1 – point a

Text proposed by the Commission

(a) the subsequent applicant has written agreement in the form of a letter of access **from the first applicant** that he can use that information,

Amendment

(a) the subsequent applicant has written agreement in the form of a letter of access **in accordance with Article 50** that he can use that information,

Or. de

Justification

The first applicant is not necessarily the owner of the information. Moreover, the option of a second applicant or a second company owning or being able to acquire the information as the result of information sharing or joint information development should be permitted. The participants involved with the inclusion of substances in Annex I, who are already entitled to refer to information contained in applications, should thus not be required to prove each time whether or not they are the actual data owners.

Amendment 80

Proposal for a regulation

Article 48 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the subsequent applicant is also an owner of the information.

Or. de

Justification

The first applicant is not necessarily the owner of the information. Moreover, the option of a second applicant or a second company owning or being able to acquire the information as the result of information sharing or joint information development should be permitted. The participants involved with the inclusion of substances in Annex I, who are already entitled to refer to information contained in applications, should thus not be required to prove each time

whether or not they are the actual data owners.

Amendment 81

Proposal for a regulation Article 48 – paragraph 4

Text proposed by the Commission

(4) The list referred to in paragraph 2 shall be entered by the Agency in the Biocides Data Sharing Register.

Amendment

(4) Each item of information in the list referred to in paragraph 2 shall be identified by a unique code and entered by the Agency – with all relevant details and linked to the identity of the initial applicant and the information owner – in the Biocides Data Sharing Register.

Or. de

Justification

All the items of information or documents that are on the list must be contained in the register. Giving each document submitted an identification number is a useful means of avoiding misunderstandings in relation to similar titles, changes in studies or unedited information on studies. Linking the items of information to the information owners and applicants will ensure that property rights are recognised.

Amendment 82

Proposal for a regulation Article 49 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Information submitted for the purposes of Directive 98/8/EC or of this Regulation shall benefit from data protection under the conditions laid down in this Article. The protection period for this information shall start when the information is submitted.

Amendment

Does not affect the English version.

Or. de

Justification

Does not affect the English version.

Amendment 83

Proposal for a regulation

Article 49 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Information protected under Directive 98/8/EC or under this Article **or** for which the protection period expired under Directive 98/8/EC **or under this Article** shall **not** be protected again.

Amendment

Information protected under Directive 98/8/EC or under this Article for which the protection period expired under Directive 98/8/EC shall, **on application**, be protected again.

Or. de

Justification

The principle of data protection under Directive 98/8/EC has never been unequivocally established.

The date on which an application is submitted ought also to be the date of entry of most of the items of information but later submissions and other activities will result in a number of submission dates. Entering a submission date for each individual document will reflect this situation accurately. Establishing that each item of information is covered by data protection is justifiable because each item has entailed an investment on the information owner's part.

Amendment 84

Proposal for a regulation

Article 49 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

An entry date should be individually established for each document that has been given a unique code in accordance with Article 48(4).

Or. de

Justification

The principle of data protection under Directive 98/8/EC has never been unequivocally established.

The date on which an application is submitted ought also to be the date of entry of most of the items of information but later submissions and other activities will result in a number of

submission dates. Entering a submission date for each individual document will reflect this situation accurately. Establishing that each item of information is covered by data protection is justifiable because each item has entailed an investment on the information owner's part.

Amendment 85

Proposal for a regulation Article 49 – paragraph 4

Text proposed by the Commission

Amendment

(4) By way of derogation from the first subparagraph of paragraph 2, the protection period for information submitted to a Member State under national systems or practices for the approval of biocidal products, before it was submitted for the purposes of Directive 98/8/EC or of this Regulation, shall end at the expiry of any remaining period provided for under national rules or on 14 May 2014, whichever is the earlier, unless this information has been generated after 14 May 2000.

deleted

Or. de

Justification

There is no justification for making a distinction between new and existing information.

Amendment 86

Proposal for a regulation Article 50 – paragraph 2

Text proposed by the Commission

Amendment

(2) Revocation of a letter of access prior to its expiry date shall **not affect the validity of** the authorisation issued on the basis of the letter of access in question.

(2) Revocation of a letter of access prior to its expiry date shall **invalidate** the authorisation issued on the basis of the letter of access in question **with immediate effect.**

Or. de

Justification

The Commission proposal would permit free-riding because, having obtained a letter of access, a company could easily switch to a different supplier. Information owners and/or participants would not then be in a position to recoup their costs.

As rule, letters of access are issued free of charge in connection with supply agreements. Providing for the revocation of letters of access if agreements are broken is a means of protecting information owners' investments.

Amendment 87

Proposal for a regulation

Article 51 - paragraph 2 - subparagraph 2

Text proposed by the Commission

Where those tests or studies have already been submitted in connection with a previous application, the competent authority or the Agency shall without delay communicate the name and contact details of the owner of the information to the prospective applicant.

Amendment

Where those tests or studies have already been submitted in connection with a previous application, ***the competent authority or the Agency shall without delay assess technical equivalence in relation to the comparison source. If the technical equivalence assessment is positive,*** the competent authority or the Agency shall without delay communicate the name and contact details of the owner of the information to the prospective applicant.

Or. de

Justification

Before the studies become the subject of a data exchange, technical equivalence must be ascertained. Otherwise it is not possible to ascertain whether the data available are applicable to the subsequent applicant's article for testing.

Amendment 88

Proposal for a regulation

Article 52 - paragraph 3

Text proposed by the Commission

3. Where no such agreement is reached two

Amendment

3. Where no such agreement is reached two

months after the request was made according to Article 51(2), the prospective applicant shall without delay inform the Agency **and the owner of the information** thereof. Within two months of being informed about the failure to reach an agreement, the Agency shall give the prospective applicant the right to refer to the tests or studies involving tests on vertebrate animals. **National courts** shall decide on the proportionate share of **the cost** that the prospective applicant shall pay to the data owner.

months after the request was made according to Article 51(2), **both the data owner and** the prospective applicant shall without delay inform the Agency thereof. Within two months of being informed about the failure to reach an agreement, the Agency shall give the prospective applicant the right to refer to the tests or studies involving tests on vertebrate animals. **A Union arbitration body** shall decide on the proportionate share of **all costs associated with producing and using the information** that the prospective applicant shall pay to the data owner.

Or. de

Justification

As the attempt to reach agreement between two parties (i.e. the owner and the subsequent applicant) may fail, both parties must inform the Agency. It makes no sense for the subsequent applicant to inform the owner, as the latter is one of the parties to the failed agreement. In order to ensure that the compulsory data exchange proceeds in a harmonised manner at EU level, the Commission should establish an arbitration body for the Union.

Amendment 89

Proposal for a regulation Article 53 - paragraph 1 - subparagraph 1

Text proposed by the Commission

1. In the case of a biocidal product which has already been authorised in accordance with Articles 15, 25 or 28, and where all periods of protection of information according to Article 49 have expired, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the biocidal product is similar to and its active substances are technically equivalent to the one formerly authorised, including degree of purity and nature of impurities.

Amendment

1. In the case of a biocidal product which has already been authorised in accordance with Articles 15, 25 or 28, and where all periods of protection of information according to Article 49 have expired, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant, **and if the periods of protection of information according to Article 49 have not expired, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant**

pursuant to Article 52, in both cases in so far as the subsequent applicant can provide evidence that the biocidal product is similar to and its active substances are technically equivalent to the one formerly authorised, including degree of purity and nature of impurities.

Or. de

Justification

Similarity and technical equivalence must also be demonstrated where the protection of information has not yet expired but a subsequent applicant wishes to share data.

Amendment 90

Proposal for a regulation
Article 54 - paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The competent authorities shall perform official controls in order to ensure that manufacturers of active substances which are placed on the market for use in biocidal products have submitted to the Commission the information about the active substance referred to in Annex II or in a letter of access to a dossier which complies with the requirements of Annex II.

Or. de

Justification

Market surveillance should also apply to active substances which are placed on the market for use in biocidal products. Under the regulation, manufacturers are required to comply with many rules in order to attain the level of respect which must be guaranteed at national level.

Amendment 91

Proposal for a regulation Article 54 - paragraph 4

Text proposed by the Commission

4. The Commission shall draw up a report on the implementation of this Regulation and, in particular, on the functioning of the Community authorisation procedure and mutual recognition, by 1 January 2023. The Commission shall submit the report to the European Parliament and the Council.

Amendment

4. The Commission shall draw up a report on the implementation of this Regulation and, in particular, on the functioning of the Community authorisation procedure and mutual recognition, by 1 January 2023. The Commission shall submit the report to the European Parliament and the Council.
On the basis of this report the Commission shall perform an assessment in order to verify whether or not the regulation needs to be amended.

Or. de

Justification

The report which the Commission draws up should be a preliminary to a broader review process so that the main difficulties can be identified as early as possible and the regulation can be amended at the appropriate time if necessary.

Amendment 92

Proposal for a regulation Article 55 - paragraph 3

Text proposed by the Commission

3. Any person submitting information related to an active substance to the Agency or a competent authority for the purposes of this Regulation can request that the information in Article 56(2) shall not be made available including a justification as to why the disclosure of the information could be harmful for his or any other concerned party's commercial interests.

Amendment

3. Any person submitting information related to an active substance ***or a biocidal product*** to the Agency or a competent authority for the purposes of this Regulation can request that the information in Article 56(2) shall not be made available including a justification as to why the disclosure of the information could be harmful for his or any other concerned party's commercial interests.

Or. de

Justification

This article should also apply to information concerning biocidal products.

Amendment 93

Proposal for a regulation

Article 56 - paragraph 2 - point e

Text proposed by the Commission

Amendment

(e) subject to Article 24 of Regulation (EC) No 1272/2008, the name in the IUPAC nomenclature for active substances referred to in paragraph 1(a) of this Article that are only used as one or more of the following:
(i) in scientific research and development;
(ii) in product and process orientated research and development.

deleted

Or. de

Justification

Information about research and development should be confidential.

Amendment 94

Proposal for a regulation

Article 61 a (new)

Text proposed by the Commission

Amendment

Article 61a

- 1. Member States shall ensure that all professional users, distributors and advisers have access to appropriate information on the use, risks and safe employment of biocidal products.*
- 2. Member States shall take the necessary measures to provide the public with information about the uses and risks associated with biocidal products and ways of minimising the use of those products.*

Justification

This will help to inform professional users and consumers about the safe use of products and about compatible alternatives and harmless biocidal products.

Amendment 95**Proposal for a regulation****Article 70 – paragraph 2 – point d**

Text proposed by the Commission

Amendment

(d) an annual fee shall be paid by persons placing biocidal products on the market; and ***deleted***

Justification

Fees should be related to the required work which has been performed in an appropriate and efficient manner. An annual fee is therefore not acceptable without a justification, and fees should only be charged when they are genuinely necessary.

Amendment 96**Proposal for a regulation****Article 77 - paragraph 3 - subparagraph 3**

Text proposed by the Commission

Amendment

Biocidal products, for which an application for a product authorisation has not been submitted in accordance with the second subparagraph, shall no longer be placed on the market ***with effect from six months*** after the date on which the inclusion becomes effective. Disposal, storage and use of existing stocks of biocidal products for which an application for authorisation has not been submitted in accordance with the second subparagraph are allowed until ***eighteen*** months after the date on which the inclusion becomes effective.

Biocidal products, for which an application for a product authorisation has not been submitted in accordance with the second subparagraph, shall no longer be placed on the market after the date on which the inclusion becomes effective. Disposal, storage and use of existing stocks of biocidal products for which an application for authorisation has not been submitted in accordance with the second subparagraph are allowed until ***six*** months after the date on which the inclusion becomes effective.

Justification

Longer periods should not be required, as downstream users should know their obligations and the status of the testing of the active substance.

Amendment 97

**Proposal for a regulation
Article 80 - paragraph 1**

Text proposed by the Commission

1. Applications for the authorisation of substances, mixtures and devices considered as biocidal products in accordance with the second sentence of point (a) of Article 3(1) which were available on the market on ... [OJ: insert the date referred to in the first subparagraph of Article 85] shall be submitted at the latest by 1 January 2017 .

Amendment

1. Applications for the authorisation of substances, mixtures and devices considered as biocidal products in accordance with the second sentence of point (a) of Article 3(1) which were available on the market on ... [OJ: insert the date referred to in the first subparagraph of Article 85] shall be submitted at the latest by 1 January 2017. ***This paragraph shall not apply to active substances generated in situ for the purpose of disinfecting drinking water.***

Justification

Disinfection of drinking water is adequately regulated by the European drinking water directive (98/83/EC) and the REACH Regulation.

Amendment 98

**Proposal for a regulation
Article 83 - paragraph -1 a (new)**

Text proposed by the Commission

Amendment

(-1a). As from 1 January 2014, every manufacturer of an existing active substance which is on the market for use in biocidal products shall submit an application to the Agency for inclusion of the active substance in Annex I. The

competent authorities shall carry out official controls as required by Article 54(1).

Or. de

Justification

Only undertakings which contribute to the system should be allowed to manufacture and market active substances intended for use in biocidal products. Appropriate checks on the market for active substances are the best way of overcoming the 'free rider' problem. Member States should be required to ascertain what biocidal products exist on their market and whether the manufacturers of the active substance have submitted a dossier for inclusion in Annex I, and should take responsibility for the appropriate implementation.

Amendment 99

Proposal for a regulation

Article 83 - paragraph 2 - subparagraph 2 a (new)

Text proposed by the Commission

Amendment

The competent authorities shall carry out official controls as required by Article 54(1).

Or. de

Justification

Only undertakings which contribute to the system should be allowed to manufacture and market active substances intended for use in biocidal products. Appropriate checks on the market for active substances are the best way of overcoming the 'free rider' problem. Member States should be required to ascertain what biocidal products exist on their market and whether the manufacturers of the active substance have submitted a dossier for inclusion in Annex I, and should take responsibility for the appropriate implementation.

Amendment 100

Proposal for a regulation

Annex III - paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Whenever possible, the information should be derived from existing data in order to reduce the number of tests on

animals. In particular, the provisions of Directive 1999/45/EC or Regulation (EC) No 1272/2008 shall apply.

Or. de

Justification

Avoidance of unnecessary tests on vertebrates.

Amendment 101

**Proposal for a regulation
Annex III - Title 1 - point 2.2**

Text proposed by the Commission

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

Amendment

2.2. Detailed quantitative and qualitative information on the composition of the biocidal product, e.g. active substance(s), impurities, adjuvants, inert components, ***taking account of the concentrations referred to in Article 16(2b) (new)***

Or. de

Justification

Amendment required in the interests of compatibility with the amendment inserting Article 16(2b) (new).

Amendment 102

**Proposal for a regulation
Annex VI - point 22 a (new)**

Text proposed by the Commission

Amendment

(22a) In order to reduce the number of tests on animals, adverse effects should whenever possible be studied on the basis of the information about the active substance and existing information about the substances that give cause for concern which the biocidal product contains. In particular, the provisions of Directive

***1999/45/EC or Regulation (EC) No
1272/2008 shall be applied for the
purpose of ascertaining adverse effects of
the biocidal product.***

Or. de

Justification

Avoidance of unnecessary tests on vertebrates.

EXPLANATORY STATEMENT

Biocidal products are part of our civilisation, and our standard of living depends on them. They are essential in order to maintain the high standards of health and hygiene on which we insist. Because of high population density and international mobility, our society requires particular forms of hygiene to prevent germs and diseases from being transmitted. Biocidal products must be effective, which often also makes them dangerous. Special sensitivity is therefore called for in dealing with these substances.

At the same time the new regulation on biocidal products must ensure that manufacturers, the majority of whom are medium-sized companies, can apply the regulations in their production without being placed at a competitive disadvantage, as that might in some circumstances even result in raw materials or products ceasing to be available.

The aim of this regulation is to unify the existing European legislation and update it according to the state of the art. Both consumers and manufacturers of biocidal products or of products containing them must be able to rely on minimum standards applicable throughout the EU.

The rapporteur considers that the Commission's proposal for a regulation is in considerable need of improvement in order to achieve the stated purposes, such as eliminating the shortcomings in the existing directive, improving the authorisation procedure and streamlining decision-making while further developing the high level of protection.

The new regulation must take account of three essential fields: environmental protection, consumer protection and safe and practical implementation by manufacturers.

Regarding the environment:

The authorisation procedure, marketing and use of biocidal products must accord with the precautionary principle and clear exclusion criteria. Only then can the highest possible standard of protection of human and animal health alike be attained and Creation as a whole preserved.

The authorisation rules laid down in the regulation should also make allowance for the further technical development of active substances, for example nanomaterials, the use of which is increasingly widespread. In order to guarantee a high standard of protection for the future as well as legal certainty for producers, therefore, the rapporteur considers that a uniform definition of nanomaterials should be formulated and that the text of the regulation should be regularly updated in the light of technical developments.

Regarding consumer protection:

Consumers must be able to rely on the assumption that the products they acquire comply with uniform minimum standards in the EU internal market, irrespective of which Member State they have purchased a product in. So that these standards cannot be evaded, it is also necessary for the products of non-European manufacturers and the materials and active substances which they use to comply with EU standards. Clear labelling of materials

processed and of products is therefore just as necessary as appropriate authorisation of biocidal products, whether produced inside or outside the European Union.

Professional users and consumers of biocidal products must also be informed about how to use them safely, about compatible alternatives and that biocidal products are safe. This should without fail entail training of relevant target groups, at least among professional users.

Regarding the practical application and enforcement of the regulation:

In catering for the increasingly stringent requirements applicable to biocidal products, not only production itself is important but so, in particular, are research and development. However, the biocidal products industry is one which is particularly required to combine small quantities of product with complex manufacturing processes and authorisation procedures. It follows that the registration and authorisation of biocidal products must involve a proportionate amount of administration, fair conditions and acceptable costs without removing the incentive for undertakings to continue to develop existing products and research new ones.

In this connection the introduction of a Community authorisation system represents a significant step towards a harmonised European market for biocidal products. It is the best and most efficient system for improving the availability of these products, providing incentives for innovation and creating added value for human health and nature conservation. A central authorisation system will also have an unequivocally positive effect on the internal market as it will facilitate consistent assessments and uniform enforcement of the requirements in all EU Member States. This will, in particular, also improve consumer protection. The Community authorisation procedure should therefore be extended to all categories of products.

It is important that the authorisation procedure should be designed to prevent free-rider and cashing-in effects, for example with regard to product information or business secrets. The future regulation provides for a simplified procedure for product authorisation subject to certain conditions in order to avoid unnecessary costs and excessive fees. It should also be made clear that different procedures are to be applied, depending on the extent of proposed changes to a biocidal product in comparison with that which was originally authorised. Minor changes in biocidal products would therefore require only a simplified procedure rather than a cumbersome and time-consuming procedure, provided that this was not detrimental either to the risk assessment or to its effectiveness.