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*****I**

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)0267 – C7-0036/2009 – 2009/0076(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Christa Klauf

Rapporteur for the opinion(*):
Amalia Sartori, Committee on the Internal Market and Consumer Protection

(*) Associated committees – Rule 50 of the Rules of Procedure

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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(*) Associated committee – Rule 50 of the Rules of Procedure

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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)0267 – C7-0036/2009 – 2009/0076(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to 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 European Economic and Social Committee of 17 February 2010¹,
 - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
 - having regard to Rules 55 and 37 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 (A7-0239/2010),
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, the Commission and the national parliaments.

¹ Not yet published in the Official Journal.

Amendment 1

Proposal for a regulation

Recital 3

Text proposed by the Commission

(3) The purpose of this Regulation is to increase the free movement of biocidal products within the *Community*. In order to remove as far as possible obstacles to trade in biocidal products *stemming from the different levels of protection in the Member States*, *harmonised* rules should be laid down for the approval of active substances and the placing on the market and use of biocidal products, including the rules on the mutual recognition of authorisations and on parallel trade.

Amendment

(3) The purpose of this Regulation is to increase the free movement of biocidal products within the *Union* ***and to ensure a high level of protection of both human and animal health and the environment. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied to this Regulation in order to ensure that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.*** In order to remove as far as possible obstacles to trade in biocidal products, rules should be laid down for the approval of active substances and the placing on the market and use of biocidal products, including the rules on the mutual recognition of authorisations and on parallel trade.

Amendment 2

Proposal for a regulation

Recital 13

Text proposed by the Commission

(13) Active substances can, on basis of their intrinsic hazardous properties, be designated as candidates for substitution with other active substances, whenever such substances considered as efficient towards the targeted harmful organisms become available in sufficient variety to avoid the development of resistances

Amendment

(13) Active substances can, on basis of their intrinsic hazardous properties, be designated as candidates for substitution with other active substances, whenever such substances considered as efficient towards the targeted harmful organisms become available in sufficient variety to avoid the development of resistances

amongst harmful organisms. In order to allow for a regular examination of substances identified as candidates for substitution, the inclusion period for these substances should not, even in the case of renewal, exceed *ten years*. Furthermore, the identification of substances which are considered as candidates for substitution should be considered as a first step of a comparative assessment.

amongst harmful organisms. In order to allow for a regular examination of substances identified as candidates for substitution, the inclusion period for these substances should not, even in the case of renewal, exceed *seven years*. Furthermore, the identification of substances which are considered as candidates for substitution should be considered as a first step of a comparative assessment.

Justification

The renewal period for substances that are candidates for substitution should be the same as in the PPP regulation.

Amendment 3

Proposal for a regulation Recital 26

Text proposed by the Commission

Amendment

(26) In order to encourage the use of low-risk biocidal products with more favourable environmental or human health profile compared to other biocidal products, it should be allowed to authorise low-risk biocidal products without prior approval of the active substances contained therein.

deleted

Justification

Low-risk products should be primarily products with intrinsic low-risk properties. In order to judge this the active substances contained therein should be in all cases approved for use.

Amendment 4

Proposal for a regulation Recital 31 a (new)

Text proposed by the Commission

Amendment

(31a) In order to help applicants, and in particular SMEs, to comply with the

requirements of this Regulation, Member States should establish national helpdesks. These should be in addition to the operational guidance documents provided by the Agency.

Amendment 5

Proposal for a regulation Recital 33 a (new)

Text proposed by the Commission

Amendment

(33a) Infestation with harmful organisms should be avoided by means of suitable deterrents to banish or repel such organisms. In addition, other precautionary steps should be taken, e.g. proper warehousing of goods, compliance with hygiene standards and immediate disposal of waste. Only if such measures have no effect should further steps be taken. Biocidal products that pose lower risks for humans, animals and the environment should always be used in preference to other products where those lower risk products provide an effective remedy in particular situations. Biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress should be used as a last resort.

Justification

The sustainable use of biocides will be achieved by acknowledging the need for preventive measures as a first course.

Amendment 6

Proposal for a regulation Recital 45

Text proposed by the Commission

Amendment

(45) In view of the benefits for the internal

(45) In view of the benefits for the internal

market and for the consumer, it is desirable to establish harmonised rules for parallel trade of *substantially* identical biocidal products that are authorised in different Member States.

market and for the consumer, it is desirable to establish harmonised rules for parallel trade of identical biocidal products that are authorised in different Member States.

Justification

In order to find an appropriate balance between free trade of goods and a safe market then this article on parallel trade should be limited to identical products based on the same specification and content of active substances and co-formulants.

Amendment 7

Proposal for a regulation Recital 48

Text proposed by the Commission

(48) 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

(48) 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 ***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.

Justification

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

Amendment 8

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

Amendment

(49) In view of ensuring that all proprietary information submitted in support of an inclusion of an active substance ***in Annex I***

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 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.

Justification

Clarification.

Amendment 9

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 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.

Amendment

(51) It is essential to minimise the number of tests on animals and to ensure that testing ***with biocidal products 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, 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 *Union* 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.

Justification

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

Amendment 10

Proposal for a regulation
Recital 54

Text proposed by the Commission

(54) It is necessary to provide for the effective communication of information on risks resulting from biocidal products and risk management measures as it forms an essential part of the system established by this Regulation. While facilitating access to information, competent authorities, the Agency and the Commission should respect the principle of confidentiality and avoid any disclosure of information which could be harmful for the commercial interests of the person concerned.

Amendment

(54) It is necessary to provide for the effective communication of information on risks resulting from biocidal products and risk management measures as it forms an essential part of the system established by this Regulation. While facilitating access to information, competent authorities, the Agency and the Commission should respect the principle of confidentiality and avoid any disclosure of information which could be harmful for the commercial interests of the person concerned, ***except where it is necessary for the protection of human health and the environment.***

Amendment 11

Proposal for a regulation
Recital 60

Text proposed by the Commission

(60) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission¹⁵.

Amendment

deleted

¹⁵ OJ L 184, 17.7.1999, p. 23.

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 12

Proposal for a regulation
Recital 61

Text proposed by the Commission

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 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 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.

deleted

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article

Amendment 13

Proposal for a regulation Recital 61 a (new)

Text proposed by the Commission

Amendment

(61a) There is scientific uncertainty about the safety of nanomaterials for human health and the environment and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has identified some specific health hazards as well as toxic effects on environmental organisms for some nanomaterials. SCENIHR has furthermore found a general lack of high-quality exposure data for both humans and the environment, concluding that the knowledge on the methodology for both exposure estimates and hazard identification needs to be further developed, validated and standardised. More and more biocidal products contain nanosilver. 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.

Amendment 14

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.

Amendment 15

Proposal for a regulation Recital 62

Text proposed by the Commission

Amendment

(62) When, on imperative grounds of urgency, the normal time limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of decisions to amend the inclusion of an active substance in Annex I or to remove it from that Annex on basis of Article 13.

deleted

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 16

Proposal for a regulation Recital 62 a (new)

Text proposed by the Commission

Amendment

(62a) According to Article 291 TFEU, rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers are to be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, and given the necessity to adopt as soon as possible this Regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission¹ continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable. References to provisions of that Decision should nevertheless be replaced with references to the rules and principles set out in the new regulation as soon as that regulation enters into force.

¹ OJ L 184, 17.7.1999, p. 23.

Justification

To provide for transitional measures until the new rules on implementing acts are adopted.

Amendment 17

Proposal for a regulation Recital 66

Text proposed by the Commission

Amendment

(66) Taking into consideration that some products were not previously covered by the Community legislation in the field of biocidal products, it is appropriate to allow for a transitional period for the companies to be prepared to apply the rules

(66) Taking into consideration that some products were not previously covered by the Community legislation in the field of biocidal products, it is appropriate to allow for a transitional period for the companies to be prepared to apply the rules

concerning in situ generated active substances, treated articles and materials **and food contact materials**.

concerning in situ generated active substances **and** treated articles and materials.

Justification

Food contact materials should not be within the scope of the Proposal as this would lead to double regulation and assessment. Food contact materials are already regulated by the Food Contact Materials Framework Regulation (EC) No 1935/2004. Should any changes be made to the rules governing food contact materials, they should be addressed through a revision of the food contact legislation, not by extending the scope of the BPR.

Amendment 18

Proposal for a regulation

Article 1 - paragraph 1 a (new)

Text proposed by the Commission

Amendment

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. Special attention shall be paid to protecting children, pregnant women and the sick.

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 19

Proposal for a regulation

Article 2 – paragraph 2 – point p a (new)

Text proposed by the Commission

Amendment

(pa) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food¹;

¹*OJ L 338, 13.11.2004, p. 4.*

Justification

Food contact materials are already governed by Regulation (EC) No 1935/2004. This Regulation may not cover all aspects of assessment of materials and their use. However, new restrictions should be introduced through a review of the legislation specific to food contact materials and in the Biocidal Products Regulation in order to avoid duplication of rules and assessments.

Amendment 20

Proposal for a regulation

Article 2 – paragraph 2 – point p b (new)

Text proposed by the Commission

Amendment

(pb) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption¹;

¹ *OJ L 330, 5.12.1998, p. 32.*

Amendment 21

Proposal for a regulation

Article 2 - paragraph 3 - 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 policy¹.

¹ *OJ L 327, 22.12.2000, p. 1.*

Amendment 22

Proposal for a regulation

Article 3 - paragraph 1 - point a

Text proposed by the Commission

(a) 'biocidal product' means

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.

All substances, mixtures and devices placed on the market with the intention to generate active substances shall also be considered biocidal products;

Amendment

(a) 'biocidal product' means

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.

All substances, mixtures and devices placed on the market with the intention to generate active substances shall also be considered biocidal products;

Justification

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

Amendment 23

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, ***immediately or in the more distant future***, on humans, ***especially children***, 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 normally be a

substance classified as dangerous according to Directive 67/548/EEC and present in the biocidal product at a concentration leading to the product being 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 24

Proposal for a regulation

Article 3 – paragraph 1 – point g

Text proposed by the Commission

(g) 'harmful organism' means

organisms, including pathogenic agents, which have an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, or on animals or the environment;

Amendment

(g) 'harmful organism' means

organisms, including pathogenic agents, which have an unwanted presence or a detrimental effect, ***immediately or in the more distant future***, on humans, ***especially children, human*** activities or the products they use or produce, or on animals or the environment;

Justification

It would seem appropriate to highlight the fact that children are more vulnerable to harmful products than adults, on whom the proposal for a regulation is basing tolerance criteria. Children often find themselves in places which have been sprayed with biocidal products and pesticides, and show reactions - immediately or in the longer term - which are directly or indirectly attributable to the harmful substances.

Amendment 25

Proposal for a regulation

Article 3 – paragraph 1 – point h

Text proposed by the Commission

(h) 'residues' means

Amendment

(h) 'residues' means

substances present in or on plants or products of plant origin, edible animal products, drinking water or elsewhere in the environment and resulting from the use of a biocidal product, including their metabolites, breakdown or reaction products;

substances present in or on plants or products of plant origin, edible animal products, **water resources**, drinking water or elsewhere in the environment and resulting from the use of a biocidal product, including their metabolites, breakdown or reaction products;

Amendment 26

Proposal for a regulation

Article 3 – paragraph 1 – point i

Text proposed by the Commission

(i) 'placing on the market' means the **first** supply of a biocidal **product for distribution or for use on the Community market** in the course of a commercial activity, whether in return for payment or free of charge;

Amendment

(i) 'placing on the market' means the supply of a biocidal product **to third parties**, whether in return for payment or free of charge, **or the making available of a biocidal product to third parties**. **Importation shall be deemed to be placing on the market. No supply to third parties is involved when** in the course of a commercial activity **treated materials or products are individually manufactured and then incorporated by the manufacturer**.

Justification

Not just the 'first supply', but 'any supply' should be deemed to be placing on the market, as in other chemicals legislation (see REACH). Derogations should only be admitted when, for example, a craftsman is commissioned by a client to paint a façade with a substance that contains an authorised biocidal product. This clarification is necessary.

Amendment 27

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**

Amendment

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

intention to protect the substance, mixture, material or article from deterioration caused by harmful organisms;

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 28

Proposal for a regulation

Article 3 – paragraph 1 – point k a (new)

Text proposed by the Commission

Amendment

(ka) 'external biocidal effect' means the effect of applications whereby the incorporated biocidal product is intended to be released under normal or reasonably foreseeable conditions of use.

Justification

The term 'external effect' is not defined in the regulation on biocidal products itself, but in the 'Manual of Decisions'.

Amendment 29

Proposal for a regulation

Article 3 – paragraph 1 – point p

Text proposed by the Commission

Amendment

(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

(p) 'frame formulation' means

a group of ***low-risk*** 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;

specifications where such permitted variations do not adversely affect the level of risk or the efficacy of these products
and where the variation is a reduction in the percentage of the active substance or a change in percentage composition of one or more of the non-active substances;

Justification

This brings the frame formulation in accordance with Directive 98/8/EC. Underlining that the frame-formulations only apply for low-risk products will encourage sustainable product innovation and an appropriate risk-management.

Amendment 30

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 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;

Amendment

(q) 'letter of access' means

an original document, signed by the owner or owners of information ***or their authorised 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***;

Justification

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

Amendment 31

Proposal for a regulation

Article 3 – paragraph 1 – point t a (new)

Text proposed by the Commission

Amendment

(ta) 'administrative change' means

a variation to an existing authorisation of a purely administrative nature, which does not involve a re-assessment of the risk for public health or the environment or the efficacy of the product;

Justification

It is necessary to define the type of variations that can be made to an existing authorised biocidal product.

Amendment 32

Proposal for a regulation

Article 3 – paragraph 1 – point t b (new)

Text proposed by the Commission

Amendment

(tb) 'minor change' means

a variation to an existing authorisation which cannot be deemed to be an administrative variation as it involves a limited re-assessment of the risk for public health or the environment or of the efficacy of the product, and does not adversely affect the level of risk for public health or the environment and the efficacy of the product;

Justification

It is necessary to define the type of variations that can be made to an existing authorised biocidal product.

Amendment 33

Proposal for a regulation

Article 3 – paragraph 1 - point t c (new)

Text proposed by the Commission

Amendment

(tc) 'major change' means

a variation to an existing authorisation which cannot be deemed to be an administrative change or a minor change;

Justification

It is necessary to define the type of variations that can be made to an existing authorised biocidal product.

Amendment 34

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 properties that are characteristic of the nanoscale. Properties that are characteristic of the nanoscale include:

(i) those related to the large specific surface area of the materials considered; and/or

(ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material;

Amendment 35

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;***

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 36

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 uses biocidal products in the framework of his professional activity.

Amendment 37

Proposal for a regulation

Article 3 – paragraph 1 – point u d (new)

Text proposed by the Commission

Amendment

(ud) 'vulnerable groups' means

persons needing specific consideration when assessing the acute and chronic health effects of biocidal products. These include pregnant and nursing women, the unborn, infants and children, the elderly and workers and residents subject to high biocide exposure over the long term;

Justification

The regulation should include a definition of vulnerable groups, in line with regulation 1107/2009 and the REACH legislation.

Amendment 38

Proposal for a regulation

Article 3 – paragraph 1 – point u e (new)

Text proposed by the Commission

Amendment

(ue) 'SMEs' means

small and medium-sized enterprises as defined in the Commission Recommendation 2003/361/EC of 6 May

2003 concerning the definition of micro, small and medium-sized enterprises¹.

¹ OJ L 124, 20.5.2003, p. 36.

Justification

Following the example in REACH Regulation, it is better to separately set the definition for SMEs.

Amendment 39

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission

1. An active substance shall be included in Annex I for an initial period not exceeding 10 years if the biocidal products containing that active substance **fulfil** the conditions laid down in point (b) of Article 16(1).

Amendment

1. An active substance shall be included in Annex I for an initial period not exceeding 10 years if **at least one of** the biocidal products containing that active substance **fulfils** the conditions laid down in point (b) of Article 16(1). **An active substance referred to in Article 5 may only be included in Annex I for an initial period of 5 years.**

Justification

Substances that fall under the exclusion criteria should only be included in Annex I for a maximum period of 5 years. This is in line with the PPP regulation.

Amendment 40

Proposal for a regulation
Article 4 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Active substances as such or in biocidal products may be placed on the market in the Union for use in biocidal products only if they have been included in Annex I in accordance with the provisions of this Regulation.

Amendment 41

Proposal for a regulation

Article 4 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. Unless otherwise provided in this Regulation, all manufacturers of an active substance, as such or in a biocidal product, shall submit to the Agency an application for inclusion in Annex I.

Justification

Only if manufacturers are obliged to comply with the same data requirements in Annex II will fair treatment be possible.

Amendment 42

Proposal for a regulation

Article 4 - paragraph 3 - introductory part

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:

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 43

Proposal for a regulation

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

Text proposed by the Commission

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 44

Proposal for a regulation

Article 5

Text proposed by the Commission

Amendment

Article 5

Article 5

Exclusion criteria

Exclusion criteria

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:

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

(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;

(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, carcinogen category 1A or 1B;

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

(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) 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

(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

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.

reproduction category 1A or 1B;

(d) active substances which, on the basis of the assessment of Union or internationally agreed test guidelines or other peer-reviewed scientific data and information, including a review of the scientific literature, reviewed by the Agency, are considered as having endocrine-disrupting properties that may cause adverse effect in humans, or which are identified under Article 57(f) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties.

Not later than 13 December 2013, the Commission shall adopt, by means of delegated acts in accordance with Articles 71a and subject to the conditions of Articles 71 b and 71 c, measures on specific scientific criteria for determining endocrine-disrupting properties. Pending the adoption of those 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 as having 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 as having 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

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.

Council of 29 April 2004 on persistent organic pollutants¹;

2. The active substances referred to in paragraph **1** **may** be included in Annex I only **if** at least one of the **following** conditions is met:

(a) the exposure of humans or to the environment to the active substance in question in a biocidal product, under normal conditions of use, is negligible, meaning that the product is used in closed systems or under other conditions excluding contact with humans;

(b) it is shown by evidence that the active substance is necessary to prevent or control a serious danger to public or animal health or to the environment, to food and feed safety, or to the public interest and that there are no effective alternative substances or technologies available.

The use of any biocidal product containing active substances included in Annex I pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment is minimised.

A Member State authorising a biocidal product containing an active substance included in Annex I pursuant to this paragraph shall draw up a substitution plan concerning the control of the serious danger by other means including non-chemical methods, which are as effective as the biocidal product concerned and shall without delay transmit that plan to the Commission. The use of the biocidal product with the active substance concerned shall be restricted to those Member States where the serious danger has to be prevented or, if it occurs, controlled.

¹ OJ L 158, 30.4.2004, p. 7.

Amendment 45

Proposal for a regulation

Article 6 - paragraph 1 - point a

Text proposed by the Commission

(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;

Justification

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

Amendment 46

Proposal for a regulation

Article 6 - paragraph 1- point b

Text proposed by the Commission

(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.

Justification

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

Amendment 47

Proposal for a regulation

Article 6 – paragraph 2 – point a

Text proposed by the Commission

(a) the information is not necessary ***owing to the*** exposure ***associated with*** the proposed uses;

Amendment

(a) the information is not necessary ***as all relevant*** exposure ***can be ruled out under*** the proposed uses;

Justification

This information should only be waived if there is no relevant exposure.

Amendment 48

Proposal for a regulation

Article 6 – paragraph 4 – subparagraph 1

Text proposed by the Commission

4. The Commission shall adopt the measures designed to set the criteria defining what constitutes adequate justification to adapt the data required under paragraph 1 on the ground referred to in paragraph 2(a).

Amendment

4. In order to define what constitutes adequate justification to adapt the data required under paragraph 1 on the ground referred to in paragraph 2(a), **the Commission shall adapt the criteria by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c.**

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 49

Proposal for a regulation

Article 6 – paragraph 4 – subparagraph 2

Text proposed by the Commission

Those measures 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).

Amendment

deleted

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 50

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission

1. The applicant shall submit an application to include an active substance in Annex I, or to make subsequent amendments to the conditions of inclusion of an active substance, to the European Chemicals Agency (hereinafter referred to as 'the Agency') **and inform it of** the name of the competent authority of the Member State that **he chooses** to evaluate **his** application. That competent authority (hereinafter referred to as 'the evaluating competent authority') shall be responsible for the evaluation of the application.

Amendment

1. The applicant shall submit an application to include an active substance in Annex I, or to make subsequent amendments to the conditions of inclusion of an active substance, to the European Chemicals Agency (hereinafter referred to as 'the Agency'). **The Agency shall indicate** the name of the competent authority of the Member State that **it has chosen** to evaluate **the** application. That competent authority (hereinafter referred to as 'the evaluating competent authority') shall be responsible for the evaluation of the application.

Justification

Steps must be taken to ensure that certain Member States are not required to deal with a plethora of applications, thereby guaranteeing a balanced division of tasks among the Member States.

Amendment 51

Proposal for a regulation
Article 7 - paragraph 1 a (new)

Text proposed by the Commission

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.

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 52

Proposal for a regulation

Article 7 - paragraph 3 - introductory part

Text proposed by the Commission

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:

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 53

Proposal for a regulation

Article 7 – paragraph 4 - subparagraph 1

Text proposed by the Commission

4. 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.

Amendment

4. 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 time limit **of up to two months** for the submission of that information.

Justification

A set time limit is needed for the provision of documentation which should be as concise as possible in order to quickly proceed with evaluation.

Amendment 54

Proposal for a regulation

Article 7 - paragraph 4 - subparagraph 2

Text proposed by the Commission

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.

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 55

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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

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 56

Proposal for a regulation

Article 8 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Amendment

2. If, when the dossiers are evaluated, it

2. If, when the dossiers are evaluated, it

appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, **and** shall inform the Agency *thereof*.

appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit ***that shall not exceed six months. In exceptional circumstances and following proper justification, the time limit may be extended by up to a further six months.*** ***The evaluating competent authority*** shall inform the Agency ***about its request to the applicant and the extension of the time limit. Where such additional information includes animal testing, the applicant shall be advised by experts from the Agency or competent authorities regarding suitable alternative methods and testing strategies to replace, reduce or refine the use of vertebrate animals.***

Amendment 57

Proposal for a regulation Article 8 – paragraph 3

Text proposed by the Commission

3. If the evaluating competent authority considers that there are concerns with regard to the cumulative effects from the use of biocidal products containing the same active substance, it shall document its concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 and include this as part of its conclusions.

Amendment

3. If the evaluating competent authority considers that there are concerns with regard to the cumulative effects from the use of biocidal products containing the same active substance, ***or different substances with similar or common effects on the same endpoints, whether by the same or different mechanism of action,*** it shall document its concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 and include this as part of its conclusions.

Amendment 58

Proposal for a regulation Article 8 – paragraph 4

Text proposed by the Commission

Amendment

4. Within nine months after the receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the inclusion of the active substance in Annex I.

4. Within nine months after the receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the inclusion of the active substance in Annex I ***having regard to the conclusions of the evaluating competent authority.***

Justification

It should be clarified that the opinion by the Agency is done with regard to the conclusions by the evaluating competent authority.

Amendment 59

**Proposal for a regulation
Article 8 – paragraph 5**

Text proposed by the Commission

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. In order to keep the list of authorised active substances updated, on receipt of the opinion of the Agency, the Commission shall adopt, ***by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c,*** a decision to include the active substance in Annex I.

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 60

**Proposal for a regulation
Article 9 – paragraph 1 - introductory part**

Text proposed by the Commission

Amendment

1. An active substance ***fulfilling at least***

1. An active substance shall be considered

one of the following criteria shall be considered a candidate for substitution in accordance with the procedure referred to in paragraph 2:

a candidate for substitution in accordance with the procedure referred to in paragraph 2 ***where***:

Amendment 61

Proposal for a regulation

Article 9 – paragraph 1 – point b

Text proposed by the Commission

(b) it meets ***two*** of the criteria to be considered as a persistent, bio-accumulative and toxic substance as set out in Annex XIII of Regulation (EC) No 1907/2006;

Amendment

(b) it meets ***one*** of the criteria to be considered as a persistent, bio-accumulative and toxic substance as set out in Annex XIII of Regulation (EC) No 1907/2006;

Amendment 62

Proposal for a regulation

Article 9 – paragraph 1 – point c

Text proposed by the Commission

(c) there are reasons for concern linked to the nature of the critical effects, in particular developmental neurotoxic or immunotoxic effects, which, in combination with the use patterns, amount to use that could still cause concern, even with very restrictive risk management measures;

Amendment

(c) there are reasons for concern linked to the nature of the critical effects, in particular developmental neurotoxic or immunotoxic effects, which, in combination with the use patterns, amount to use that could still cause concern, ***such as high potential of risk to groundwater,*** even with very restrictive risk management measures;

Justification

Considering water resources protection by analogy to the regulation concerning the placing of plant protection products on the market (1107/2009) Annex II, 4, 3rd indent.

Amendment 63

Proposal for a regulation

Article 9 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) it is very persistent and very bioaccumulative according to the criteria set out in Annex XIII to Regulation (EC) No 1907/2006;

Justification

For reasons of consistency between the two regulations, the criteria for identifying candidates of substitution are aligned with the criteria for substances to be authorised under Regulation (EC) No 1907/2006 (REACH) (Article 57). Since the Agency (ECHA) will own the task of examining if an active substance fulfils any of the criteria, consistency between the two regulations is advisable.

Amendment 64

Proposal for a regulation

Article 9 – paragraph 1 – point d

Text proposed by the Commission

Amendment

d) it contains a significant proportion of non-active isomers; ***deleted***

Justification

Non-active isomers do not pose a danger to health or the environment. There is therefore no need to include them among substances that are candidates for substitution.

Amendment 65

Proposal for a regulation

Article 9 – paragraph 1 – point e

Text proposed by the Commission

(e) it is classified or meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, mutagen category 1A or 1B or toxic for reproduction category 1A or 1B;

Amendment

(e) it is classified or meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as **respiratory sensitisers**, carcinogen category 1A or 1B, mutagen category 1A or 1B or toxic for reproduction category 1A or 1B;

Amendment 66

Proposal for a regulation

Article 9 – paragraph 1 – point f

Text proposed by the Commission

(f) it is considered to have endocrine disrupting properties that may cause adverse effect on humans on the basis of the assessment of *Community* or internationally agreed test guidelines or other available data.

Amendment

(f) it is considered to have endocrine disrupting properties that may cause adverse effect on humans **or the environment** on the basis of the assessment of *Union* or internationally agreed test guidelines or other available data; **or**

Amendment 67

Proposal for a regulation

Article 9 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) for the uses specified in the dossier of the active substance, an alternative authorised biocidal product or a non-chemical control or prevention method already exists which presents significantly lower risk for human or animal health or the environment.

Justification

In compliance with the substitution principle, a new Subparagraph g) should be added to Article 9, 1 This would also account for equal treatment of biocidal products that are already authorised and new active substances.

Amendment 68

Proposal for a regulation Article 9 – paragraph 2

Text proposed by the Commission

2. When preparing an opinion on the inclusion or renewal of the inclusion of an active substance in Annex I, the Agency shall examine whether the active substance fulfils any of the criteria listed in paragraph 1 and address the matter in its opinion.

Amendment

2. When preparing an opinion on the inclusion or renewal of the inclusion of an active substance in Annex I, the Agency shall examine whether the active substance fulfils any of the criteria listed in paragraph 1 **and whether exposure is not adequately controlled, bearing in mind the intrinsic hazards of the substance**, and shall address the matter in its opinion.

Amendment 69

Proposal for a regulation Article 9 – paragraph 4

Text proposed by the Commission

4. By way of derogation from Article 10(3), the inclusion of an active substance in Annex I that is considered as a candidate for substitution shall be renewed for a period not exceeding **ten years**.

Amendment

4. By way of derogation from **Article 4(1) and** Article 10(3), the inclusion of an active substance in Annex I that is considered as a candidate for substitution shall be **granted or** renewed for a period not exceeding **seven years**.

Justification

The inclusion period for substances that are candidates for substitution should be the same as in the PPP regulation.

Amendment 70

Proposal for a regulation Article 10 – paragraph 1

Text proposed by the Commission

1. The Commission shall renew the inclusion of an active substance in Annex I if the active substance still complies with

Amendment

1. The Commission shall renew the inclusion of an active substance in Annex I if the active substance still complies with

the requirements referred to in Article 4.

the requirements referred to in Articles 4
and 5.

Amendment 71

Proposal for a regulation Article 10 – paragraph 3

Text proposed by the Commission

3. Unless ***otherwise*** specified in the decision to renew the inclusion of an active substance in Annex I, the ***renewal shall*** be for ***an unlimited period of time***.

Amendment

3. Unless ***more strictly*** specified in the decision to renew the inclusion of an active substance in Annex I, the renewal ***may*** be ***renewed*** for a period ***not exceeding 10 years***.

Justification

Indefinite authorisations of new active substances will limit the incentive to conduct new research and provide new scientific data. In line with the current directive on biocides as well as the pesticides/plant protection legislation, there is a need for review of the active substances on a regular basis.

Amendment 72

Proposal for a regulation Article 11 – paragraph 4 - subparagraph 1

Text proposed by the Commission

4. 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.

Amendment

4. 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 time limit ***of up to two months*** for the submission of that information.

Justification

A set time limit is needed for the provision of documentation which should be as concise as possible in order to quickly proceed with evaluation.

Amendment 73

Proposal for a regulation
Article 12 – paragraph 5

Text proposed by the Commission

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).***

Amendment

5. In order to keep the list of authorised active substances updated, at the end of the period referred to in paragraph 3 or on receipt of the opinion of the Agency, the Commission shall adopt, ***by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c,*** a decision concerning a renewal of the inclusion of the active substance in Annex I.

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU

Amendment 74

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. In order to keep the list of authorised active substances updated, the Commission may review the inclusion of an active substance in Annex I at any time where there are indications that ***any of*** the requirements in ***Articles 4 and 5*** 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), Article 4(1)(b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may not be achieved.*** Where those indications are confirmed, the Commission shall adopt, ***by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c,*** a decision amending the inclusion of an active substance in Annex I or removing it from

that Annex.

Justification

Reference to the Water Framework Directive.

Amendment 75

Proposal for a regulation

Article 13 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

That decision, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 72(5).

deleted

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 76

Proposal for a regulation

Article 13 – paragraph 2

Text proposed by the Commission

Amendment

2. The Commission may consult the Agency on any questions of a scientific or technical nature related to the review of inclusion of an active substance in Annex I. The Agency shall, within **nine** months from the request, prepare an opinion and submit it to the Commission.

2. The Commission may consult the Agency on any questions of a scientific or technical nature related to the review of inclusion of an active substance in Annex I. The Agency shall, within **six** months from the request, prepare an opinion and submit it to the Commission.

Justification

Amendment for sake of consistency since everywhere else in the proposal the limit for issuing an opinion by the Agency at the request of the Commission is six months.

Amendment 77

Proposal for a regulation Article 14 – title

Text proposed by the Commission

Amendment

Implementing measures

Detailed procedures for renewal and review

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 78

Proposal for a regulation Article 14 – paragraph 1

Text proposed by the Commission

Amendment

The Commission may adopt detailed measures ***for the implementation of Articles 10 to 13 of this Regulation specifying the procedures related to the renewal and review of an inclusion of an active substance in Annex I.***

In order to ensure the smooth functioning of the renewal and review procedures, the Commission may adopt ***further*** detailed measures ***by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c.***

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 79

Proposal for a regulation Article 14 – paragraph 2

Text proposed by the Commission

Amendment

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure

deleted

with scrutiny referred to in Article 72(4).

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 80

Proposal for a regulation

Article 15 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. Application for authorisation shall be made by, or on behalf of, the person who **shall** be responsible for the placing on the market of a biocidal product in a particular Member State or in the *Community*.

Amendment

2. Application for authorisation shall be made by, or on behalf of, the person who **will be the holder of the authorisation. The person may be, but is not necessarily, the person** responsible for the placing on the market of a biocidal product in a particular Member State or in the *Union*.

Justification

The person responsible for placing an authorised product on the market is not always the holder of the authorisation. The industry needs this flexibility in the supply chain. The regulation should make it clear that, where the applicant wishes to obtain authorisation for a frame formulation, he must submit a single application for authorisation to cover all products to be included in the formulation.

Amendment 81

Proposal for a regulation

Article 15 - paragraph 2 - subparagraph 2

Text proposed by the Commission

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').

Application for **Community** authorisation shall be submitted to the Agency.

Amendment

Application for authorisation shall be submitted to the Agency. ***When an applicant submits an application for national authorisation, that applicant***

shall, with the agreement of the Member State concerned on whose territory the national authorisation would be applicable, identify the evaluating competent authority in the application itself, as laid down in Article 22.

(Note: This amendment applies throughout the text. If adopted, reference to "receiving competent authority" is to be replaced by reference to "Agency" or "evaluating competent authority", as appropriate, throughout the text.)

Justification

The ECHA should conduct the initial validation of all applications.

Amendment 82

Proposal for a regulation

Article 15 – paragraph 2 – subparagraph 3 a (new)

Text proposed by the Commission

Amendment

A single application for authorisation may be made by the applicant for a group of products intended to be authorised under a frame formulation.

Justification

The industry needs this flexibility in the supply chain. The text should explicitly specify that in case the applicant would like to have an authorisation granted for a frame formulation, then one single application is to be made to cover all products intended to be part of the frame. Such a clarification does not currently appear in the text.

Amendment 83

Proposal for a regulation

Article 15 – paragraph 5 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

Infestation with harmful organisms shall be avoided by suitable measures of deterrence to banish or repel these

organisms. In addition, other precautionary steps have to be taken, such as proper warehousing of goods, compliance with hygiene standards and immediate disposal of waste. Only if these measures show no effect shall further steps be taken. Biocidal products that pose low risks for humans, animals and the environment shall always be used in preference to others. Biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress shall only be applied as a last resort.

Justification

Article 15 should be extended by a new Paragraph 1 to include regulations on the sustainable use of biocides.

Amendment 84

Proposal for a regulation

Article 15 – paragraph 5 – subparagraph 2 b (new)

Text proposed by the Commission

Amendment

Mandatory measures shall be established and implemented with a framework directive for Union action in order to achieve the sustainable professional use of biocidal products including the introduction of National Action Plans, integrated pest management, risk reduction measures and the promotion of alternatives.

*By ... *, the Commission shall submit a proposal to the European Parliament and the Council.*

** Please insert date two years after adoption of this Regulation.*

Amendment 85

Proposal for a regulation

Article 16 – paragraph 1 – point b – point iii

Text proposed by the Commission

(iii) it **has** no **unacceptable effects** itself or as a result of its residues, **directly or indirectly, on human** or animal health;

Amendment

(iii) it **has** no **immediate or delayed harmful effect on groundwater or on human health** itself or as a result of its residues, **including that of vulnerable groups**, or animal health, **directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Agency to assess such effects are available**;

Justification

It is unacceptable to speak of "unacceptable" effects when speaking about human health. In the context of the authorisation of plant protection products, the term "unacceptable" was only used in the context of environmental effects. The wording from the PPP regulation should be used here, all the more that it also includes cumulative and synergistic effects.

Amendment 86

Proposal for a regulation

Article 16 – paragraph 1 – point b – point iv – indent 2

Text proposed by the Commission

- contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil;

Amendment

- contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, **taking into account locations distant from its use following long-range environmental transportation**;

Justification

To be in line with the wording adopted for PPP.

Amendment 87

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 ***metabolites and*** residues of toxicological or environmental significance, which result from uses to be authorised, ***should*** be determined according to the relevant requirements in Annexes II and III;

Justification

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

Amendment 88

Proposal for a regulation

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

Commission proposal

Amendment

(da) where nanomaterials are used in that product, the risk to the environment and to health has been assessed separately.

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 89

Proposal for a regulation

Article 16 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) cumulative or synergistic effects.

Justification

Ensures a consistent protection of the environment and human health. It is necessary to comply with all relevant Community standards for the protection of the environment. This is also ensured with the Biocidal Products Directive 98/8/EC. In addition, the protection of vulnerable groups – like it is prescribed according to Regulation (EC) 1107/2009 concerning provisions on plant protection products - and combination effects should be taken into consideration.

Amendment 90

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.

Justification

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

Amendment 91

Proposal for a regulation

Article 16 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. The evaluation of the compliance of the biocidal product with the criteria set out in points (b) and (c) of paragraph 1 shall not take into account a substance contained in the biocidal product if it is present in a preparation at a concentration lower than any of the following:

(a) the applicable concentrations laid down in Article 3(3) of Directive 1999/45/EC;

(b) the concentration limit values laid down in Annex I to Directive 67/548/EEC;

(c) the concentration limit values laid down in Part B of Annex II to Directive 1999/45/EC;

(d) the concentration limit values laid down in Part B of Annex III to Directive 1999/45/EC;

(e) the concentration limit values laid down in an agreed entry in the classification and labelling inventory established under Title V of Regulation (EC) No 1272/2008;

(f) 0.1% weight by weight (w/w), if the substance meets the criteria in Annex XIII to Regulation (EC) No 1907/2006.

Justification

The aim is to avoid unnecessary animal testing by providing a clearer definition of the procedures for comparing existing information, while complying with the requirements of REACH with regard to the Chemical Safety Report thresholds.

Amendment 92

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission

3. An authorisation to place a low-risk biocidal product on the market shall be subject to compliance with the requirements of points (b), (c) and (d) of paragraph 1.

Amendment

3. An authorisation to place a low-risk biocidal product on the market ***can be granted only if the active substances are evaluated as low-risk active substances and included in Annex I (or a separate annex) in accordance with Articles 4 and 5. The authorisation*** shall be subject to compliance with the requirements of points (a), (b), (c) and (d) of paragraph 1.

Justification

The Commission's proposal does not guarantee any kind of evaluation on EU-level of low risk active substances. It is completely unclear what active substances a low-risk product can contain. In order to categorise anything as a low-risk product, it is crucial to know what it contains. Therefore, the active substances of a low risk product should as a very minimum be evaluated on an EU-level and be included on annex I in order for the product to be recognized as a low-risk product.

Amendment 93

Proposal for a regulation
Article 16 – paragraph 5 – point b a (new)

Text proposed by the Commission

Amendment

(ba) considered to have endocrine-disrupting properties;

Justification

Because of the health hazards of these substances, they should not be allowed in the hands of the general public

Amendment 94

Proposal for a regulation
Article 16 – paragraph 5 – point b b (new)

Text proposed by the Commission

Amendment

(bb) developmental neurotoxic or immunotoxic effects.

Amendment 95

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) elimination 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) elimination of one or more non-active substances;

(d) an alteration in percentage composition of one or more non-active substances;

(e) the replacement of one or more non-active substances by others presenting the same or lower risk.

Justification

A biocidal product may contain more than one active substance.

Amendment 96

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.

Justification

This guarantees uniform implementation of the Regulation.

Amendment 97

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 1 - introductory part

Text proposed by the Commission

Amendment

1. A biocidal product shall be considered a low-risk biocidal product if ***both*** the following conditions are fulfilled:

1. A biocidal product shall be considered a low-risk biocidal product ***if the active substances therein are included in Annex I and if all of*** the following conditions are fulfilled:

Justification

The Commission's proposal does not guarantee any kind of evaluation on EU-level of low risk active substances. It is completely unclear what active substances a low-risk product can contain. In order to categorise anything as a low-risk product, it is crucial to know what it contains. Therefore, the active substances of a low risk product should as a very minimum be evaluated on an EU-level and be included on annex I in order for the product to be recognized as a low-risk product.

Amendment 98

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 1 - point b a (new)

Text proposed by the Commission

Amendment

(ba) the cumulative effects of both active substances and non-active substances are taken into consideration and defined as low-risk.

Amendment 99

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 2 – point a

Text proposed by the Commission

Amendment

(a) it contains one or more **active** substances which fulfil the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII of Regulation (EC) No 1907/2006;

(a) it contains one or more substances which fulfil the criteria for being **a POP under Regulation (EC) No 850/2004**, persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII of Regulation (EC) No 1907/2006;

Amendment 100

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 2 – point c – introductory part

Text proposed by the Commission

Amendment

(c) it contains one or more active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as or which *meets* the criteria to be classified as one of the following:

(c) it contains one or more active substances which **are substances of concern or which** have been classified in accordance with Regulation (EC) No 1272/2008 as or which *meet* the criteria to be classified as one of the following:

Justification

Definition in line with the regulation on PPP which stipulates that a low-risk product must not contain a substance of concern (Art. 47(1)(b)).

Amendment 101

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 2 – point c – point vi a (new)

Text proposed by the Commission

Amendment

(via) corrosive;

Amendment 102

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 2 – point c – point vi b(new)

Text proposed by the Commission

Amendment

(vib) very toxic or toxic.

Justification

It must be ensured that biocidal products of low-risk are of low-hazard.

Amendment 103

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) it contains a nanomaterial;

Justification

Based on current knowledge or lack thereof, a biocidal product containing nanomaterials disqualifies as low-risk.

Amendment 104

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 2 – point c b (new)

Text proposed by the Commission

Amendment

(cb) it is classified or meets the criteria to be classified in any category according to Regulation (EC) 1272/2008;

Amendment 105

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 2 – points c c (new)

Text proposed by the Commission

Amendment

(cc) it is explosive;

Amendment 106

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 2 – point c d (new)

Text proposed by the Commission

Amendment

(cd) it contains any substance of concern;

Amendment 107

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 2 – points c e (new)

Text proposed by the Commission

Amendment

(ce) it is highly flammable;

Amendment 108

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 2 – points c f (new)

Text proposed by the Commission

Amendment

cf) it is self-igniting at application temperature.

Amendment 109

Proposal for a regulation Article 17 – paragraph 2

Text proposed by the Commission

Amendment

2. Notwithstanding paragraph 1, a biocidal product shall be considered a low-risk biocidal product if the active substances in the biocidal product are contained in such way that only a negligible exposure can take place under normal conditions of use and the product is handled under strictly controlled conditions during all other stages of its lifecycle.

deleted

Justification

A product cannot fall into a low-risk product category if it does not fulfil the criteria given in the articles above

Amendment 110

Proposal for a regulation Article 18 - paragraph 1 - point d a (new)

Commission proposal

Amendment

(da) if the active substance contained in a low-risk biocidal product has been included in Annex I, a letter of access if the appropriate protection period for information according to Article 49 has not expired.

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 111

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.

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 112

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.

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 113

Proposal for a regulation Article 19 – paragraph 1

Text proposed by the Commission

Amendment

1. Notwithstanding Article 18, the applicant need not provide data required under that Article if any of the following grounds applies:

deleted

a) the information is not necessary owing to the exposure associated with the proposed uses;

b) it is not scientifically necessary to supply the information;

c) it is not technically possible to supply the information.

Amendment 114

Proposal for a regulation Article 19 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Amendment

2. The applicant may propose to adapt the data required under Article 18 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with reference to the specific rules in Annex IV.

deleted

Amendment 115

Proposal for a regulation Article 19 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Amendment

3. The Commission shall adopt the measures designed to set the criteria

3. In order to define what constitutes adequate justification to adapt the data

defining what constitutes adequate justification to adapt the data required under Article 18 on the ground referred to in paragraph 1(a).

required under Article 18 on the ground referred to in paragraph 1(a), ***the Commission shall adapt the criteria by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c.***

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 116

Proposal for a regulation

Article 19 – paragraph 3 – subparagraph 2

Text proposed by the Commission

Amendment

Those measures 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).

deleted

Amendment 117

Proposal for a regulation

Article 20 - paragraph 2 - point e

Commission proposal

Amendment

(e) qualitative and quantitative composition in terms of the active substances and non-active substances, ***knowledge of which is essential*** for proper use of the biocidal product;

(e) qualitative and quantitative composition in terms of the active substances and non-active substances, ***taking account of the concentration limits in Article 16(2b) and in so far as this information is required*** for proper use of the biocidal product;

Justification

A restriction should help minimise the disclosure of confidential information.

Amendment 118

Proposal for a regulation
Article 20 – paragraph 2 – point o a (new)

Text proposed by the Commission

Amendment

oa) for toxicologically and ecotoxicologically relevant components of biocidal products and/or residues thereof, analytical methods including recovery rates and the limits of determination (LOD).

Amendment 119

Proposal for a regulation
Article 20 – paragraph 3 – point a

Text proposed by the Commission

Amendment

a) the reference biocidal product within the group of products comprising the frame formulation *that has the highest allowed concentration of the active substances*;

a) the reference biocidal product within the group of products comprising the frame formulation;

Justification

Reference biocidal products are not necessarily defined by the highest concentration. In addition, further to the amendments to Articles 3(1)(p) and 16(6), more than one reference biocidal product may be permitted. The list of accepted variations within a frame formulation is already clearly set out in Article 16(6). Reference to this article will ensure a consistent approach.

Amendment 120

Proposal for a regulation
Article 20 – paragraph 3 – point b

Text proposed by the Commission

Amendment

b) the permitted alteration of the composition of this reference biocidal product expressed *in* percentage of the non-active substances contained in the biocidal products which are considered to belong to that frame formulation;

b) the permitted alteration of the composition of this reference biocidal product expressed *as a reduction in the* percentage of the *active substance(s) or as an alteration in the percentage of the* non-active substances contained in the biocidal products which are considered to belong to

that frame formulation;

Justification

Paragraph 3(b) should be fully consistent with Article 16(6), i.e. '...in the case of a frame formulation, a reduction in the percentage of the active substance in the reference biocidal product may be allowed'. The content of the authorisation should therefore reflect this possibility.

Amendment 121

Proposal for a regulation

Article 20 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. In the case of a frame formulation, one single authorisation number shall be provided for all biocidal products which belong to that frame.

Justification

A new paragraph is needed to specify that in case of an authorised frame a single authorisation number will be provided for all products belonging to that frame. No such clarification currently exists in the BPR proposal.

Amendment 122

Proposal for a regulation

Article 21 – paragraph 1

Text proposed by the Commission

Amendment

1. The receiving competent authority or, in the case of evaluation of an application for a *Community* authorisation, the evaluating competent authority shall perform a comparative assessment as part of the evaluation of an application for an authorisation or a renewal of an authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 9(1).

1. The receiving competent authority or, in the case of evaluation of an application for a *Union* authorisation, the evaluating competent authority shall perform a comparative assessment as part of the evaluation of an application for an authorisation or a renewal of an authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 9(1). ***The comparative assessment must be carried out in relation***

to all biocidal products having the same purpose, when sufficient experience has been gained in their use and they have been in use for at least five years.

Justification

The aim is to provide a clearer definition of how the comparative assessment should be carried out. One element to be taken into consideration is the need for sufficient experience in the use of the product. This should be the rule and not the exception.

Amendment 123

Proposal for a regulation

Article 21 – paragraph 3– point a

Text proposed by the Commission

Amendment

(a) for the uses specified in the application, ***another*** authorised biocidal ***product or a non-chemical control or prevention method*** already ***exists*** which ***presents*** significantly lower risk for human or animal health or the environment;

(a) for the uses specified in the application, ***other*** authorised biocidal ***products*** already ***exist*** which ***present*** significantly lower risk for human or animal health or the environment ***and which prove equally effective and involve no significant increase in the risks for any other parameter;***

Amendment 124

Proposal for a regulation

Article 21 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The Commission shall, on the basis of paragraph 3, adopt measures laying down the procedure necessary for the definition of an application for comparative assessment of biocidal products. These measures shall define the criteria and algorithms to be used in a comparative assessment to ensure that

there is a uniform application throughout the Union.

Justification

An application for comparative assessment should, as the rule and not the exception, take account of experience from use of the product in practice. An application for comparative assessment should therefore be confined to the renewal of authorisations for those products which contain active substances that have been identified as candidates for substitution in accordance with Article 9.

Amendment 125

Proposal for a regulation

Article 21 – paragraph 5 – subparagraph 2

Text proposed by the Commission

The Commission shall adopt implementing rules specifying the procedures related to comparative assessments involving questions of Community interest. Those rules, 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).

Amendment

In order to specify the procedures related to comparative assessments involving questions of Union interest, the Commission shall adapt the criteria by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c.

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 126

Proposal for a regulation

Article 21 – paragraph 6

Text proposed by the Commission

6. Notwithstanding Article 15(4), an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted

Amendment

6. Notwithstanding Article 15(4), an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted

for *a period* not exceeding five years.

for *periods* not exceeding five years.

Justification

As long as essential and viable biocidal products exist based on active substances that are candidates for substitution, the renewal of their authorisation should be allowed, and not be limited to a one-off renewal period of maximum five years.

Amendment 127

Proposal for a regulation

Article 21 – paragraph 6 - subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Member States shall establish and implement a substitution plan in order to ensure that the application of the relevant biocidal product is phased out within the authorisation period and that the relevant active substance or product can be replaced with chemical or non-chemical sound alternatives.

Amendment 128

Proposal for a regulation

Article 21 – paragraph 7

Text proposed by the Commission

Amendment

7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or amendment of the authorisation shall take effect ***five years*** after the decision or at the end of the inclusion period of the candidate for substitution, whichever is the earlier.

7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or amendment of the authorisation shall take effect ***three years*** after the decision or at the end of the inclusion period of the candidate for substitution, whichever is the earlier.

Justification

It is unacceptable to allow a biocidal product to stay on the market for another five years when better alternatives are available. The same timeline as agreed in the PPP regulation should apply.

Amendment 129

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:

(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.

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 Union 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 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.

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 130

Proposal for a regulation Article 22 – paragraph 2

Text proposed by the Commission

2. If the receiving competent authority

Amendment

2. Within three weeks after the receipt of

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.

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 131

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 *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 132

Proposal for a regulation

Article 22 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. An applicant may, in accordance with Article 67, submit an appeal against the decision of the Agency under the third subparagraph of paragraph 3.

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 133

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 to that effect.

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 134

Proposal for a regulation

Article 23 – paragraph 1

Text proposed by the Commission

Amendment

1. The receiving competent authority shall, within **twelve months** after the validation referred to in Article 22, decide on the application in accordance with Article 16.

1. The receiving competent authority shall, within **six months** after the validation referred to in Article 22, decide on the application in accordance with Article 16.

Justification

Given the fact that, before being included in Annex I to the regulation, active substances used in biocidal products are already subject to lengthy assessment, it is felt that the period of twelve months provided for in the proposal for a regulation is too long for the authorisation of a biocidal product based on authorised active substances.

Amendment 135

Proposal for a regulation

Article 24 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. The authorisation holder or its representative shall submit an application for renewal of a national authorisation to the receiving competent authority at least **18 months** before the expiry date of the authorisation.

Amendment

1. The authorisation holder or his representative shall submit an application for renewal of a national authorisation to the receiving competent authority at least **12 months** before the expiry date of the authorisation.

Justification

12 months would be a more appropriate length of time for the renewal of an authorisation.

Amendment 136

Proposal for a regulation
Article 25 – paragraph 3

Text proposed by the Commission

3. The receiving competent authority may require a translation of the national authorisation and application into one **or several** of the official languages of the Member State where that competent authority is situated.

Amendment

3. The receiving competent authority may require a translation of the national authorisation and application into one of the official languages of the Member State where that competent authority is situated.

Applications for a national authorisation which involve a mutual recognition procedure may be submitted to the competent authority in English, including the documents referred to in Article 18(1).

Justification

The possibility of requiring translations in more than one official language (in cases where there are more than 1 in a given Member State) could place an unnecessary financial and administrative burden on the applicant.

Amendment 137

Proposal for a regulation Article 25 – paragraph 5

Text proposed by the Commission

5. The receiving competent authority shall authorise the biocidal product concerned under the same conditions as the reference competent authority.

Amendment

5. The receiving competent authority shall authorise the biocidal product concerned under the same conditions as the reference competent authority, ***unless specific national circumstances justify a deviation according to Article 29.***

A single authorisation number shall be used in all the Member States involved.

Justification

To simplify matters, a single authorisation number should be assigned in all Member States in the case of products for which a mutual recognition procedure has been followed.

Amendment 138

Proposal for a regulation Article 25 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. The Commission shall adopt, by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c, measures specifying the criteria and procedures for assigning the single authorisation number referred to in paragraph 5 of this Article.

Amendment 139

Proposal for a regulation Article 27 – paragraph 1 – subparagraph 2

Text proposed by the Commission

The Commission shall adopt a decision on whether the grounds set out by the

Amendment

The Commission shall, ***after consultation with the applicant,*** adopt a decision on

competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

Within three months of receiving the notification, the Commission shall make a proposal for a decision. Should the Commission ask the Agency for an opinion under the procedure set out in Article 30, the three-month period shall be suspended until the Agency has forwarded its opinion.

Justification

The regulation should set out the time period for the resolution of disputes between Member States. A period of three months is thought to be adequate to enable the Commission to draw up a proposal for a decision to refuse to recognise or to restrict the authorisation.

Amendment 140

Proposal for a regulation

Article 28 – paragraph 8 - subparagraphs 1 a (new)

Text proposed by the Commission

Amendment

A single authorisation number shall be used in all the Member States involved.

Justification

To simplify matters, a single authorisation number should be assigned in all Member States in the case of products for which a mutual recognition procedure has been followed.

Amendment 141

Proposal for a regulation

Article 28 – paragraph 8 – subparagraph 1 b (new)

Text proposed by the Commission

Amendment

The Commission shall adopt, by means of delegated acts in accordance with Article

71 a and subject to the conditions of Articles 71 b and 71 c, delegated actsspecifying the criteria and procedures for assigning the single authorisation number referred to in subparagraph 1a.

Amendment 142

Proposal for a regulation

Article 28 – paragraph 9 – subparagraph 2

Text proposed by the Commission

The Commission shall adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

Amendment

The Commission shall, ***following consultation of the applicant***, adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

Amendment 143

Proposal for a regulation

Article 28 – paragraph 9 – subparagraph 3

Text proposed by the Commission

If the Commission decision ***dismisses*** the grounds presented for refusing or restricting the ***national*** authorisation the competent authority that ***proposed to refuse to recognise the authorisation, or to restrict the authorisation***, shall without delay ***authorise the biocidal product concerned in accordance with the national authorisation issued by the reference competent authority***.

Amendment

If the Commission decision ***confirms*** the grounds presented for refusing or restricting the ***subsequent*** authorisation, the competent authority that ***had previously authorised the biocidal product*** shall without delay ***review its national authorisation to comply with that decision***.

If the Commission decision confirms the initial national authorisation, the competent authority that proposed to refuse to recognise a national authorisation, or to recognise the national authorisation subject to certain conditions, shall without delay authorise

***the biocidal product concerned in
accordance with the initial authorisation.***

Justification

This current wording only presents the option whereby the Commission dismisses the grounds for refusal but not the case where the Commission agrees with these, as is correctly presented in paragraph 2 of Article 27 - same wording has been applied here as well.

Amendment 144

Proposal for a regulation

Article 29 – paragraph 1 – subparagraph 1 - introductory part

Text proposed by the Commission

1. The competent authority that has received an application for mutual recognition in accordance with Articles 25 or 28 may, within two months from the receipt of the application, propose to the applicant that certain conditions referred to in points (e), (f), (h), (j) and (l) of Article 58(2) in the authorisation be adjusted to local circumstances, so that conditions for issue of an authorisation laid down in Article 16 are satisfied, and shall inform the Commission thereof, if it establishes that, in its territory, one of the following conditions is met:

Amendment

1. The competent authority that has received an application for mutual recognition in accordance with Articles 25 or 28 may, within two months from the receipt of the application, propose to the applicant that certain conditions referred to in points (**d**), (e), (f), (h), (j), (**k**) and (l) of Article 58(2) in the authorisation be adjusted to local circumstances, so that conditions for issue of an authorisation laid down in Article 16 are satisfied, and shall inform the Commission thereof, if it establishes that, in its territory, one of the following conditions is met:

Justification

In line with the PPP regulation, Member States should also be allowed to adjust the uses of the biocides (Article 58(2)(d)) and the categories of users (Article 58(2)(k)).

Amendment 145

Proposal for a regulation

Article 29 – paragraph 1 – subparagraph 1 – point c

Text proposed by the Commission

(c) the relevant circumstances of use, in particular the climate or the breeding period of the target species, differ

Amendment

(c) the relevant circumstances of use, in particular the climate or the breeding period of the target species, differ

significantly from those in the Member State where the initial evaluation was carried out or the Member State where the initial national authorisation was issued, ***and an unchanged national authorisation may therefore present unacceptable risks to humans or to the environment.***

significantly from those in the Member State where the initial evaluation was carried out or the Member State where the initial national authorisation was issued.

Justification

Member States should be allowed to adjust to local circumstances whenever the climate or the breeding period differs significantly. This is even more strict than the PPP regulation, which allows for national adjustments without any conditions (see Article 36(3) of the PPP regulation).

Amendment 146

Proposal for a regulation

Article 29 – paragraph 1 – subparagraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) an unchanged national authorisation may present harmful effects on human health or unacceptable effects on the environment.

Justification

In the PPP regulation, there are no conditions for the adjustment of authorisations to local circumstances. As such, it should be possible for Member States to adjust in general in case they consider that an unchanged national authorisation would present harmful effects on human health or unacceptable effects on the environment.

Amendment 147

Proposal for a regulation

Article 29 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Subject to Union law, appropriate conditions may be imposed with respect to the requirements referred to in Article 15 and other risk-mitigation measures deriving from specific conditions of use.

Justification

Additional measures to reduce the risk to humans and the environment with regard to the use of biocides, in the light of specific circumstances in a Member State.

Amendment 148

Proposal for a regulation

Article 29 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The Commission shall adopt a decision on the proposed adjustment of the conditions of the national authorisation to local circumstances in accordance with the procedure referred to in Article 72(3). The competent authority of the concerned Member State shall without delay adopt all appropriate measures to comply with that decision.

Amendment

The Commission shall, ***after consultation with the applicant***, adopt a decision on the proposed adjustment of the conditions of the national authorisation to local circumstances in accordance with the procedure referred to in Article 72(3). The competent authority of the concerned Member State shall without delay adopt all appropriate measures to comply with that decision.

Amendment 149

Proposal for a regulation

Article 29 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(2a) Within three months of receiving the notification, the Commission shall make a proposal for a decision. Should the Commission ask the Agency for an opinion under the procedure set out in Article 30, the three-month period shall be suspended until the Agency has forwarded its opinion.

Justification

The regulation should set out the time period for the resolution of disputes between Member States. Three months is an adequate period of time for the Commission to make a proposal for a decision setting out the grounds for recognising or not recognising authorisations.

Amendment 150

Proposal for a regulation Article 31 – title

Text proposed by the Commission

Amendment

Derogation regarding certain product-types

Derogation regarding certain **active substances or** product-types

((Linked to the amendment of Article 31.))

Justification

Member States should be allowed to refuse mutual recognition for substances that fall under the exclusion criteria and for substances that are candidates for substitution.

Amendment 151

Proposal for a regulation Article 31

Text proposed by the Commission

Amendment

By way of derogation from **Articles 25 and 28**, competent authorities of Member States may refuse mutual recognition of national authorisations granted for product types 15, 17 and 23 of Annex V provided that such a refusal can be justified on grounds of the protection of health of humans, animals or plants, the protection of national treasures possessing artistic, historic or archaeological value, or the protection of industrial and commercial property. Competent authorities of Member States shall without delay inform each other and the Commission of any decision taken in this respect and shall indicate the reasons thereof.

By way of derogation from **Articles 25 - 29**, competent authorities of Member States may refuse mutual recognition of national authorisations granted for **active substances referred to in Articles 5 and 9 and for** product types 15, 17 and 23 of Annex V provided that such a refusal can be justified on grounds of the protection of health of humans, **particularly of vulnerable groups, the protection of the health of** animals or plants, the protection of **environment**, national treasures possessing artistic, historic or archaeological value, or the protection of industrial and commercial property. Competent authorities of Member States shall without delay inform each other and the Commission of any decision taken in this respect and shall indicate the reasons thereof.

Justification

Member States should be allowed to refuse mutual recognition for substances that fall under the exclusion criteria and for substances that are candidates for substitution.

Amendment 152

Proposal for a regulation

Article 33 – paragraph 1

Text proposed by the Commission

Amendment

1. The <i>Community</i> authorisation may be granted to <i>the following categories</i> of biocidal products:	The <i>Union</i> authorisation may be granted to <i>any category</i> of biocidal products.
<i>(a) biocidal products containing one or more new active substances;</i>	
<i>(b) low-risk biocidal products.</i>	

Justification

A centralised authorisation system has clear benefits for the functioning of the internal market by ensuring consistent assessments and a harmonised implementation of the requirements in all Member States, driving best practices and same standards of consumer protection across Europe. The Community authorisation procedure should therefore extend to all product categories instead of only a small minority of products (low risk biocidal products and products with new active substances).

Amendment 153

Proposal for a regulation

Article 33 – paragraph 1a (new)

Text proposed by the Commission

Amendment

1a. A Union authorisation may not be granted for biocidal products that contain active substances that fall under Articles 5 or 9.

Amendment 154

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).

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 155

Proposal for a regulation Article 33 a (new)

Text proposed by the Commission

Amendment

Article 33a

Biocidal products with similar conditions of use

In accordance with point (ba) of Article 33(1), a product shall be considered a biocidal product with similar use conditions if all of the following criteria are met:

(a) it has similar conditions of use across

the Union, according to use instructions;

(b) it has already been placed or is intended to be placed on the market in at least [...] Member States within two years of the authorisation being granted;

The Commission shall, by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c, define or adapt the number of Member States referred to in point (b). The number of Member States shall not be reduced by more than two every two years.

Justification

The criteria are based on the targeted and consistent application and use of those types of products across the EU (number of Member States to be specified), as well as their positive contribution to human and animal safety protection. Annex VI lays down the principles for the evaluation of dossiers for biocidal products to ensure a harmonised high level of protection for humans and the environment. This involves detailed risk assessment of products during their use.

Amendment 156

Proposal for a regulation

Article 35 – paragraph 3 – subparagraph 1

Text proposed by the Commission

(3) Within **nine** 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.

Amendment

(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.

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 157

Proposal for a regulation
Article 35 - paragraph 4 - subparagraph 2

Text proposed by the Commission

The *Commission may, on the request of a Member State, decide that the Community authorisation shall not apply in the territory of that Member State* for a biocidal product of the product-types 15, 17 or 23 of Annex V *provided that such a request can* be justified on grounds of the protection of health *of humans*, animals *or* plants, *the protection of* national treasures possessing artistic, historic or archaeological value, *or the protection of* industrial and commercial property.

Amendment

The Member State *shall notify the Commission where it restricts or prohibits* the *Union* authorisation for a biocidal product of the product-types 15, 17 or 23 of Annex V *in the territory of that Member State. Such restriction or prohibition must* be justified on grounds of the protection of:

- (a) human health, particularly that of vulnerable groups,*
- (b) the environment, particularly vulnerable ecosystems,*
- (c) animals,*
- (d) plants,*
- (e) national treasures possessing artistic, historic or archaeological value, or*
- (f) industrial and commercial property.*

Amendment 158

Proposal for a regulation
Article 35 - paragraph 4 - subparagraph 3

Text proposed by the Commission

The Commission *may, on the request of a Member State, decide that certain conditions of the Community* authorisation should be adjusted to the different local circumstances in that Member State in accordance with Article 29.

Amendment

A Member State shall inform the Commission if it decides that the *Union* authorisation should be adjusted to the different local circumstances in that Member State in accordance with Article 29.

Amendment 159

Proposal for a regulation

Article 36 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. The authorisation holder or his representative shall submit an application for renewal of a *Community* authorisation to the Agency at least **18 months** before the expiry date of the authorisation.

Amendment

1. The authorisation holder or his representative shall submit an application for renewal of a *Union* authorisation to the Agency at least **12 months** before the expiry date of the authorisation.

Justification

Unless there is new data to evaluate, 18 months is not necessary to renew an authorisation of a product. 12 months would be a more appropriate time frame.

Amendment 160

Proposal for a regulation

Article 37 – paragraph 2 - subparagraph 1

Text proposed by the Commission

2. If the evaluating competent authority that carried out the initial evaluation of the application for *Community* authorisation decides that a full evaluation of the application is not necessary, it shall, within **twelve months** after the validation, prepare and submit to the Agency a recommendation on the renewal of the authorisation.

Amendment

2. If the evaluating competent authority that carried out the initial evaluation of the application for *Union* authorisation decides that a full evaluation of the application is not necessary, it shall, within **six months** after the validation, prepare and submit to the Agency a recommendation on the renewal of the authorisation.

Justification

In Article 12.2 for renewal of inclusion of active substance in Annex I, when full evaluation is not necessary it is required that the evaluating authority issues a recommendation for renewal in 6 months not 12.

Amendment 161

Proposal for a regulation

Article 38 – paragraph 1 – point a

Text proposed by the Commission

(a) new knowledge or information on the effects of the active substance or biocidal product for humans or the environment;

Amendment

(a) new knowledge or information on the effects of the active substance or biocidal product for humans or the environment, ***especially effects on vulnerable groups;***

Amendment 162

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.

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 163

Proposal for a regulation

Article 39 - paragraph 1 - point a

Text proposed by the Commission

Amendment

(a) the requirements referred to in Article 16 ***are not satisfied;***

(a) ***where there is failure to comply with the requirements referred to in Article 16 or Union standards for the protection of human health and the environment, particularly laid down in Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive)¹, Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration², Directive 2000/60/EC, Directive 98/83/EC and Council Directive 96/61/EC of 24***

September 1996 concerning integrated pollution prevention and control³;

¹ OJ L 164, 25.6.2008, p. 19.

² OJ L 372, 27.12.2006, p. 19.

³ OJ L 257, 10.10.1996, p. 26.

Amendment 164

Proposal for a regulation

Article 39 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) there are indications that the objectives of Article 4(1)(a)(iv), Article 4(1)(b)(i) and Article 7(2) and (3) of Directive 2000/60/ may not be achieved.

Justification

Analogous to the rapporteur's Amendment 39. In addition to revision of the inclusion of an active substance in Annex I, an indication (from practical measurements) that the aims of the Water Framework Directive are jeopardised must also be grounds for cancelling or amending the authorisation of a biocidal product.

Amendment 165

Proposal for a regulation

Article 42 – title

Text proposed by the Commission

Amendment

Implementing measures

Detailed procedures on cancellation and amendments

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 166

Proposal for a regulation

Article 42 – paragraph 1

Text proposed by the Commission

Amendment

The Commission shall adopt **implementing** measures specifying the criteria and procedures related to a cancellation of an authorisation or amendments of the terms and conditions of an authorisation under Articles 39 to 41, including a dispute settlement mechanism.

In order to ensure the smooth functioning of the cancellation and amendment procedures, the Commission shall adopt ***further detailed*** measures specifying the criteria and procedures related to a cancellation of an authorisation or amendments of the terms and conditions of an authorisation under Articles 39 to 41, including a dispute settlement mechanism, ***by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c.***

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 167

**Proposal for a regulation
Article 42 – paragraph 2**

Text proposed by the Commission

Amendment

Those measures, 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).

deleted

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 168

**Proposal for a regulation
Article 44 – paragraph 1 – subparagraph 1**

Text proposed by the Commission

1. A competent authority of a Member State (hereinafter referred to as 'Member State of introduction') may grant a parallel trade permit for a biocidal product that is authorised in another Member State (hereinafter referred to as 'Member State of origin') to be placed on the market and used in the Member State of introduction, if it determines that the biocidal product is **substantially** identical in composition to a biocidal product already authorised in that Member State (hereinafter referred to as 'the reference product').

Amendment

1. A competent authority of a Member State (hereinafter referred to as 'Member State of introduction') may grant a parallel trade permit for a biocidal product that is authorised in another Member State (hereinafter referred to as 'Member State of origin') to be placed on the market and used in the Member State of introduction, if it determines that the biocidal product is identical in composition to a biocidal product already authorised in that Member State (hereinafter referred to as 'the reference product').

(The deletion of the word "substantially" is a horizontal amendment. Adopting it will necessitate corresponding changes throughout the text.)

Justification

In order to find an appropriate balance between free trade of goods and a safe market then this article on parallel trade should be limited to identical products based on the same specification and content of active substances and co-formulants.

Amendment 169

Proposal for a regulation

Article 44 – paragraph 3 – introductory part

Text proposed by the Commission

3. A biocidal product shall be considered as **substantially** identical to the reference product if **one** of the following conditions **is** met:

Amendment

3. A biocidal product shall be considered as identical to the reference product if **all** of the following conditions **are** met:

Justification

In order to find an appropriate balance between free trade of goods and a safe market then this article on parallel trade should be limited to identical products based on the same specification and content of active substances and co-formulants.

Amendment 170

Proposal for a regulation

Article 44 – paragraph 3 – point a

Text proposed by the Commission

(a) ***the source of the active substances it contains is the same in terms of manufacturer and location of the production plant;***

Amendment

(a) ***it has been manufactured by the same company or by an associated undertaking or under licence in accordance with the same manufacturing process;***

Justification

In order to find an appropriate balance between free trade of goods and a safe market then this article on parallel trade should be limited to identical products based on the same specification and content of active substances and co-formulants.

Amendment 171

Proposal for a regulation

Article 44 – paragraph 3 – point b

Text proposed by the Commission

(b) it is ***either the same or similar*** with regard to the ***non-active*** substances ***present*** and the type of formulation;

Amendment

(b) it is ***identical*** with regard to the ***specification and content of the active*** substances and ***in*** the type of formulation;

Justification

In order to find an appropriate balance between free trade of goods and a safe market then this article on parallel trade should be limited to identical products based on the same specification and content of active substances and co-formulants.

Amendment 172

Proposal for a regulation

Article 44 – paragraph 3 – point c

Text proposed by the Commission

(c) it is either the same or equivalent in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the

Amendment

(c) it is either the same or equivalent ***with regard to the co-formulants present and the packaging size, material or form,*** in terms of the potential adverse impact on

environment.

the safety of the product with regard to human or animal health or the environment.

Justification

In order to find an appropriate balance between free trade of goods and a safe market then this article on parallel trade should be limited to identical products based on the same specification and content of active substances and co-formulants.

Amendment 173

Proposal for a regulation

Article 44 – paragraph 4 – point a (new)

Text proposed by the Commission

Amendment

(aa) the registration numbers of the active substances contained in the product and a letter of access in accordance with Article 50 from the applicant referred to in Article 7;

Justification

The application for a parallel trade licence must also contain the number of registrations for the active substances.

Amendment 174

Proposal for a regulation

Article 44 – paragraph 4 – point c

Text proposed by the Commission

Amendment

(c) name and address of the authorisation holder in the Member State of origin;

(c) name and address of the authorisation holder in the Member State of origin ***and a letter of access in accordance with Article 50 from the authorisation holder;***

Justification

The application for a parallel trade licence must also contain information relating to the letter of access, as indicated in Article 50.

Amendment 175

Proposal for a regulation

Article 45 - paragraph 1 - subparagraph 1

Text proposed by the Commission

1. By way of derogation from Articles 15 and 16, a competent authority may authorise for a period not exceeding **nine months**, the placing on the market of a biocidal product not complying with the provisions of this Regulation for a limited and controlled use if such a measure is necessary because of a danger to public health or the environment which cannot be contained by other means.

Amendment

1. By way of derogation from Articles 15 and 16, a competent authority may authorise for a period not exceeding **four months**, the placing on the market of a biocidal product not complying with the provisions of this Regulation for a limited and controlled use if **all of the following conditions are met:**

(a) such a measure is necessary because of a danger to public health or the environment which cannot be contained by other means;

(b) **the active substances concerned are approved for inclusion into Annex I or evaluated according to Article 4 of this Regulation and a full dossier is provided;**

(c) **if the relevant active substances are classified as cut-off substances or candidates for substitution, a mandatory substitution plan is established and implemented by the applicant or competent authority in order to replace the relevant substances with non-hazardous chemical or non-chemical alternatives within two years of the date of approval; and**

(d) **the application of the product is restricted to professional users who are certified pursuant to the requirements for an integrated pest management and the use is appropriately monitored.**

Amendment 176

Proposal for a regulation
Article 45 - paragraph 2

Text proposed by the Commission

Amendment

*(2) By way of derogation from point (a) **deleted**
Article 16(1) and until an active substance
is listed in Annex I, competent authorities
and the Commission may authorise, for a
period not exceeding three years, the
placing on the market of a biocidal
product containing a new active substance
not listed in Annex I.
Such an authorisation may be issued only
if, after dossiers have been evaluated in
accordance with Article 8, the evaluating
competent authority has submitted a
recommendation for inclusion of the new
active substance in Annex I and the
competent authority which received the
application for the provisional
authorisation or in case of Community
authorisation, the Agency, considers that
the biocidal product may be expected to
comply with points (c) and (d) of Articles
16(1).*

*The competent authorities or the
Commission shall enter the information
on the authorisation referred to in Article
23(5) in the Community Register of
Biocidal Products.*

*If the Commission decides not to include
an active substance in Annex I, the
competent authority which granted an
authorisation referred to in the first
subparagraph or the Commission shall
cancel that authorisation.*

*Where a decision on the inclusion of an
active substance in Annex I has not yet
been adopted by the Commission when
the period of three years expires, the
competent authority which granted a
provisional authorisation, or the*

*Commission, may extend the provisional
authorisation for a period not exceeding
one year, provided there are good reasons*

to believe that the active substance will satisfy the requirements of Article 4. Competent authorities which extended the provisional authorisation shall inform the other competent authorities and, where appropriate, the Commission of such action.

Amendment 177

Proposal for a regulation Article 46 – paragraph 2

Text proposed by the Commission

2. An unauthorised biocidal product or an active substance for exclusive use in a biocidal product shall not be placed on the market for the purpose of any experiment or test which may involve, or result in, release of the biocidal product into the environment unless the competent authority has assessed the data submitted by the person interested in the placing of such product on the market and ***issued a national authorisation*** for this purpose ***which limits the quantities to be used and the areas to be treated and*** which may impose further conditions. The competent authority ***shall without delay inform the Commission and other competent authorities about the issued national authorisation.***

Amendment

2. An unauthorised biocidal product or an active substance for exclusive use in a biocidal product shall not be placed on the market for the purpose of any experiment or test which may involve, or result in, release of the biocidal product into the environment unless the competent authority has assessed the data submitted by the person interested in the placing of such product on the market and ***delivered a favourable opinion*** for this purpose which may impose further conditions. ***If the competent authority fails to deliver an opinion within 30 days after notification of the information required in paragraph 1, the biocidal product or active substance may be placed on the market for the purposes of the notified experiment or test.***

Justification

Under the Commission proposal, a test on an unauthorised biocidal product for research and development purposes which involved the release of the product into the environment would require prior national authorisation. The time required in order to obtain it could hamper innovation. It is proposed instead that a fifteen-day period be set to allow the authority to assess whether the proposed test gives rise to any concern and to deliver its opinion.

Amendment 178

Proposal for a regulation

Article 46 – paragraph 3 – subparagraph 2

Text proposed by the Commission

If the proposed experiments or tests referred to in paragraphs 1 and 2 may have harmful effects on human or animal health or any unacceptable adverse effect on the environment, the competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The competent authority shall without delay inform the Commission and other competent authorities about such measures.

Amendment

If the proposed experiments or tests referred to in paragraphs 1 and 2 may have harmful effects, ***whether immediate or delayed*** on human ***health, in particular on the health of children***, or animal health or any unacceptable adverse effect on the environment, ***humans, or animals***, the competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The competent authority shall without delay inform the Commission and other competent authorities about such measures.

Justification

It would seem appropriate to highlight the fact that children are more vulnerable to harmful products than adults, on whom the proposal for a regulation is basing tolerance criteria. Children are often to be found - unbeknown to themselves - in places which have been sprayed with biocidal products and pesticides, and show reactions – immediately or in the longer term – which are directly or indirectly attributable to the harmful substances.

Amendment 179

Proposal for a regulation

Article 46 – paragraph 4 – subparagraph 1

Text proposed by the Commission

4. The Commission shall adopt measures 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 in accordance with paragraph 2.

Amendment

4. ***In order to encourage research and development in active substances and biocidal products***, the Commission shall adopt, ***by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c***, measures 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 in accordance with

paragraph 2.

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 180

Proposal for a regulation

Article 46 – paragraph 4 – subparagraph 2

Text proposed by the Commission

Amendment

Those measures 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).

deleted

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 181

Proposal for a regulation

Article 47 – paragraph 1

Text proposed by the Commission

Amendment

1. Treated materials or articles that incorporate one or more biocidal products shall not be placed on the market unless the **biocidal product(s)** used for treating the materials or articles are **authorised for this use in the Community or in at least one Member State**.

1. Treated materials or articles that incorporate one or more biocidal products shall not be placed on the market unless the **active substances** used for treating the materials or articles are **included in Annex I**.

Amendment 182

Proposal for a regulation

Article 47 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The person responsible for placing treated articles or materials on the market shall obtain a letter of certification by the authorisation holder in respect of all biocidal products which have been used in the treatment of those articles or materials or which have been inserted into the articles or materials.

Justification

Any person placing articles or materials treated with biocides on the market should also have a letter of certification listing all the biocides which have been used in the articles and materials.

Amendment 183

Proposal for a regulation

Article 47 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission

Amendment

(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;

(a) the words ***"treated with biocidal products"***, followed by the name, using wherever possible common nomenclature (e.g. INCI), of all active substances that were used to treat the article or materials or that were incorporated in the articles or materials, ***where relevant, and for all active substances which are intended to be released under normal or foreseeable conditions of use from the treated article or material, unless at least equivalent labelling requirements or alternative means to meet information requirements already exist under sector-specific legislation; the names of all nanomaterials followed by the word "nano" in brackets;***

Justification

The labelling provisions for treated articles and materials should not lead to requirements for unnecessary information and should not overlap with existing requirements under sectoral legislation. Existing sectoral legislation and their information requirements (e.g. labelling,)

should always be taken into consideration. E.g, under the Detergent Regulation, the INCI name of the preservative must be labelled on products for the general public and reported in the SDS for Institutional and Industrial products. Additional labelling requirements are therefore unnecessary.

Amendment 184

Proposal for a regulation

Article 47 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

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

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

Justification

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

Amendment 185

Proposal for a regulation

Article 47 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission

Amendment

c) ***the authorisation number of all biocidal products that were used for the treatment or were incorporated in the articles or materials***; ***deleted***

Justification

The inclusion of the authorisation number does not have any consumer safety benefits. On the contrary, a long list of authorisation numbers would arise as it is not uncommon to have multiple suppliers of one active substance. This would create confusion among consumer. For the purposes of enforcement by competent authorities, the authorisation number can be obtained through other means.

Amendment 186

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 is intended to be released under normal or reasonably foreseeable conditions of use.***

Justification

More stringent rules should apply to products which have an external biocidal effect. In this respect the wording of Article 47 needs to be clarified.

Amendment 187

Proposal for a regulation

Article 47 – paragraph 2 – subparagraphs 2 and 3

Text proposed by the Commission

The labelling shall be clearly visible, easily legible ***and*** appropriately durable.

Amendment

The labelling shall be clearly visible, easily legible, appropriately durable ***and*** printed ***on the article or material***, on the packaging, on the instructions for use or on the warranty of the treated article or material ***in the national language or languages of the Member State on whose market the treated article or material is to be placed.***

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.

In the case of treated materials or articles which are not produced as part of a series, but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the relevant information with the customer.

Justification

It should be clarified that treated articles and materials, as with other products, should always be labelled in the national language or languages of the Member State on whose market the product is placed. (The rapporteur has amended his proposed Amendment 37 of his draft opinion to take account of Member States with more than one national language.)

Amendment 188

Proposal for a regulation

Article 47 – paragraph 2 – subparagraph 3 a (new)

Text proposed by the Commission

Amendment

This paragraph shall apply unless such labelling requirements already exist under other Union legislation.

Amendment 189

Proposal for a regulation

Article 48 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(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,

(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,

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 190

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.

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 191

Proposal for a regulation

Article 48 – paragraph 4

Text proposed by the Commission

Amendment

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

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.

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 192

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

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 193

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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

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 194

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

Justification

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

Amendment 195

Proposal for a regulation Article 51 – paragraph 1

Text proposed by the Commission

Amendment

1. *In order to avoid* animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. Testing on vertebrate animals shall not be repeated for the purposes of this Regulation.

1. *Given that* animal testing *should be avoided*, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort *where no alternative solution can be employed without producing an impact on humans or animals*. Testing on vertebrate animals shall not be repeated for the purposes of this Regulation.

Justification

The regulation is aiming for a sustainable approach emphasising product safety and compatibility in terms of human and animal health and the environment.

Amendment 196

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.

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 197

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

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***

nature of impurities.

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.

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 198

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

Text proposed by the Commission

Amendment

-1. 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 substances referred to in Annex II or are in the possession of a letter of access to a dossier which complies with the requirements of Annex II.

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 199

**Proposal for a regulation
Article 54 – paragraph 3 – introductory part**

Text proposed by the Commission

Amendment

3. Every ***three years***, starting in 2013, competent authorities shall submit to the

3. Every ***year***, starting in 2013, competent authorities shall submit to the Commission

Commission a report on the implementation of this Regulation in their respective territories. The report shall include:

a report on the implementation of this Regulation in their respective territories. ***The implementation reports shall be published annually on the relevant website of the Commission.*** The report shall include:

Justification

Implementation reports should be up to date as much as possible and best practices should be disseminated on a regular basis among member states.

Amendment 200

Proposal for a regulation

Article 54 – paragraph 3 – point b

Text proposed by the Commission

b) information on any poisonings involving biocidal products.

Amendment

b) information on any poisonings involving biocidal products, , ***especially regarding vulnerable groups, and the actions undertaken to lower the risk of future cases.***

Justification

Best practices should be disseminated among member states.

Amendment 201

Proposal for a regulation

Article 54 – paragraph 3 – point b a (new)

Text proposed by the Commission

Amendment

(ba) information on the impact on the environment.

Amendment 202

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 *Union* authorisation procedure and mutual recognition, by **1 January 2016**. The Commission shall submit the report to the European Parliament and the Council.

Amendment 203

Proposal for a regulation Article 54 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. At the latest two years after the entry into force of this Regulation, the Commission shall submit to the European Parliament and Council a report on the assessment of the risks to human health and the environment presented by the use of nanomaterials in biocidal products and on specific measures to be taken with regard to them.

Justification

Substances incorporating nanomaterials fall within the scope of the Regulation. However, the impact of these substances on health and the environment is largely unknown at present. It is imperative to initiate without delay research to assess their impact in order to be able to consider specific measures if appropriate.

Amendment 204

Proposal for a regulation Article 54 – paragraph 4 b (new)

Text proposed by the Commission

Amendment

4b. Not later than five years after the entry into force of this Regulation, the Commission shall draw up a report on the impact of the spread of biocidal products in the environment. The Commission shall submit the report to the European Parliament and the Council.

Justification

Many biocidal products are not used in closed systems but released into the environment, for example in effluent. Insufficient data are available in this field. A thorough study of their environmental impact is needed.

Amendment 205

Proposal for a regulation

Article 55 – paragraph 2 – points d a - d d (new)

Text proposed by the Commission

Amendment

(da) Names and addresses of manufacturers of the active substances, including location of manufacturing sites;
(db) the location of a biocidal product's manufacturing site;
(dc) the date of issue of an authorisation and the expiry date;
(dd) doses and instructions for use.

Justification

The information to be treated as confidential, because it is commercially sensitive, should also include the date of issue of an authorisation and the expiry date, the stated doses and also instructions for use, and the location of the site where a biocidal product is manufactured.

Amendment 206

Proposal for a regulation

Article 55 – paragraph 2 – subparagraph 2

Text proposed by the Commission

However, where urgent action is essential to protect human health, safety or the environment, the Agency or the competent authorities *may* disclose the information referred to in this paragraph.

Amendment

However, where urgent action is essential to protect human health, safety or the environment, the Agency or the competent authorities ***shall take the necessary measures to*** disclose the information referred to in this paragraph.

Justification

It is essential to ensure transparency in urgent cases to protect health, the safety of persons or the environment.

Amendment 207

**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.

Justification

This article should also apply to information concerning biocidal products.

Amendment 208

**Proposal for a regulation
Article 56 – paragraph 1 – introductory part**

Text proposed by the Commission

1. The following information held by the competent authorities, the Agency or, as

Amendment

1. The following information held by the competent authorities, the Agency or, as

appropriate, the Commission on active substances shall be made, free of charge, publicly available:

appropriate, the Commission on active substances shall be made, free of charge, publicly available *in a single database, in a structured format at least on the relevant website of the Commission:*

Justification

Information on biocidal products shall be published in structured, researchable way on the internet, first of all on the website of the Commission dealing with biocidal products.

Amendment 209

Proposal for a regulation

Article 56 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) a clear reference if the active substance qualifies as persistent, bio-accumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006 or as an endocrine disrupter or if it has been classified in accordance with Regulation (EC) No 1272/2008 as carcinogenic, mutagenic, neurotoxic, immunotoxic, toxic to reproduction or sensitising.

Justification

A reference on the classification of certain biocidal substances according to the community legislation in force is necessary.

Amendment 210

Proposal for a regulation

Article 56 – paragraph 1 – point h

Text proposed by the Commission

Amendment

h) analytical methods if requested in accordance with Annex II or III to this Regulation which make it possible to detect a dangerous substance when

h) analytical methods if requested in accordance with Annex II or III to this Regulation which make it possible to detect a dangerous substance when

discharged into the environment as well as to determine the direct exposure of humans.

discharged into the environment (***including water resources and drinking water***) as well as to determine the direct exposure of humans.

Justification

In order to make clear that there should be also analytical methods available to analyse waters and drinking water.

Amendment 211

Proposal for a regulation

Article 56 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Public access shall be granted free of charge to an inventory containing details of biocidal products authorised pursuant to Article 16(3) and of the corresponding manufacturers.

Justification

Final users must be able to distinguish between low-risk and high-risk biocidal products and make purchasing decisions accordingly.

Amendment 212

Proposal for a regulation

Article 57 – paragraph 1

Text proposed by the Commission

Amendment

1. Producers, importers and professional users of biocidal products shall keep records of the biocidal products they produce, place on the market or use for at least ***three years***. They shall make available the relevant information contained in these records to the competent authority on request.

1. Producers, importers and professional users of biocidal products shall keep records of the biocidal products they produce, place on the market or use for at least ***ten years***. They shall make available the relevant information contained in these records to the competent authority on request.

Justification

The period for which records are kept must be sufficiently long to enable the competent authority to perform checks. The proposed period of ten years is the same as provided for by the REACH Regulation.

Amendment 213

Proposal for a regulation

Article 58 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(ba) whether the product contains nanomaterials and any specific related risks, and, following each reference to nanomaterials, the word "nano" in brackets;

Justification

The impact of nanomaterials on health and the environment is largely unknown at present. Consumers must be informed correctly.

Amendment 214

Proposal for a regulation

Article 58 – paragraph 2 – first subparagraph – point e

Text proposed by the Commission

Amendment

(e) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorisation;

(e) directions for use and the dose rate, expressed in metric units ***or in another manner which is meaningful and comprehensible to the user***, for each use provided for under the terms of the authorisation;

Justification

The dose must be expressed in a manner which is meaningful and comprehensible to the user. Particularly in the case of non-professional users, a dose in metric units is sometimes hard for users to understand. The dose in metric units should be translated into terms which are significant, comprehensible and appropriate for the consumer if necessary.

Amendment 215

Proposal for a regulation
Article 58 – paragraph 2 – point g

Text proposed by the Commission

(g) if accompanied by a leaflet, the sentence "Read attached instructions before use";

Amendment

(g) if accompanied by a leaflet, the sentence "Read attached instructions before use" ***and, where applicable, warnings for vulnerable groups;***

Justification

Better guidance on the labels of biocidal products for vulnerable groups should be provided

Amendment 216

Proposal for a regulation
Article 58 – paragraph 3

Text proposed by the Commission

3. ***Member States may require that*** biocidal products placed on the market of ***their*** territories ***are*** labelled in ***their*** national language or languages.

Amendment

3. Biocidal products placed on the market of ***the*** territories ***of the Member States shall be*** labelled in ***the*** national language or languages ***of the country where they are marketed.***

Justification

Both consumers and those acting on behalf of supervisory authorities must be able to gain access to the information in their mother tongue.

Amendment 217

Proposal for a regulation
Article 59 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Safety data sheets shall contain the following information:

(a) important categories of product whose active substance has been included in Annex I;

(b) the name of at least one Member State where the biocidal product has been

authorised;

(c) the authorisation number of the biocidal product as such or present in a treated article or material.

Justification

Consistently with the information requested concerning manufacturers of active substances, safety data sheets accompanying biocidal products too should contain such information to help the supervisory authorities and competent authorities to check the origin of the substances in products placed on the market.

Amendment 218

Proposal for a regulation
Article 60 – paragraph 5

Text proposed by the Commission

5. The Commission may adopt detailed rules on the types of information to be entered in the **Community Register for Biocidal Products** and the procedures related to it, *in accordance with the procedure referred to in Article 72(2).*

Amendment

5. In order to ensure the proper functioning of the Union Register for Biocidal Products, the Commission may adopt, *by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c*, detailed rules on the types of information to be entered in the Register and the procedures related to it.

Justification

The proper functioning of the Community Register for Biocidal Products throughout the EU requires that detailed measure related to the running of the Register are established by delegated acts.

Amendment 219

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 benefits, risks and safe use of biocidal products.

2. Member States shall take the necessary measures to provide the public with information about the benefits and risks associated with biocidal products and ways of minimising the use of those products.

3. The Commission shall make available on the internet a list of all active substances available within the internal market.

The persons responsible for the placing on the market of biocidal products shall make available on the internet a list of such products. This website shall serve to increase transparency for consumers and to facilitate an easy and fast collection of data on the properties and conditions of use of these products.

Access to the aforementioned websites shall not be subject to any restriction or condition and their content shall be kept up to date. The relevant website addresses shall be indicated on the labelling of the biocidal products in a visible manner.

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 220

Proposal for a regulation

Article 66 – paragraph 2 – point d

Text proposed by the Commission

(d) providing advice and assistance to applicants for the inclusion of an active substance in Annex I or for a *Community* authorisation;

Amendment

(d) providing advice and assistance to applicants, ***and in particular to SMEs***, for the inclusion of an active substance in Annex I or for a *Union* authorisation;

Justification

It should be noted that SMEs will more often be in a position to require assistance with their applications and this should be provided whenever possible by Commission, Agency and Member States.

Amendment 221

Proposal for a regulation

Article 66 – paragraph 2 – point i a (new)

Text proposed by the Commission

Amendment

(ia) providing guidance and tools for the use phase, particularly:

- measures for integrated pest management, for specified vermin,*
- monitoring biocidal product use,*
- best practice of biocidal product use to limit use of such products to the minimum necessary dose,*
- pest management in sensitive areas like schools, workplaces, kindergartens, public spaces, lake, canal and river sides, geriatric care centres,*
- technical equipment for biocidal product application and its inspection.*

Amendment 222

Proposal for a regulation

Article 70 – paragraph 2 – point a

Text proposed by the Commission

Amendment

a) a reduced fee shall be set for small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises;

a) a reduced fee shall be set for small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises; ***this shall have no bearing on the responsibility of the relevant competent authority to carry out a careful assessment in accordance with the provisions of this Regulation;***

Justification

Fees should reflect the work required and the fact that it 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 223

Proposal for a regulation

Article 70 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the fee structure shall take into account whether the product submitted for authorisation complies with the criteria for a low-risk product;

Justification

The fee structure may make it possible to provide incentives for production of low-risk products.

Amendment 224

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 225

Proposal for a regulation

Article 71 a (new)

Text proposed by the Commission

Amendment

Article 71a

Exercise of the delegation

1. The power to adopt the delegated acts referred to in Articles 6(4), 8(5), 12(5), 13(1), 14, 19(3), 21(5), 42, 46(4), 60(5), 70(1), 73 and 77(1) shall be conferred on the Commission for a period of 5 years following the entry into force of this Directive. The Commission shall make a report in respect of the delegated powers at the latest 6 months before the end of the 5 year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament and the Council revokes it in accordance with Article 71b.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 71b and 71c.

Justification

Pursuant to Article 290 TFEU, detailed provisions on the delegation of powers have to be set out in the Regulation.

Amendment 226

**Proposal for a regulation
Article 71 b (new)**

Text proposed by the Commission

Amendment

Article 71b

Revocation of the delegation

1. The delegation of powers referred to in Articles 6(4), 8(5), 12(5), 13(1), 14, 19(3),

21(5), 42, 46(4), 60(5), 70(1), 73 and 77(1) may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of powers shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the Official Journal of the European Union.

Justification

Pursuant to Article 290 TFEU, detailed provisions on the delegation of powers have to be set out in the Regulation.

Amendment 227

Proposal for a regulation Article 71 c (new)

Text proposed by the Commission

Amendment

Article 71c

Objections to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of three months from the date of notification.

At the initiative of the European Parliament or the Council this period shall be extended by one month.

2. If, on expiry of that period, neither the

European Parliament nor the Council has objected to the delegated act, it shall be published in the Official Journal of the European Union and shall enter into force on the date stated therein.

3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Justification

Pursuant to Article 290 TFEU , detailed provisions on the delegation of powers have to be set out in the Regulation.

Amendment 228

**Proposal for a regulation
Article 72 – paragraph 5**

Text proposed by the Commission

Amendment

5. Where reference is made to this paragraph, Article 5a (1), (2), (4) and (6), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

deleted

Justification

Due to the alignment of the comitology regime to the new system of delegated acts pursuant to Article 290 TFEU, the regulatory procedure with scrutiny will not apply for the implementation of the Regulation.

Amendment 229

**Proposal for a regulation
Article 73 – paragraph 1**

Text proposed by the Commission

Amendment

The Commission *may* adapt the Annexes to scientific and technical progress.

In order to take account of technical progress, the Commission shall, by means of delegated acts in accordance with Article 71 a and subject to the conditions

of Articles 71 b and 71 c, adapt the Annexes to scientific and technical progress.

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 230

**Proposal for a regulation
Article 73 – paragraph 2**

Text proposed by the Commission

Amendment

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

deleted

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 231

**Proposal for a regulation
Article 75 a (new)**

Text proposed by the Commission

Amendment

Article 75a

National helpdesks in Member States

Member States shall establish national helpdesks to provide advice to applicants, in particular to SMEs, and any other interested parties on their respective responsibilities and obligations under this Regulation. These shall be in addition to any assistance provided by the Agency under Article 66(2)(d).

Amendment 232

Proposal for a regulation Article 76 – paragraph 1

Text proposed by the Commission

Where, *based on* new evidence, a Member State has justifiable grounds to consider that a biocidal product, although satisfying the requirements of this Regulation, constitutes a serious risk to human or animal health or to the environment, it may take appropriate provisional measures. The Member State shall without delay inform the Commission and the other Member States thereof and give reasons for its decision *based on the new evidence*.

Amendment

Where, *on the basis of* new evidence, a Member State has justifiable grounds to consider that a biocidal product, although satisfying the requirements of this Regulation, constitutes a serious *immediate or long-term* risk to human *health, in particular as regards children*, or animal health or to the environment, *particularly to vulnerable groups, or to achieving the quality standards of Directive 2000/60/EC*, it may take appropriate provisional measures. The Member State shall without delay inform the Commission and the other Member States thereof and give reasons for its decision.

Justification

It would seem appropriate to highlight the fact that children are more vulnerable to harmful products than adults, on whom the proposal for a regulation is basing tolerance criteria. Children are often to be found - unbeknown to themselves - in places which have been sprayed with biocidal products and pesticides, and show reactions – immediately or in the longer term – which are directly or indirectly attributable to the harmful substances.

Amendment 233

Proposal for a regulation Article 76 – paragraph 2

Text proposed by the Commission

The Commission shall, in accordance with the procedure referred to in Article 72(3), either authorise the provisional measure for a time period defined in the decision or require the Member State to revoke the provisional measure.

Amendment

deleted

Justification

According to Article 193 of the newly adopted EU-Treaty member states can maintain or introduce more stringent protective measures for the improvement of the quality of the environment and the protection of human health.

Amendment 234

Proposal for a regulation

Article 77 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. The Commission shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC and achieve it by 14 May 2014. The Commission may adopt implementing rules to carry out the work programme and to specify the related rights and obligations of the competent authorities and the participants in the programme. ***Those measures, 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).***

Amendment

1. The Commission shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC and achieve it by 14 May 2014. ***In order to ensure a smooth transition,*** the Commission may adopt, ***by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c,*** implementing rules to carry out the work programme and to specify the related rights and obligations of the competent authorities and the participants in the programme, ***and, depending upon the progress of the work programme, a decision to extend the duration of the work programme for a determined period.***

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 235

Proposal for a regulation

Article 77 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Depending upon the progress of the work programme, the Commission may extend

Amendment

deleted

the duration of the work programme for a determined period. That measure, 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).

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 236

Proposal for a regulation

Article 77 – paragraph 1 – subparagraph 3

Text proposed by the Commission

During the work programme, the Commission shall decide ***pursuant to the procedure laid down in Article 72(4)*** that an active substance shall be included in Annex I of this Regulation and under which conditions, or, in cases where the requirements of Article 4 are not satisfied or where the requisite information and data have not been submitted within the prescribed period, that such active substance shall not be included in Annex I of this Regulation. The decision shall specify the date on which the inclusion in Annex I becomes effective.

Amendment

In order to progress with the work programme, the Commission shall decide, ***by means of delegated acts in accordance with Article 71 a and subject to the conditions of Articles 71 b and 71 c,*** that an active substance shall be included in Annex I of this Regulation and under which conditions, or, in cases where the requirements of Article 4 are not satisfied or where the requisite information and data have not been submitted within the prescribed period, that such active substance shall not be included in Annex I of this Regulation. The decision shall specify the date on which the inclusion in Annex I becomes effective.

Justification

To align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU.

Amendment 237

Proposal for a regulation

Article 77 - paragraph 3 - subparagraph 3

Text proposed by the Commission

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.

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 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 238

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 239

Proposal for a regulation Article 81

Text proposed by the Commission

By way of derogation from Article 47, treated articles and materials that incorporate biocidal products which are not authorised in the *Community* or in at least one Member State and which were available on the market on ... [OJ: insert the date referred to in the first subparagraph of Article 85] may, until the date of a decision granting authorisation to these biocidal products, continue to be placed on the market if the application for authorisation is submitted at the latest by **1 January 2017**. In the case of a refusal to grant an authorisation to place a biocidal product on the market, treated articles and materials that incorporate such biocidal product shall no longer be placed on the market within six months after such decision.

Amendment 240

Proposal for a regulation Article 81 - paragraph 1 a (new)

Text proposed by the Commission

Amendment

By way of derogation from Article 47, treated articles and materials that incorporate biocidal products which are not authorised in the *Union* or in at least one Member State and which were available on the market on ... [OJ: insert the date referred to in the first subparagraph of Article 85] may, until the date of a decision granting authorisation to these biocidal products, continue to be placed on the market if the application for authorisation is submitted at the latest by **1 January 2015**. In the case of a refusal to grant an authorisation to place a biocidal product on the market, treated articles and materials that incorporate such biocidal product shall no longer be placed on the market within six months after such decision.

Disposal, storage and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission are allowed until twelve months after the date of the decision referred to in the first subparagraph of Article 80(2) or twelve months after the date referred to in the

*second subparagraph of Article 80(2),
whichever is the later.*

Justification

The addition of this paragraph taken from Article 80 ensures consistent measures for the new products which will fall under the scope of the Biocidal Products Regulation.

Amendment 241

**Proposal for a regulation
Article 83**

Text proposed by the Commission

Article 83

Transitional measures concerning access to
the active substance dossier

As of 1 January 2014, the person responsible for the placing on the market of a biocidal product containing one or more existing active substances shall own a dossier or have a letter of access to a dossier, or to each component of the dossier, satisfying the requirements set out in Annex II for each of these active substances unless all relevant protection periods referred to in Article 49 have expired.

Amendment

Article 83

Transitional measures concerning access to
the active substance dossier

1. By 1 January 2015, manufacturers of existing active substances which are on the market for use in biocidal products shall submit to the Agency a dossier or a letter of access to a dossier which complies with the requirements of Annex II for each of these active substances.

For the purpose of subparagraph 1, Article 52(3) shall apply to all data included in the dossier.

The applicant for the authorisation of a biocidal product containing an active substance for which a letter of access has been submitted in accordance with subparagraph 1 shall be allowed to use that letter of access for the purposes of Article 18(1).

2. The Agency shall make publicly available the list of manufacturers which have submitted a dossier or a letter of access to a dossier in accordance with

Biocidal products for which *the person responsible for the placing on the market does not fulfil the requirement of the first subparagraph* shall *no longer* be placed on the market.

Disposal, storage and use of existing stocks of biocidal products which *do not fulfil the requirement of the first subparagraph* is allowed until *1 January 2015*.

paragraph 1.

3. Biocidal products *containing existing active substances* for which *a dossier or a letter of access to a dossier has not been submitted in accordance with paragraph 1* shall *not* be placed on the market *after 1 January 2015*.

Disposal, storage and use of existing stocks of biocidal products *for which a dossier or a letter of access to a dossier has not been submitted in accordance with paragraph 1* is allowed until *1 January 2016*.

4. For the purpose of paragraph 3, competent authorities shall carry out official controls as required by Article 54(2).

Amendment 242

Proposal for a regulation

Annex I - introductory paragraph (new)

Text proposed by the Commission

Amendment

Substances listed in Annex I do not cover nanomaterials, except where specifically mentioned.

Justification

Nanomaterials are used due to their different or enhanced properties as compared to substances in bulk form. Due to their miniscule size and the resulting increase of relative surface area, they may pose new risks. Thus, they require an assessment in their own right. An inclusion of a substance in Annex I must not count for nanomaterials, unless specifically mentioned, otherwise nanomaterials would be given a "free-ride". The wording proposed here is taken from the cosmetics regulation, which also has a positive list approach for certain substances (preamble to Annexes II to VI).

Amendment 243

Proposal for a regulation
Annex I -difenacoum - 9th row - 8th column

Text proposed by the Commission

In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance shall be considered a candidate for substitution in accordance with Article 9.

Authorisations are subject to the following conditions:

- (1) The nominal concentration of the active substance in the products shall not exceed 75 mg/kg and only ready-for-use products shall be authorised.
- (2) Products shall contain an aversive agent and, where appropriate, a dye.
- (3) Products shall not be used as tracking powder.
- (4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by **considering and** applying all appropriate and available risk mitigation measures. These include, amongst others, **the restriction** to professional use only, **setting** an upper limit to the package size and **laying down obligations to use** tamper

Amendment

In view of the fact that the active substance characteristics **meet the criteria for classification as toxic to reproduction category 1A and** render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance shall be considered a candidate for substitution in accordance with Article 9.

In view of the risks identified for the aquatic compartments, the fact that the active substance is very toxic to birds and mammals, the risks for infant poisoning, the problem of resistance formation and the pain and prolonged suffering it causes in target animals, authorisations are subject to the following condition:

A serious danger to public health is proven that cannot be controlled by any other means.

The following risk-mitigation measures shall be taken:

- (1) The nominal concentration of the active substance in the products shall not exceed 75 mg/kg and only ready-for-use products shall be authorised.
- (2) Products shall contain an aversive agent and, where appropriate, a dye.
- (3) Products shall not be used as tracking powder.
- (4) Primary as well as secondary exposure of humans, non-target animals and the environment **must be** minimised by applying all appropriate and available risk mitigation measures. These include, amongst others, **that the use must be restricted** to professional use only, **that** an upper limit to the package size **must be set** and **that only** tamper resistant and secured

resistant and secured bait boxes.

bait boxes ***must be used***.

Justification

Difenacoum is a highly problematic substance on all accounts (toxicity, persistence, bioaccumulation, teratogenicity, effects on non-target organisms, effects on human health, suffering of target organisms). It should only be used when it has been proven that it is necessary to control a serious danger to public health that cannot be controlled otherwise. The risk mitigation measures should be made legally binding. Only professionals should be allowed to use it subject to strict criteria.

Amendment 244

Proposal for a regulation Annex II – point 1

Text proposed by the Commission

1. Dossiers on active substances shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL), Predicted Environmental Concentration (PEC) and Predicted No-Effect Concentration (PNEC).

Amendment

1. Dossiers on active substances shall contain the information needed to establish ***that exposure is below the Threshold of Toxicological Concern (TTC)***, or where relevant, ***to establish the*** Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL), Predicted Environmental Concentration (PEC) and Predicted No-Effect Concentration (PNEC).

Justification

Threshold of Toxicological Concern is a “weight of evidence” risk assessment approach used in the safety assessment of food-contact materials, and other substances of unknown toxicity but with demonstrably low human risk. When combined with known information and predicted behaviour, the approach bins chemicals into classes, with their own acceptable human exposure limits. If exposure is below these very low levels, toxicity testing may be avoided. A project is currently under by the International Life Sciences Institute on developing a TTC approach for some biocidal products.

Amendment 245

Proposal for a regulation Annex II – point 4

Text proposed by the Commission

4. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Council Regulation (EC) No 440/2008. However, if a method is inappropriate or not described, other methods shall be used which are, ***whenever possible, internationally recognised*** and must be justified in the application.

Amendment

4. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Council Regulation (EC) No 440/2008. However, if a method is inappropriate or not described, other methods shall be used which are ***scientifically appropriate*** and must be justified in the application.

Justification

The original phrasing of Paragraph 4 of Annex II is not clear enough and will hinder the use of alternatives to animal experimentation that are mentioned in Annex IV

Amendment 246

Proposal for a regulation
Annex II – title 1 - paragraph 4

Text proposed by the Commission

Before new tests are carried out to determine the properties listed in this Annex, all available in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be ***consulted*** in addition to this Annex.

Amendment

Before new tests are carried out to determine the properties listed in this Annex, all available in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on ***intelligent*** testing strategies should be ***sought from experts in alternatives to animal experimentation*** in addition to this Annex.

Justification

The necessity of advice from 3Rs experts has to be made articulate. Applicants have to be supported in the design of intelligent testing strategies to avoid unnecessary or duplicate testing and to minimise animal experimentation

Amendment 247

Proposal for a regulation

Annex II - title 1 - table - section 6.1.1 – column 3

Text proposed by the Commission

Amendment

6.1.1. The study does not need to be conducted if: **deleted**

– the substance is classified as corrosive to the skin or as a skin irritant; or
– the substance is a strong acid (pH 2,0) or base (pH 11,5); or
– the substance is flammable in air at room temperature; or
– the substance is classified as very toxic in contact with skin; or
– an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight).

Justification

The European Commission has accepted two in vitro methods for the testing of skin irritation on July 23rd, 2009: The “EpiDerm SIT” and the “SkinEthic RHE” assays. Consequently, the in vivo tests for skin irritation are no longer necessary and should be deleted from the data requirements in Annex II. The first adaptation to technical progress of Regulation (EC) No 440/2008 included a new test guideline for in vitro dermal irritation that can replace the in vivo method for the purposes of this Regulation. Consequently, the in vivo method is no longer necessary and should be deleted.

Amendment 248

Proposal for a regulation

Annex II - title 1 - table - section 6.2.1 – column 3

Text proposed by the Commission

Amendment

6.2.1. The study does not need to be conducted if: **deleted**

– the substance is classified as irritating to eyes with risk of serious damage to eyes;
or
– the substance is classified as corrosive to the skin and provided that the applicant classified the substance as eye irritant; or

- *the substance is a strong acid (pH 2,0) or base (pH 11,5); or*
- *the substance is flammable in air at room temperature.*

Justification

On September 7th 2009, the OECD officially adopted two alternative methods as Health Effects Test Guidelines for the assessment of severe eye irritation. The new test guidelines have been designated Test Guidelines TG 437: Bovine corneal opacity and permeability (BCOP) and TG 438: Isolated chicken-eye assay (ICE). Consequently, the in vivo test for eye irritation should be deleted from the data requirements in Annex II

Amendment 249

Proposal for a regulation

Annex II - title 1 - table - section 6.3 – column 3

Text proposed by the Commission

6.3. The assessment of this endpoint shall comprise the following consecutive steps:

- (1) an assessment of the available human, animal and alternative data,
- (2) In vivo testing.

Step 2 does not need to be conducted if:

- the available information indicates that the substance should be classified for skin sensitisation or corrosivity; or
- the substance is a strong acid (pH 2,0) or base (pH 11,5); or
- the substance is flammable in air at room temperature.

The Murine Local Lymph Node Assay (**LLNA**) is the first-choice method for in vivo testing. Only in exceptional circumstances should another test be used. Justification for the use of another test shall be provided.

Amendment

6.3. The assessment of this endpoint shall comprise the following consecutive steps:

- (1) an assessment of the available human, animal and alternative data,
- (2) In vivo testing.

Step 2 does not need to be conducted if:

- the available information indicates that the substance should be classified for skin sensitisation or corrosivity; or
- the substance is a strong acid (pH 2,0) or base (pH 11,5); or
- the substance is flammable in air at room temperature.

The **reduced** Murine Local Lymph Node Assay (**rLLNA**) is the first-choice method for in vivo testing ***as a screening test to distinguish between sensitisers and non-sensitisers. The full LLNA should be performed when it is known that an assessment of sensitisation potency is required.*** Only in exceptional circumstances should another test be used. Justification for the use of another test shall be provided.

Justification

As a measure to reduce the number of animals used a reduced version of the Murine The Local Lymph Node Assay (rLLNA) should be performed to distinguish between skin

sensitisers and non-sensitisers. Compare also the associated ECVAM Scientific Advisory Committee (ESAC) statement of September 27th, 2007.

Amendment 250

Proposal for a regulation

Annex II - title 1 - table - section 6.4 – column3

Text proposed by the Commission

6.4. Appropriate in vivo mutagenicity studies shall be considered in case of a positive result in any of the genotoxicity studies in Tier 1.

Amendment

6.4. Appropriate in vivo mutagenicity studies shall be considered in case of a positive result in any of the genotoxicity studies in Tier 1.

For new substances, it is advisable to assess the parameters of an in-vivo micronucleus test as part of a 28- or 90-day repeated dose toxicity study.

Justification

Tier I studies examine a variety of different modes of mutagenic/genotoxic action, which must be examined together, as part of a “weight-of-evidence” approach, in order for the complete picture to become clear.

Amendment 251

Proposal for a regulation

Annex II - title 1 - table - section 6.4.1 – column 3

Text proposed by the Commission

6.4.1 Further mutagenicity studies shall be considered in case of a positive result.

Amendment

6.4.1 Further mutagenicity studies shall be considered in case of a positive result.

Such a study does not need to be conducted in the case of antimicrobial substances or formulations.

Amendment 252

Proposal for a regulation

Annex II - title 1 - table - section 6.4.3 – column3

Text proposed by the Commission

6.4.3. The study does not **usually** need to be conducted if adequate data from a reliable *in vivo* mammalian gene mutation test are available.

Amendment

6.4.3. The study does not need to be conducted if adequate data from a reliable *in vivo* mammalian gene mutation test are available **elsewhere**.

Justification

*It has to be clarified that the applicant should not have conducted the *in vivo* studies himself or that they were conducted by his order.*

Amendment 253

Proposal for a regulation

Annex II - title 1 - table - section 6.4.4 – column 3 - paragraph 1

Text proposed by the Commission

6.4.4. If there is a positive result in any of the *in vitro* genotoxicity studies in Tier I and there are no results available from an *in vivo* study already, an appropriate *in vivo* somatic cell genotoxicity study shall be proposed by the applicant.

Amendment

6.4.4. If there is a positive result in any of the *in vitro* genotoxicity studies in Tier I and there are no results available from an *in vivo* study already, an appropriate *in vivo* somatic cell genotoxicity study shall be proposed by the applicant. ***For new substances, it should be possible to assess the parameters of an *in-vivo* micronucleus test as part of a 28- or 90-day repeated dose toxicity study.***

Justification

*In the pharmaceutical sector, it is becoming increasingly common to incorporate micronucleus assays into 28- or 90-day general toxicity studies in rats as a means of efficiently gathering mutagenicity data without a stand-alone *in vivo* study. According to this approach, micronucleus induction is determined through collection of peripheral blood at several time-Sections throughout a study, as well as from bone marrow collection at termination.*

Amendment 254

Proposal for a regulation
Annex II - title 1 - table - section 6.5 – column3

Text proposed by the Commission

Amendment

6.5. The study/ies do(es) not generally need to be conducted if:

6.5. The study/ies do(es) not generally need to be conducted if:

- the substance is classified as corrosive to the skin.

- the substance is classified as corrosive to the skin.

In addition to the oral route (6.5.1.), for substances other than gases, the information mentioned under 5.6.2. to 6.5.3. shall be provided for at least one other route. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only route need be provided.

Justification

Multi-route studies for acute toxicity should not be required or encouraged. Two recent retrospective data analyses examining the concordance among regulatory classifications for acute oral, dermal and inhalation toxicity for several hundred agrochemical and biocidal active substances and nearly 2,000 industrial chemicals have revealed that dermal studies do not add value above and beyond oral data for hazard classification purposes in more than 99% of cases. Data requirements should be revised to reflect these new findings.

Amendment 255

Proposal for a regulation
Annex II - title 1 - table - section 6.5.1 – column 3

Text proposed by the Commission

Amendment

6.5.1. The study need not be conducted if a study on acute toxicity by the inhalation route (6.5.2) is available.

6.5.1. The study need not be conducted if a study on acute toxicity by the inhalation route (6.5.2) is available.

The Acute Toxic Class Method is the first-choice method for in-vivo testing. Only in exceptional circumstances should another test be used, in which case a justification shall be provided.

Justification

The method for the assessment of acute toxicity has to be specified to minimise the number of animals used. In the Council Regulation (EC) No 440/2008, both the Acute Toxic Class Method and the Fixed Dose Method are suggested. The Acute Toxic Class Method uses less animals than the Fixed Dose Method and should therefore be the method of choice.

Amendment 256

Proposal for a regulation

Annex II - title 1 - table - section 6.5.2 – column 3

Text proposed by the Commission

6.5.2. Testing by the inhalation route is appropriate if exposure *of humans via inhalation is likely* taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.

Amendment

6.5.2. Testing by the inhalation route is appropriate *only* if *this constitutes the primary route of human* exposure taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size. *The Acute Toxic Class Method is the first-choice method for in-vivo testing. Only in exceptional circumstances should the classic “lethal concentration” (LC50) test be used. Justification for the use of another test shall be provided.*

Justification

Testing via multiple exposure routes should not be necessary if hazard classification is the primary objective. Revision of data requirements to forego redundant testing could markedly reduce costs and animal use. In cases where inhalation represents the primary human exposure scenario, the OECD Acute Toxic Class animal reduction test guideline should be used in lieu of the classical lethal poisoning method.

Amendment 257

Proposal for a regulation

Annex II - title 1 - table - section 6.5.3 – column 3

Text proposed by the Commission

6.5.3. Testing by the dermal route is appropriate if:
(1) inhalation of the substance is unlikely;
and

Amendment

deleted

(2) skin contact in production and/or use is likely; and

(3) the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.

Justification

This data requirement should be deleted on the basis of the aforementioned analysis, which found dermal classifications to be concordant with or less severe than oral classifications in over 99% of cases. Dermal classifications can therefore be based on direct read-across from oral data.

Amendment 258

Proposal for a regulation

Annex II -title 1 - table - section 6.6.1 – column 3

Text proposed by the Commission

6.6.1. The short-term toxicity study (28 days) does not need to be conducted if:

- a reliable sub-chronic (90 days) or chronic toxicity study is available, provided that an appropriate species, dosage, solvent and route of administration were used; or
- where a substance undergoes immediate disintegration and there are sufficient data on the cleavage products; or
- relevant human exposure can be excluded in accordance with Annex IV section 3

The appropriate route shall be chosen on the following basis:

Testing by the dermal route is appropriate if:

(1) inhalation of the substance is unlikely; and

Amendment

6.6.1. The short-term toxicity study (28 days) does not need to be conducted if:

- a reliable sub-chronic (90 days) or chronic toxicity study is available **or planned**, provided that an appropriate species, dosage, solvent and route of administration were **or are to be** used; or
- where a substance undergoes immediate disintegration and there are sufficient data on the cleavage products; or
- relevant human exposure can be excluded in accordance with Annex IV section 3.

Testing shall be conducted via the oral route unless:

(1) the primary route of human exposure will be dermal, and one of the following conditions is met:

- the physicochemical and toxicological properties, including an in-vitro dermal penetration study (i.e. OECD TG 428),

(2) skin contact in production and/or use is likely; and

(3) the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.

Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.

The sub-chronic toxicity study (90 days) (Tier II, section 6.6.2) shall be proposed by the applicant if: the frequency and duration of human exposure indicates that a **longer term** study is appropriate; and **one of the following conditions is met:**

– **other** available data indicate that the substance **may have a dangerous property that cannot be** detected in a short-term toxicity study; **or**

– **appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short term toxicity study but which are liable to result in adverse effects after prolonged exposure.**

Further studies **shall be proposed by the**

indicate that dermal bioavailability will be substantial; or

- significant dermal toxicity or dermal penetration is recognised for structurally related substances.

(2) the primary route of human exposure will be inhalation, taking into account the vapour pressure of the substance and likely frequency, magnitude and duration of exposure to aerosols, particles or droplets of an inhalable size.

Testing shall only be carried out via one exposure route. Estimates of toxicity via other routes shall be based upon pharmacokinetic modelling.

The sub-chronic toxicity study (90 days) (Tier II, section 6.6.2) shall be proposed by the applicant **in lieu of a 28-day study** if: the frequency and duration of human exposure indicates that a study **of > 1 month and < 12 months** is appropriate and available data indicate that the **kinetics or other properties of a substance or its metabolites are such that adverse effects could go undetected** in a short-term toxicity study.

For substances related on a molecular

applicant or may be required in case of:

level to known organ-specific toxicants (e.g. neurotoxicity), additional relevant parameters should ideally be examined in the context of a 28-day or 90-day study in lieu of a stand-alone, e.g. neurotoxicity study. Further stand-alone studies should be limited to exceptional circumstances.

– failure to identify a NOAEL in the 28 or the 90 days study, unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects; or

– toxicity of particular concern (e.g. serious/severe effects); or

– indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation.

In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity); or

– the route of exposure used in the initial repeated dose study was inappropriate in relation to the expected route of human exposure and route-to-route extrapolation cannot be made; or

– particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected); or

– effects shown in substances with a clear relationship in molecular structure with the substance being studied, were not detected in the 28 or the 90 days study.

Justification

It is only necessary with either a 28- or 90-day study. No significant new knowledge is provided by using both. Endpoint-combining is a generally accepted practice for improving testing efficiency and should be encouraged as a means of minimising the conduct of stand-alone neurotoxicity and other “special” studies.

Amendment 259

Proposal for a regulation

Annex II -title 1 - table - section 6.6.2 – column 3

Text proposed by the Commission

6.6.2. The sub-chronic toxicity study (90 days) does not need to be conducted if:

- a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure; or
- a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used; or
- a substance undergoes immediate disintegration and there are sufficient data on the cleavage products (both for systemic effects and effects at the site of uptake); or
- the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day "limit test", particularly if such a pattern is coupled with limited human exposure.

The appropriate route shall be chosen on the following basis:

Testing by the dermal route is appropriate if:

(1) skin contact in production and/or use is likely; and

Amendment

6.6.2. The sub-chronic toxicity study (90 days) does not need to be conducted if:

- a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure; or
- a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used; or
- a substance undergoes immediate disintegration and there are sufficient data on the cleavage products (both for systemic effects and effects at the site of uptake); or
- the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day "limit test", particularly if such a pattern is coupled with limited human exposure.

Testing shall be conducted via the oral route unless:

(1) the primary route of human exposure will be dermal, and one of the following conditions is met:

- the physicochemical and toxicological properties, including an in-vitro dermal penetration study (i.e. OECD TG 428), indicate that dermal bioavailability will be substantial; or

- significant dermal toxicity or dermal penetration is recognised for structurally

(2) the physicochemical properties suggest a significant rate of absorption through the skin; and

(3) one of the following conditions is met:

- toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test; or*
- systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies; or*
- in vitro tests indicate significant dermal absorption; or*
- significant dermal toxicity or dermal penetration is recognised for structurally related substances.*

Testing by the inhalation route is appropriate if:

- exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.*

Further studies shall be proposed by the applicant or may be required in case of:

- failure to identify a NOAEL in the 90 days study unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects; or*

related substances.

(2) the primary route of human exposure will be inhalation, taking into account the vapour pressure of the substance and the likely frequency, magnitude and duration of exposure to aerosols, particles or droplets of an inhalable size.

Testing shall be carried out via one exposure route. Estimates of toxicity via other routes shall be based upon pharmacokinetic modelling.

For substances related on a molecular level to known organ-specific toxicants (e.g. neurotoxicity), additional relevant parameters should ideally be examined in the context of a 28-day or 90-day study in lieu of a standalone, e.g. neurotoxicity study. Further stand-alone studies should be limited to exceptional circumstances.

- *toxicity of particular concern (e.g. serious/severe effects); or*
- *indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity); or*
- *particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected).*

Justification

It is only necessary with either a 28- or 90-day study. No significant new knowledge is provided by using both. Endpoint-combining is a generally accepted practice for improving testing efficiency and should be encouraged as a means of minimising the conduct of stand-alone neurotoxicity and other “special” studies.

Amendment 260

Proposal for a regulation

Annex II -title 1 - table - section 6.6.3 – column 3

Text proposed by the Commission

6.6.3. A long-term repeated toxicity study (≥ 12 months) may be proposed by the applicant or required if the frequency and duration of human exposure *indicates* that a *longer term study* is appropriate and *one of the following conditions is met*:

- serious or severe toxicity effects of particular concern when observed in the 28-day or 90-day study for which the available evidence is inadequate for toxicological evaluation or risk characterisation; or

Amendment

6.6.3. A long-term repeated **dose** toxicity study (≥ 12 months) may be proposed by the applicant or required **only** if:

- the frequency, **magnitude** and duration of human exposure, **indicate** that a **chronic risk assessment** is appropriate; and
- **if the application of an appropriate uncertainty factor would not be sufficiently protective for risk assessment purposes.**

- effects shown in substances with a clear relationship in molecular structure with the substance being studied were not detected in the 28-day or 90-day study; or

- the substance may have a dangerous property that cannot be detected in a 90-day study.

If carcinogenicity data are also required and are not already available, long-term repeated dose and carcinogenicity studies should be carried out using the OECD TG 453 combination study protocol.

Justification

Long-term toxicity studies are costly in both economic and animal welfare terms and can generally be avoided through the use of appropriate statistical techniques (e.g. extrapolation from shorter-term studies). In exceptional cases where empirical data are considered necessary, testing should only be carried out in a single species, and where cancer risk is also a consideration, a combined chronic toxicity-carcinogenicity study should be required in lieu of separate, standalone studies for these two endpoints.

Amendment 261

Proposal for a regulation

Annex II -title 1 - table - section 6.6.4 – column 3

Text proposed by the Commission

Amendment

6.6.4. Further studies shall be proposed by the applicant or may be required in case of: **deleted**

- toxicity of particular concern (e.g. serious/severe effects); or

- indications of an effect for which the available evidence is inadequate for toxicological evaluation and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity); or

- particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity is observed).

If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1A

or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered.

Justification

Unnecessary repetition of measures articulated in 6.6.2., 6.6.3. and 6.7.

Amendment 262

Proposal for a regulation

Annex II -title 1 - table - section 6.7.1 – column 3

<i>Text proposed by the Commission</i>	<i>Amendment</i>
6.7.1. This study does not need to be conducted if:	6.7.1. This study does not need to be conducted if:
– the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or	– the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or
– the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or	– the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or
– <i>relevant</i> human exposure <i>can be excluded</i> in accordance with Annex IV section 3; or	<i>–there is no significant</i> human exposure in accordance with Annex IV section 3; or
– a pre-natal developmental toxicity study (Tier II, 6.7.2) or a two-generation reproductive toxicity study (Tier II, section 6.7.3) is available.	– a pre-natal developmental toxicity study (Tier II, 6.7.2) or a <i>one- or</i> two-generation reproductive toxicity study (Tier II, section 6.7.3) is available.
If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing	If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for <i>pre-natal</i> development toxicity must be

for development toxicity must be considered.

considered.

If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.

If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.

In cases where there are serious concerns about the potential for adverse effects on fertility or development, *either a pre-natal developmental toxicity study (Tier II, section 6.7.2) or a two generation reproductive toxicity study (Tier II, section 6.7.3)* may be proposed by the applicant instead of the screening study.

In cases where there are serious concerns about the potential for adverse effects on fertility or development, *an enhanced one-generation reproductive toxicity study, with or without a pre-natal developmental toxicity module (Tier II, section 6.7.3)*, may be proposed by the applicant instead of the screening study.

Justification

Minor technical edits; refer to justification for Section 6.7.3 for additional discussion.

Amendment 263

Proposal for a regulation

Annex II - title 1 - table - section 6.7.2 – column 3

Text proposed by the Commission

6.7.2. The study shall be *initially* performed on one species. *A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data.*

Amendment

6.7.2. The study shall be performed on one species *only, ideally in combination with an enhanced one-generation reproductive toxicity study as applicable (Tier II, section 6.7.3).*

Justification

A retrospective review of substances in the EU New Chemicals Database reveals that fewer than 5% of substances tested in developmental toxicity studies are classified as harmful to development. Given the low prevalence of this effect, it follows that the likelihood of a “false negative” result by testing in a single species is equally low. On the other hand, routine testing in a second species can inflate the rate of false positive findings, severely detracting from the specificity of a testing strategy. As such, testing in a second species should be neither required nor encouraged..

Amendment 264

Proposal for a regulation

Annex II - title 1 - table - section 6.7.3 – column 1

Text proposed by the Commission

6.7.3. Two-generation reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, *unless already provided as part of Tier 1 requirements*

Amendment

6.7.3. Pending EU-level or international acceptance of the test method, enhanced one-generation reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure.

Justification

Routine conduct of multigenerational studies should not be required or encouraged. Recent retrospective data analyses examining more than 350 two-generation studies have revealed that in approximately 99% of cases, breeding a second generation contributed nothing to either the regulatory classification or risk assessment that could not be gleaned from first generation data. Data requirements should be revised to reflect this important innovation.

Amendment 265

Proposal for a regulation

Annex II - title 1 - table - section 6.7.3 – column 3

Text proposed by the Commission

6.7.3. The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second

Amendment

deleted

species should be based on the outcome of the first test and all other relevant available data.

Justification

Reference to the conduct of a two-generation study in a second species was an error introduced in an early draft of REACH. It has since been corrected, and should not be perpetuated in the Biocidal Products Regulation.

Amendment 266

Proposal for a regulation

Annex II - title 1 - table - section 6.8.1 – column 1

Text proposed by the Commission

Amendment

6.8.1. Dermal absorption study

6.8.1. ***In-vitro*** dermal absorption study

Justification

An OECD test guideline for in vitro dermal irritation has been available since 2004 and is capable of fully replacing the in vivo method for the purposes of the Biocidal Products Regulation. Consequently, these data requirements should specifically cite the in vitro method as the only necessary or acceptable approach for fulfilling this endpoint.

Amendment 267

Proposal for a regulation

Annex II - title 1 - table - section 6.9 – column 3

Text proposed by the Commission

Amendment

6.9. A carcinogenicity study may be proposed by the applicant or may be required if:

- the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure; and
- the substance is classified as mutagen category 2 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-

6.9. A carcinogenicity study may be proposed by the applicant or may be required if:

- the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure; and
- the substance is classified as mutagen category 2 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-

neoplastic lesions.

If the substance is classified as mutagen category 1A or 1B, the default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required.

neoplastic lesions.

If the substance is classified as mutagen category 1A or 1B, the default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required.

If long-term toxicity data are also required and are not already available, carcinogenicity and long-term repeated dose studies should be carried out using the OECD TG 453 combination study protocol.

Justification

Carcinogenicity studies are costly in both economic and animal welfare terms and can generally be avoided through the use of analysis of mutagenicity/genotoxicity data (it is generally accepted that substances that are not genotoxic in vivo are not genotoxic carcinogens). Where empirical data is considered necessary, testing should only be carried out in a single species and where chronic toxicity is also a consideration, a combined carcinogenicity-chronic toxicity study should be required in lieu of separate, standalone studies for these two endpoints.

Amendment 268

Proposal for a regulation

Annex II - title 1 - table- section 7.1 – column 3

Text proposed by the Commission

7.1. Long-term toxicity testing shall be proposed by the applicant if the assessment performed under Tier I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the assessment performed under Tier I.

Amendment

7.1. Requirements for aquatic toxicity testing on vertebrate animals may be waived if the use profile for a substance does not indicate significant potential for exposure to the aquatic environment.

Long-term toxicity testing shall be proposed by the applicant if the assessment performed under Tier I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the assessment performed under Tier I.

Justification

The requirement for aquatic toxicity testing should be exposure-driven rather than absolute, particularly with respect to testing on vertebrate animals.

Amendment 269

Proposal for a regulation

Annex II - title 1 - table - section 7.1.3 – column 1

Text proposed by the Commission

Amendment

7.1.3. Short-term toxicity testing on fish:
The applicant may consider long-term toxicity testing instead of short-term.

7.1.3. Short-term toxicity testing on fish:
threshold approach.

Justification

The ECVAM-validated “threshold approach” addresses fish toxicity by initially using a single- concentration test (limit test) requiring less fish compared to the full acute fish toxicity study. The selection of a single concentration is based on the derivation of a threshold concentration from algae and daphnia toxicity data (Section 7.1.1.). Fish toxicity is then tested at the threshold concentration. If no deaths are seen in the limit test, the threshold concentration can be used as a surrogate to the “lethal concentration” (LC50) value in the further hazard or risk assessment.

Amendment 270

Proposal for a regulation

Annex II - title 1 - table - section 7.1.6 – column 1

Text proposed by the Commission

Amendment

7.1.6. Long-term toxicity testing on fish,
(unless already provided as part of Tier I requirements)

7.1.6. Long-term toxicity testing on fish, ***if indicated by substance use profile and/or physical-chemical properties***

The information shall be provided for one of the sections 7.1.6.1, 7.1.6.2 or 7.1.6.3.

The information shall be provided for one of the sections 7.1.6.1, 7.1.6.2 or 7.1.6.3.

Justification

Currently no conditions are set for triggering Tier II studies; however, reasonable conditions include use profile/exposure and physical-chemical properties.

Amendment 271

Proposal for a regulation

Annex II - title 1 - table - section 7.4.1

Text proposed by the Commission

Amendment

7.4.1. Acute toxicity test on one other, non-aquatic, non-target organism **deleted**

Justification

It is not clear what study is envisioned by this data requirement. The only non-aquatic species commonly subject to acute ecotoxicological studies are birds, and a separate avian data requirements section is included elsewhere. If additional specificity is not provided, including reference to an accepted EU or international test guideline, this requirement should be deleted.

Amendment 272

Proposal for a regulation

Annex II -title 1 - table - section 8.1 - column 1 - introductory part

Text proposed by the Commission

Amendment

8.1. Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances.

8.1. Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances, ***Annex I Part B to Directive 98/83/EC on the quality of water intended for human consumption, or Annex X to Directive 2000/60/EC.***

Justification

The measures necessary to protect man, animals and the environment should also include identification of the substances relevant for drinking water and for water policy in general.

Amendment 273

Proposal for a regulation

Annex II -title 1 - table - section 11.1 – column 3

Text proposed by the Commission

Amendment

11.1. Avian toxicity data is not required unless the use profile for a substance indicates significant potential for exposure or harmful effects to birds.

Justification

The requirement for avian testing should be exposure-driven rather than absolute, particularly given the interest in minimising testing on vertebrate animals.

Amendment 274

Proposal for a regulation

Annex II - title 1 - table - section 11.1.1

Text proposed by the Commission

Amendment

11.1.1. Acute oral toxicity - this need not be done if an avian species was selected for study in section 7.4.1 ***deleted***

Justification

According to REACH technical guidance, “few (if any) scenarios are likely to lead to acute poisoning risks for birds”, and “evidence from pesticides suggests that chronic effects cannot be reliably extrapolated or inferred from acute toxicity data.” Accordingly, this data requirement will contribute little or nothing to an environmental risk assessment and should therefore be deleted.

Amendment 275

Proposal for a regulation

Annex II - title 1 - table - section 11.1.2 - column 1

Text proposed by the Commission

Amendment

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

11.1.2. Short-term toxicity - eight-day dietary study in one species

Justification

Avian dietary toxicity testing, where indicated by use profile and other considerations, should be strictly limited to a single species.

Amendment 276

Proposal for a regulation

Annex II -title 1 - table - section 11.1.3 – column 3

Text proposed by the Commission

Amendment

11.1.3 This test is not required if the dietary toxicity study (section 11.1.2) shows that the LC50 is above 2,000 mg/kg.

Justification

Reference:

REACH technical guidance: http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r7c_en.pdf?vers=20_08_08

Amendment 277

Proposal for a regulation

Annex II - title 1 - table - section 11.2

Text proposed by the Commission

Amendment

11.2. Effects on aquatic organisms ***deleted***

11.2.1. Prolonged toxicity to an appropriate species of fish

11.2.2. Effects on reproduction and growth rate on an appropriate species of fish

11.2.3. Bioaccumulation in an appropriate species of fish

11.2.4. Daphnia magna reproduction and growth rate

Justification

This section duplicates section 7.1. and should be deleted.

Amendment 278

Proposal for a regulation

Annex II -title 1 - table - section 12

Text proposed by the Commission

Amendment

12. Classification and labelling

deleted

Justification

Unless specific data requirements are provided, together with rules for adaptation, this section should be deleted.

Amendment 279

Proposal for a regulation

Annex II – title 2 – point 5.2.1 – paragraph 1 (new)

Text proposed by the Commission

Amendment

The assessment of this endpoint shall comprise the following consecutive steps:

(1) an assessment of the available human, animal and alternative data,

(2) in-vivo testing.

The reduced Murine Local Lymph Node Assay (rLLNA) is the first-choice method for in vivo testing as a screening test to distinguish between sensitisers and non sensitisers. The full LLNA should be performed when it is known that an assessment of sensitisation potency is required. Only in exceptional circumstances should another test be used, in which case a justification shall be provided.

Justification

The ECVAM-validated “reduced” Local Lymph Node Assay (rLLNA) should be the default approach for distinguishing between skin sensitisers and non-sensitisers. Reference: •

ECVAM validation statement: http://ecvam.jrc.it/publication/ESAC26_statement_

rLLNA_20070525_C.pdf It is problematic that this section does not (i) include rules for adaptation of in vivo data requirements, or (ii) identify accepted EU or international test guidelines for fulfilling data requirements, which are particularly critical in the case of microbial agents.

Amendment 280

Proposal for a regulation

Annex II – title 2 – point 5.2.2 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Testing shall be conducted via the oral route unless the primary route of human exposure is expected to be inhalation. Testing shall be carried out via only a single exposure route.

Justification

As discussed above under Section 6.5.1., testing via multiple exposure routes should not be necessary if hazard classification is the primary objective. Revision of data requirements to forego redundant testing could markedly reduce costs and animal use. It is problematic that this section does not (i) include rules for adaptation of in vivo data requirements, or (ii) identify accepted EU or international test guidelines for fulfilling data requirements, which are particularly critical in the case of microbial agents.

Amendment 281

Proposal for a regulation

Annex II – title 2 – point 5.2.2.2 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Testing by the inhalation route is appropriate only if this constitutes the primary route of human exposure.

Justification

As discussed above, testing via multiple exposure routes should not be necessary if hazard classification is the primary objective. Revision of data requirements to forego redundant testing could markedly reduce costs and animal use. It is problematic that this section does not (i) include rules for adaptation of in vivo data requirements, or (ii) identify accepted EU

or international test guidelines for fulfilling data requirements, which are particularly critical in the case of microbial agents.

Amendment 282

Proposal for a regulation

Annex II – title 2 – point 5.2.2.3

Text proposed by the Commission

Amendment

**5.2.2.3. Intraperitoneal/subcutaneous
single dose**

deleted

Justification

Neither i.p. nor s.c. injection are relevant routes of exposure. Consequently, the value of such studies for human risk assessment is dubious, and this data requirement should be deleted. It is problematic that this section does not (i) include rules for adaptation of in vivo data requirements, or (ii) identify accepted EU or international test guidelines for fulfilling data requirements, which are particularly critical in the case of microbial agents.

Amendment 283

Proposal for a regulation

Annex II – title 2 – point 5.2.5 – paragraph 1 (new)

Text proposed by the Commission

Amendment

***Testing shall be conducted via the oral
route unless the primary route of
exposure is expected to be inhalation.
Testing shall be carried out via only a
single exposure route.***

Justification

Testing via multiple exposure routes should not be necessary or encouraged. It is problematic that this section does not (i) include rules for adaptation of in vivo data requirements, or (ii) identify accepted EU or international test guidelines for fulfilling data requirements, which are particularly critical in the case of microbial agents.

Amendment 284

Proposal for a regulation

Annex II – title 2 – point 5.2.5.1 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Testing by the inhalation route is appropriate only if this constitutes the primary route of human exposure.

Justification

Testing via multiple exposure routes should not be necessary or encouraged. It is problematic that this section does not (i) include rules for adaptation of in vivo data requirements, or (ii) identify accepted EU or international test guidelines for fulfilling data requirements, which are particularly critical in the case of microbial agents.

Amendment 285

Proposal for a regulation

Annex II – title 2 – point 5.3 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Testing may be waived if there is no evidence of specific toxicity in earlier studies.

Justification

This should be a conditional Tier II requirement. It is problematic that this section does not (i) include rules for adaptation of in vivo data requirements, or (ii) identify accepted EU or international test guidelines for fulfilling data requirements, which are particularly critical in the case of microbial agents.

Amendment 286

Proposal for a regulation

Annex II – title 2 – point 5.4 – paragraph 1 (new)

Text proposed by the Commission

Amendment

For new substances, it should be possible to assess the parameters of an in-vivo micronucleus test as part of a repeated

exposure study.

Justification

In the pharmaceutical sector, it is becoming increasingly common to incorporate micronucleus assays into 28- or 90-day general toxicity studies in rats as a means of efficiently gathering mutagenicity data without a stand-alone in vivo study. This section should include (i) rules for adaptation of in vivo data requirements, or (ii) identify accepted EU or international test guidelines for fulfilling data requirements, which are particularly critical in the case of microbial agents.

Amendment 287

Proposal for a regulation

Annex II – title 2 – point 5.5 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Testing may be waived if there is no evidence of genotoxicity in somatic cell studies.

Justification

This should be a conditional Tier II requirement. It is problematic that this section does not (i) include rules for adaptation of in vivo data requirements, or (ii) identify accepted EU or international test guidelines for fulfilling data requirements, which are particularly critical in the case of microbial agents.

Amendment 288

Proposal for a regulation

Annex II – title 2 – point 8.1 – paragraphs 1 and 2 (new)

Text proposed by the Commission

Amendment

An avian dietary toxicity study in a single species may be proposed where a substance use profile indicates the potential for significant exposure to birds.

An avian reproduction study is not generally required, and is not appropriate if the dietary toxicity study (section 8.1.1.) shows that the LC50 is above 5,000

mg/kg.

Justification

Avian dietary toxicity testing, where indicated by use profile and other considerations, should be strictly limited to a single species. Reference: • REACH technical guidance: http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r7c_en.pdf?vers=20_08_08 It is problematic that this section does not (i) include rules for adaptation of in vivo data requirements, or (ii) identify accepted EU or international test guidelines for fulfilling data requirements, which are particularly critical in the case of microbial agents.

Amendment 289

Proposal for a regulation

Annex II – title 2 – point 8.2.1 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Requirements for aquatic toxicity testing on vertebrate animals may be waived if the use profile for a substance does not indicate significant potential for exposure to the aquatic environment.

Justification

The requirement for aquatic toxicity testing should be exposure-driven rather than absolute, particularly with respect to testing on vertebrate animals. It is problematic that Annex II, Title 2, does not (i) include rules for adaptation of in vivo data requirements, or (ii) identify accepted EU or international test guidelines for fulfilling data requirements, which are particularly critical in the case of microbial agents.

Amendment 290

Proposal for a regulation

Annex II – title 2 – point 8.7.2

Text proposed by the Commission

Amendment

8.7.2. Mammals

deleted

Justification

Unless a reference is provided to accepted EU or international test guidelines to address this data requirement, it should be deleted.

Amendment 291

Proposal for a regulation Annex III – point 1

Text proposed by the Commission

1. Dossiers on **product** shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL), Predicted Environmental Concentration (PEC) and Predicted No-Effect Concentration (PNEC).

Amendment

1. Dossiers on **biocidal products** shall contain the information needed to establish ***that exposure is below the Threshold of Toxicological Concern (TTC)***, or where relevant, ***to establish*** Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL), Predicted Environmental Concentration (PEC), and Predicted No-Effect Concentration (PNEC).

Justification

Threshold of Toxicological Concern is a “weight of evidence” risk assessment approach used extensively in the safety assessment of food additives, flavourings, food-contact materials, and other substances of unknown toxicity but with demonstrably low human exposure. When combined with known structural information and predicted metabolism or other behaviour, the approach bins chemicals into classes, each of which has its own acceptable human exposure limits. If exposure is below these very low levels, toxicity testing may be avoided.

Amendment 292

Proposal for a regulation Annex III – point 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 and Regulation (EC) No 1272/2008 shall apply.

Justification

Avoidance of unnecessary tests on vertebrates.

Amendment 293

Proposal for a regulation Annex III – point 5

Text proposed by the Commission

5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. However, if a method is inappropriate or not described, other methods shall be used which are , ***whenever possible, internationally recognised*** and must be justified in the application.

Amendment

5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in ***Council*** Regulation (EC) No 440/2008. ***Methods listed in Annex I do not cover nanomaterials, except where specifically mentioned.*** However, if a method is inappropriate or not described, other methods shall be used which are ***scientifically satisfactory*** and ***the validity of which*** must be justified in the application.

Justification

Nanomaterials are used due to their different or enhanced properties as compared to substances in bulk form. Due to their miniscule size and the resulting increase of relative surface area, they may pose new risks. The relevant scientific committee of the Commission concluded that the knowledge on the methodology for both exposure estimates and hazard identification needs to be further developed, validated and standardized for nanomaterials. As such, existing methods for bulk chemicals cannot be assumed to provide relevant data, unless clearly specified

Amendment 294

Proposal for a regulation Annex III – point 7

Text proposed by the Commission

7. Where testing is done, a detailed description (specification) of the material used and its impurities must be provided. ***Where necessary, data as established in Annex II shall be required for all the toxicologically/eco-toxicologically***

Amendment

7. Where testing is done, a detailed description (specification) of the material used and its impurities must be provided.

relevant chemical components of the biocidal product, in particular if the components are substances of concern as defined in Article 3.

Justification

It is unacceptable that data requirements for inclusion of an active substance in Annex I and for authorisation of a biocidal product result in duplicate testing or the repetition of tests, especially if they include animal experimentation. Non-active substances in a biocidal product formulation will be regulated under REACH. This provision should therefore be deleted in order to prevent confusion or potential duplicative vertebrate testing

Amendment 295

Proposal for a regulation Annex III –point 8

Text proposed by the Commission

8. Where test data exist that have been generated before ... [OJ: insert the date referred to in the first subparagraph of Article 85] by methods other than those laid down in Regulation (EC) No 440/2008, the adequacy of such data for the purposes of this Regulation and the need to conduct new tests according to the Regulation (EC) No 440/2008 must be decided by the competent authority of the Member State, on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrate animals.

Amendment

8. Where test data exist that have been generated before ... [OJ: insert the date referred to in the first subparagraph of Article 85] by methods other than those laid down in Regulation (EC) No 440/2008, the adequacy of such data for the purposes of this Regulation and the need to conduct new tests according to the Regulation (EC) No 440/2008 must be decided by the competent authority of the Member State ***concerned in agreement with the ECHA***, on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrate animals.

Amendment 296

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

Text proposed by the Commission

2.2. Detailed quantitative and qualitative

Amendment

2.2. Detailed quantitative and qualitative

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

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)***

Justification

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

Amendment 297

**Proposal for a regulation
Annex III – title 1 – point 3.7**

Text proposed by the Commission

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

Amendment

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

Storage stability and shelf life will be generally determined based on the stability of the active substance. In the case of readily decomposable active substances, the storage stability and the shelf life may be determined by other valid scientific means, such as extrapolating the analytical data of the active substance from product aging experiments until reaching the efficacy threshold.

Justification

Standard stability tests that are based on the measurements and quantification of the active substance are not appropriate for products containing readily decomposable active substances, such as sodium hypochlorite. These substances are known to decompose beyond accepted guidelines (FAO, WHO limits). Therefore, in such cases, it is more appropriate that the stability and the shelf-life is determined by other means, such as extrapolating the analytical data of the active substance from product aging experiments until reaching the efficacy threshold.

Amendment 298

Proposal for a regulation

Annex III – title 1 – point 6.1

Text proposed by the Commission

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

Amendment

For studies of Sections 6.1.1 to 6.1.3, ***without prejudice to Articles 6 and 9 of regulation (EC) No 1272/2008, classification by calculation may be the default approach. Only in exceptional cases should additional in-vivo testing be considered, and in such cases, only the single most relevant exposure route should be tested***. Gases and volatile liquids should be administered by the inhalation route.

Justification

Annex II of Directive 1999/45/EC provides for “classification by calculation” as an alternative to redundant in vivo testing for formulated preparations comprised of well characterised active substances and other ingredients. This approach should be promoted under the Biocidal Products Regulation. Research shows that dermal studies do not add value above and beyond oral data for hazard classification purposes in more than 99% of cases. Hence, data requirements should be revised to reflect these new findings.

Amendment 299

Proposal for a regulation

Annex III – title 1 – point 6.1.2

Text proposed by the Commission

6.1.2. Dermal

Amendment

deleted

Justification

This data requirement should be deleted on the basis of the aforementioned analysis, which found dermal classifications to be concordant with or less severe than oral classifications in over 99% of cases. Dermal classifications can therefore be based on direct read-across from oral data.

Amendment 300

Proposal for a regulation

Annex III – title 1 – point 6.1.3 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Testing by the inhalation route is appropriate only if (i) classification by calculation is not feasible and (ii) this constitutes the primary route of human exposure, taking into account the vapour pressure of the substance and the possibility of exposure to aerosols, particles or droplets of an inhalable size.

The Acute Toxic Class Method is the first-choice method for in-vivo testing. Only in exceptional circumstances should the classic “lethal concentration” (LC50) test be used. Justification for the use of another test shall be provided.

Justification

Annex II of Directive 1999/45/EC provides for “classification by calculation” as an alternative to redundant in vivo testing for formulated preparations comprised of well characterised active substances and other ingredients. This approach should be promoted under the Biocidal Products Regulation. Research shows that dermal studies do not add value above and beyond oral data for hazard classification purposes in more than 99% of cases. Hence, data requirements should be revised to reflect these new findings.

Amendment 301

Proposal for a regulation

Annex III – title 1 – point 6.1.4

Text proposed by the Commission

Amendment

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

deleted

Justification

This requirement should be deleted, as it would lead to unnecessary use of vertebrate animals in lethal/distressing studies with limited or no public health value beyond what can be gleaned from other acute test data.

Amendment 302

Proposal for a regulation

Annex III – title 1 – point 6.2 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Classification by calculation may be the default approach.

Justification

Annex II of Directive 1999/45/EC expressly provides for “classification by calculation” as an alternative to redundant in vivo testing for formulated preparations comprised of well characterised active substances and other ingredients. This approach should be more strongly promoted under the Biocidal Products Regulation. References: • Directive 1999/45/EC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0045:EN:HTML>

Amendment 303

Proposal for a regulation

Annex III – title 1 – point 6.3 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Classification by calculation may be the default approach.

Justification

Annex II of Directive 1999/45/EC expressly provides for “classification by calculation” as an alternative to redundant in vivo testing for formulated preparations comprised of well characterised active substances and other ingredients. This approach should be more strongly promoted under the Biocidal Products Regulation. References: • Directive 1999/45/EC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0045:EN:HTML> It is problematic that this title does not include rules for adaptation of in vivo data requirements.

Amendment 304

Proposal for a regulation Annex III - title 1 - point 6.4

Text proposed by the Commission

Amendment

(6.4) Information on dermal absorption

(6.4) Information on ***in-vitro*** dermal absorption

Justification

An OECD test guideline for in vitro dermal irritation has been available since 2004 and is capable of fully replacing the in vivo method for the purposes of the Biocidal Products Regulation. Consequently, these data requirements should specifically cite the in vitro method as the only necessary or acceptable approach for fulfilling this end Section.

Amendment 305

Proposal for a regulation Annex III – title 1 – point 9.2.1

Text proposed by the Commission

Amendment

**9.2.1. Where relevant all the information
required in Annex II, Section 12** ***deleted***

Justification

The requirement being referenced currently lacks any description of the specific data being sought, rules for adaptation, or rationale for why a “classification by calculation” approach would not suffice based on Annex II data for the active substance.

Amendment 306

Proposal for a regulation Annex III - title 1 - point 9.3.1.1

Text proposed by the Commission

Amendment

**9.3.1.1. Acute oral toxicity, if not already
done in accordance with Annex II,
Section 7** ***deleted***

Justification

According to REACH technical guidance, “few (if any) scenarios are likely to lead to acute poisoning risks for birds”, and “evidence from pesticides suggests that chronic effects cannot be reliably extrapolated or inferred from acute toxicity data.” Accordingly, this data requirement will contribute little or nothing to an environmental risk assessment and should therefore be deleted.

Amendment 307

Proposal for a regulation

Annex III – title 1 – point 9.3.3.1

Text proposed by the Commission

Amendment

**9.3.3.1. Toxicity to terrestrial vertebrates
other than birds** **deleted**

Justification

Unless a reference is provided to accepted EU or international test guidelines to address this data requirement, it should be deleted. It is problematic that this section does not include rules for adaptation of in vivo data requirements.

Amendment 308

Proposal for a regulation

Annex III – title 2 – point 6.1.1 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Without prejudice to Articles 6 and 9 of Regulation (EC) No 1272/2008, classification by calculation may be the default approach. Only in exceptional cases should additional in-vivo testing be considered, and in such cases, only the single most relevant exposure route should be tested.

Justification

Annex II of Directive 1999/45/EC provides for “classification by calculation” as an alternative to redundant in vivo testing for formulated preparations comprised of well

characterised active substances and other ingredients. This approach should be promoted under the Biocidal Products Regulation. Research shows that dermal studies do not add value above and beyond oral data for hazard classification purposes in more than 99% of cases. Hence, data requirements should be revised to reflect these new findings.

Amendment 309

Proposal for a regulation

Annex III – title 2 – point 6.1.2 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Testing by the inhalation route is appropriate only if this constitutes the primary route of human exposure.

Justification

Annex II of Directive 1999/45/EC provides for “classification by calculation” as an alternative to redundant in vivo testing for formulated preparations comprised of well characterised active substances and other ingredients. This approach should be promoted under the Biocidal Products Regulation. Research shows that dermal studies do not add value above and beyond oral data for hazard classification purposes in more than 99% of cases. Hence, data requirements should be revised to reflect these new findings.

Amendment 310

Proposal for a regulation

Annex III – title 2 – point 6.2.1 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Classification by calculation may be the default approach.

Justification

Annex II of Directive 1999/45/EC expressly provides for “classification by calculation” as an alternative to redundant in vivo testing for formulated preparations comprised of well characterised active substances and other ingredients. This approach should be more strongly promoted under the Biocidal Products Regulation. References: • Directive 1999/45/EC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0045:EN:HTML> It is problematic that this section does not include rules for adaptation of in vivo data requirements.

Amendment 311

Proposal for a regulation

Annex III – title 2 – point 6.2.2 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Classification by calculation may be the default approach.

Justification

Annex II of Directive 1999/45/EC expressly provides for “classification by calculation” as an alternative to redundant in vivo testing for formulated preparations comprised of well characterised active substances and other ingredients. This approach should be more strongly promoted under the Biocidal Products Regulation. References: • Directive 1999/45/EC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0045:EN:HTML> It is problematic that this section does not include rules for adaptation of in vivo data requirements.

Amendment 312

Proposal for a regulation

Annex III – title 2 – point 6.2.3 – paragraph 1 (new)

Text proposed by the Commission

Amendment

Classification by calculation may be the default approach.

Justification

Annex II of Directive 1999/45/EC expressly provides for “classification by calculation” as an alternative to redundant in vivo testing for formulated preparations comprised of well characterised active substances and other ingredients. This approach should be more strongly promoted under the Biocidal Products Regulation. References: • Directive 1999/45/EC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0045:EN:HTML> It is problematic that this section does not include rules for adaptation of in vivo data requirements.

Amendment 313

Proposal for a regulation
Annex III - title 2 - point 9.1

Text proposed by the Commission

Amendment

9.1. Effects on birds

deleted

Justification

Unnecessary for formulated product. Annex II of Directive 1999/45/EC expressly provides for “classification by calculation” as an alternative to redundant in vivo testing for formulated preparations comprised of well characterised active substances and other ingredients. This approach should be more strongly promoted under the Biocidal Products Regulation.

Amendment 314

Proposal for a regulation
Annex III - title 2 - point 9.2

Text proposed by the Commission

Amendment

9.2. Effects on aquatic organisms

deleted

Justification

Annex II of Directive 1999/45/EC expressly provides for “classification by calculation” as an alternative to redundant in vivo testing for formulated preparations comprised of well characterised active substances and other ingredients. This approach should be more strongly promoted under the Biocidal Products Regulation.

Amendment 315

Proposal for a regulation
Annex III - title 2 - point 9.7.2

Text proposed by the Commission

Amendment

9.7.2. Mammals

deleted

Justification

Unless a reference is provided to accepted EU or international test guidelines to address this data requirement, it should be deleted.

Amendment 316

Proposal for a regulation
Annex IV – point 1.1.3 a (new)

Text proposed by the Commission

Amendment

1.1.3a. Calculation methods for the evaluation of health hazards of preparations

Data requirements for preparations may generally be waived consistent with Annex II to Directive 1999/45/EC and/or Annex I to Regulation (EC) No 1272/2008, which takes into consideration all the health hazards of substances contained in the preparation. Guidance is specifically provided for the following categories of adverse health effects:

- acute lethal effects***
- non-lethal irreversible effects after a single exposure***
- severe effects after repeated or prolonged exposure***
- corrosive or irritant effects***
- sensitising effects***
- carcinogenic effects***
- mutagenic effects***
- reprotoxic effects***

Justification

Annex II of Directive 1999/45/EC expressly provides for “classification by calculation” as an alternative to redundant in vivo testing for formulated preparations comprised of well characterised active substances and other ingredients. This approach should be more strongly promoted under the Biocidal Products Regulation. References: • Directive 1999/45/EC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0045:EN:HTML>

Amendment 317

Proposal for a regulation
Annex IV – point 1.4 – paragraph 2 – point 2

Text proposed by the Commission

Amendment

(2) results are adequate for the purpose of classification and labelling **and** risk assessment; and

(2) results are adequate for the purpose of classification and labelling **and/or** risk assessment; and

Justification

Some toxicity tests (e.g. acute studies) are used exclusively for classification and labelling purposes and not for risk assessment; thus, it is important to accommodate these different regulatory purposes with the term “and/or”.

Amendment 318

**Proposal for a regulation
Annex V – Product-type 9**

Text proposed by the Commission

Amendment

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

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

These include products which inhibit surface build-ups of microorganisms (e.g. pathogenic or odour-generating germs) and thus curb or prevent the creation of odours and/or have other uses.

Justification

The catalogue of product groups must also cover biocidal products used in the textiles sector.

Amendment 319

**Proposal for a regulation
Annex VI - introduction - point 2**

Text proposed by the Commission

Amendment

2. In order to ensure a high and harmonised level of protection of human and animal

2. In order to ensure a high and harmonised level of protection of human and animal

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

health and of the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of any risks identified during the proposed normal use of the biocidal product. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product, ***taking due account of cumulative, combination and synergistic effects.***

Justification

The consideration of cumulative, combination and synergistic effects needs to be included explicitly in the common principles for the evaluation of dossiers.

Amendment 320

Proposal for a regulation Annex VI - introduction - point 3

Text proposed by the Commission

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

Amendment

3. A risk assessment on the active substance or substances present in the biocidal product is always required. This will already have been carried out for the purpose of the inclusion of the active substance into Annex I. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation, ***taking due account of cumulative, combination and synergistic effects.*** Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.

Justification

The consideration of cumulative, combination and synergistic effects needs to be included explicitly in the common principles for the evaluation of dossiers.

Amendment 321

Proposal for a regulation Annex VI – introduction – point 4

Text proposed by the Commission

Amendment

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

Justification

It is not acceptable to require risk assessments for other substances than the active substances in a biocidal product. This would lead to a duplication of testing procedures, including animal experimentation, as all chemical ingredients also have to be assessed within the scope of the REACH regulation. All available data for non-active substance ingredients rather has to be included in dossiers.

Amendment 322

Proposal for a regulation Annex VI – evaluation – point 14

Text proposed by the Commission

Amendment

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

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

Justification

It is not acceptable to require risk assessments for other substances than the active substances in a biocidal product. This would lead to a duplication of testing procedures, including animal experimentation, as all chemical ingredients also have to be assessed within the scope of the REACH regulation. All available data for non-active substance ingredients rather has to be included in dossiers.

Amendment 323

Proposal for a regulation Annex VI - evaluation - point 15

Text proposed by the Commission

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

Amendment

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

Justification

The consideration of cumulative, combination and synergistic effects needs to be included explicitly in the common principles for the evaluation of dossiers.

Amendment 324

Proposal for a regulation Annex VI – evaluation – point 20 – indent 9 a (new)

Text proposed by the Commission

Amendment

– – immunotoxicity

Amendment 325

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 on the active substance and existing information on 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.

Justification

Avoidance of unnecessary tests on vertebrates.

Amendment 326

Proposal for a regulation Annex VI – evaluation – point 47

Text proposed by the Commission

Amendment

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

47. Data shall be submitted to and evaluated by the competent authorities to assess whether the biocidal product does not cause unnecessary suffering ***and pain*** in its effect on target vertebrates. This shall include an evaluation of the mechanism by which the effect is obtained and the observed effects on the behaviour and health of the target vertebrates; where the intended effect is to kill the target vertebrate the time necessary to obtain the death of the target vertebrate and the conditions under which death occurs shall be evaluated. ***These findings shall for each authorised biocidal product be made publicly available on the Agency website.***

Amendment 327

Proposal for a regulation

Annex VI- decision making - point 59 - indent 2

Text proposed by the Commission

- the nature and severity of the effect,

Amendment

- the nature and severity of the effect,
***taking due account of cumulative,
combination and synergistic effects***

Justification

The consideration of cumulative, combination and synergistic effects needs to be considered in the decision-making process.

Amendment 328

Proposal for a regulation

Annex VI – decision making – point 77 – introductory part

Text proposed by the Commission

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

Amendment

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

Justification

Ensures to comply with the standards of Community provisions and international agreements for the protection of waters.

Amendment 329

Proposal for a regulation

Annex VI – decision making – point 77 – indent 2 a (new)

Text proposed by the Commission

Amendment

- – risk a non-achievement of the objectives or standards fixed by:*
- Directive 98/83/EC, or*
- Directive 2000/60/EC or*
- Directive 2006/118/EC or*
- Directives 2008/56/EC, or*
- Directive 2008/105/EC, or*
- international agreements containing important obligations on the protection of marine waters from pollution or*

Justification

Ensures to comply with the standards of Community provisions and international agreements for the protection of waters.

Amendment 330

Proposal for a regulation

Annex VI – decision making – point 77 – last part

Text proposed by the Commission

Amendment

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

Justification

Ensures to comply with the standards of Community provisions and international agreements for the protection of waters.

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.

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS ON THE LEGAL BASIS

Mr Jo Leinen
Chair
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on the legal basis concerning the placing on the market and use of biocidal products (COM(2009)0267 – C7-0036/2009 – 2009/0076(COD))

Dear Mr Leinen,

By letter of 21 April 2010 you asked the Committee on Legal Affairs pursuant to Rule 37(2) of the Rules of Procedure, to give its opinion on a proposed change to the legal basis of the proposal from a single basis of Article 114 TFEU to a triple basis of Articles 114, 192 and 168 TFEU.

The committee considered the above question at its meeting of 17 May 2010.

I. Background

Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market was adopted on 16 February 1998. It establishes a harmonised regulatory framework for the authorisation and the placing on the market of biocidal products, the mutual recognition of these authorisations within the EU and the establishment at EU level of a positive list of active substances that may be used in biocidal products.

The regulatory framework for biocidal products also consists of a number of implementing Commission Regulations, in particular Commission Regulation (EC) No 1451/2007¹ on the second phase of the 10-year work programme referred to in Article 16(2) of the Directive.

The report submitted by the Commission on the implementation of the Directive (COM(2008)620, hereinafter "the review") forms the basis for the proposal. The review found that modifications of the Directive including procedural simplification of product authorisation, simplification and adaptation of the scope of the Directive, a tiered approach to data requirements and simplified data protection rules, improvement of the simplified procedures, and measures to encourage innovation could be beneficial in reducing the costs and administrative burden for companies and public authorities for introducing biocidal products onto the market.

The aims of the proposal, as stated in the Explanatory Memorandum, are to "tackle the

¹ OJ L 325, 11.12.2007, p. 3.

identified weaknesses of the regulatory framework during the first eight years of its implementation, to improve and update certain elements of the system and to avoid problems anticipated in the future". As far as an overarching aim is concerned, the proposal states in its Preamble, paragraph 3: "The purpose of this Regulation is to increase the free movement of biocidal products within the Community ... to remove as far as possible obstacles to trade in biocidal products stemming from different levels of protection in the Member States".

II. The Proposed Legal Bases

The legal bases put forward for the proposed regulation are:

Article 114 TFEU

- 1. Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.*
- 2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.*
- 3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.*
- 4. If, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 36, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.*
- 5. Moreover, without prejudice to paragraph 4, if, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.*
- 6. The Commission shall, within six months of the notifications as referred to in*

paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.

When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 258 and 259, the Commission and any Member State may bring the matter directly before the Court of Justice of the European Union if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to a Union control procedure.

Article 192 TFEU

1. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall decide what action is to be taken by the Union in order to achieve the objectives referred to in Article 191¹.

¹ Article 191

1. Union policy on the environment shall contribute to pursuit of the following objectives:

- preserving, protecting and improving the quality of the environment,*
- protecting human health,*
- prudent and rational utilisation of natural resources,*
- promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change.*

2. Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at

2. By way of derogation from the decision-making procedure provided for in paragraph 1 and without prejudice to Article 114, the Council acting unanimously in accordance with a special legislative procedure and after consulting the European Parliament, the Economic and Social Committee and the Committee of the Regions, shall adopt:

- (a) provisions primarily of a fiscal nature;
- (b) measures affecting:
 - town and country planning,
 - quantitative management of water resources or affecting, directly or indirectly, the availability of those resources,
 - land use, with the exception of waste management;
- (c) measures significantly affecting a Member State's choice between different energy sources and the general structure of its energy supply.

The Council, acting unanimously on a proposal from the Commission and after consulting the European Parliament, the Economic and Social Committee and the Committee of the Regions, may make the ordinary legislative procedure applicable to the matters referred to in the first subparagraph.

3. General action programmes setting out priority objectives to be attained shall be adopted by the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions.

The measures necessary for the implementation of these programmes shall be adopted under the terms of paragraph 1 or 2, as the case may be.

4. Without prejudice to certain measures adopted by the Union, the Member States shall finance and implement the environment policy.

5. Without prejudice to the principle that the polluter should pay, if a measure based on the provisions of paragraph 1 involves costs deemed disproportionate for the public authorities of a Member State, such measure shall lay down appropriate

source and that the polluter should pay.

In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a procedure of inspection by the Union. EN C 83/132 Official Journal of the European Union 30.3.2010

3. In preparing its policy on the environment, the Union shall take account of:

- available scientific and technical data,
- environmental conditions in the various regions of the Union,
- the potential benefits and costs of action or lack of action,
- the economic and social development of the Union as a whole and the balanced development of its regions.

4. Within their respective spheres of competence, the Union and the Member States shall cooperate with third countries and with the competent international organisations. The arrangements for Union cooperation may be the subject of agreements between the Union and the third parties concerned.

The previous subparagraph shall be without prejudice to Member States' competence to negotiate in international bodies and to conclude international agreements.

provisions in the form of:

- temporary derogations, and/or*
- financial support from the Cohesion Fund set up pursuant to Article 177.*

Article 168 TFEU

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

- (a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;*

- (b) *measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;*
- (c) *measures setting high standards of quality and safety for medicinal products and devices for medical use.*

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

III. Applicable law

It is settled case-law that the choice of legal basis for a Community measure must rest on objective factors amenable to judicial review, which include in particular the aim and content of the measure¹.

In principle, a measure is to be founded on only one legal basis. If examination of the aim and the content of a Community measure reveals that it pursues a twofold purpose or that it has a twofold component, falling within the scope of different legal bases, and if one is identifiable as the main or predominant purpose or component, whereas the other is merely incidental, the measure must be based on a single legal basis, namely that required by the main or predominant purpose or component².

Only if, exceptionally, it is established that the measure simultaneously pursues a number of objectives or has several components that are indissociably linked, without one being secondary and indirect in relation to the other, will that measure have to be founded on the various corresponding legal bases, insofar as their procedures are compatible³.

¹ Case C-440/05 *Commission v. Council* [2007] ECR I-9097.

² Case C-91/05 *Commission v. Council* [2008] ECR I-3651.

³ Case C-338/01 *Commission v. Council* [2004] ECR I-4829.

Recourse to a dual legal basis is not possible where the procedures laid down for each legal basis are incompatible with each other¹.

IV. Analysis of Directive 98/8/EC and the proposal

The Directive provides for a regulatory system of authorisation, mutual recognition and a finite list of authorised active substances, which aims to overcome possible barriers to the internal market in biocidal products while taking as a condition "a high level of protection for humans, animals and the environment"².

The proposal is essentially a harmonisation measure, designed to simplify the Directive's system of authorisation of biocidal products across the Union in order to facilitate the free movement of goods and to maintain the internal market. It is aimed at the weaknesses of the Directive's regulatory framework and at updating the authorisation procedures. It also extends the scope of the Directive to include materials that might come into contact with food, and articles or materials that have been treated with biocidal products. By turning the Directive into a regulation, the proposal aims to achieve a more harmonised implementation of the regulatory framework as there will be no need for a transposition period or for national transposition measures in Member States.

V. Analysis of the legal bases proposed

Article 114 TFEU mandates via the ordinary legislative procedure Community measures "which have as their object the establishment and functioning of the internal market". This article should be read in the context of Article 26 TFEU, establishing free movement of goods as a fundamental principle in the establishment of the internal market. In addition Article 114(3) should be noted as establishing a "high level of protection" in measures dealing with health, safety, environmental and consumer protection. Paragraphs (4) to (9) permit Member States to take national measures to introduce justified prohibitions or restrictions on imports, exports or goods in transit, pursuant to Article 36 TFEU, after a harmonisation measure has been adopted. Paragraphs (4) to (9) therefore represent a significant qualification of the overall aim of the article in fostering the establishment and functioning of the internal market.

Article 168 TFEU comes under Title XIV on Public Health. It concentrates on maintaining a "high level of human health protection" in terms of health services and the prevention of cross border threats to human health. Article 168(4)(b) however provides by way of derogation a mandate for "measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health", using the ordinary legislative procedure. Whilst it could be argued that the aim of the proposal, in facilitating the internal market in biocides which can protect and preserve animal and plant life, corresponds with this provision, the proposal does not have as its "direct objective" the protection of public health. The direct objective of the proposal, as indicated in recital (3) in the preamble, is to increase the free movement of biocidal products within the Community. As will be posited in more detail below, the protection of public health should be regarded as one, but not the main or dominant, purpose of the proposal.

¹ Case C-178/03 *Commission v. Parliament and Council* [2006] ECR I-107.

² Recital (4), Directive 98/8/EC

Article 192(1) TFEU permits measures to be taken under the ordinary legislative procedure to enact Union policy under Article 191 on, *inter alia*, preserving, protecting and improving the quality of the environment, and protecting human health. Article 192(2) permits measures to be taken under a special legislative procedure which concern, *inter alia*, measures affecting the quantitative management of water resources, and land use. It is submitted that the more relevant provision in terms of the proposal is Article 192(1): in particular the proposal falls within the scope of preserving and protecting the quality of the environment and protecting human health specifically set out in that provision.

As we have seen, the case law makes it clear that where there is more than one possible legal basis for a Community measure, the general rule is that the basis which corresponds to the main or dominant purpose of the measure should be used, *unless* exceptionally the purposes of the measure are indissociably linked without one being secondary to the other, and the corresponding legal bases are procedurally compatible.

It is clear that the legal bases put forward in the Committee on the Environment, Public Health and Food Safety are procedurally compatible: those parts of the suggested articles which provide for special legislative procedure do not correspond to the scope and aim of the proposal, while the key parts of each proposed legal basis which do correspond to the scope and aim of the proposal all apply the ordinary legislative procedure. It must therefore be considered whether the aims of the proposal can be regarded as indissociably linked without one being secondary to the other: if so, a multiple legal basis may be possible.

It is posited above that the aim of maintaining the internal market by facilitating inter-Member State trade in biocidal products is the dominant or main purpose of the proposal, while the protection of the environment and human and animal life is a secondary purpose. It is instructive to compare the proposal with similar recent legislation in this area such as the REACH regulation on chemicals, Regulation (EC) No 1907/2006, which according to the Explanatory Memorandum of the proposal, was taken into consideration in the creation of the proposal. REACH, also based on Article 114 TFEU, clearly states in Article 1 that its purpose is to ensure a high level of protection of human health and the environment, *as well as* the free circulation of substances on the internal market. By contrast; the proposal acknowledges that biocidal products "can pose risks" to humans, animals and the environment, while retaining as its explicit stated purpose improving the free movement of biocidal products on the internal market. Concerning specific references to the level of protection within the proposal, REACH has embedded within Article 3 the precautionary principle which determines that where there are reasonable grounds for concern that a measure poses potentially dangerous effects to the environment, human, animal or plant health inconsistent with the high level of protection adhered to by the EU, certain action may be taken to remedy the situation as long as there is a risk which is too high to impose on society. While according to recital (10) in the preamble, the most hazardous substances are not permitted for authorisation "with a view to achieving a high level of environmental and human health protection", there is no reference to the precautionary principle itself in the preamble or the enacting terms of the proposal.

The extension of the scope of the Directive to include in the regulation devices which produce biocides and materials containing biocides which may come into contact with food, and articles treated with biocides such as furniture, as well as the phasing out of products which

contain hazardous carcinogenic substances, indicates that the proposal is also aimed at reaching an optimum balance between the benefits and risks attached to trade in biocidal products within the European Union. Recital (1) in the preamble to the proposal states as follows:

"Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured products. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic property and associated use patterns".

This demonstrates an awareness of the tension between the benefits of facilitating trade in biocidal products and the risks of making such products more widely available and therefore increasing the chance of contact with humans, animals and the environment. It is submitted however that the proposal's statements throughout the preamble that its aim is to facilitate the free movement of goods and the internal market suggest that the risks of making biocidal products more widely available are weighed as an integral part of the measures used to achieve the aim of the proposal. Protection is therefore a key aim of the proposal, but cannot be said to be its dominant or main purpose.

Further substantive elements of the proposal support this argument. There is an apparent refusal to authorise "active substances with the worst hazard profiles" in recital (10) in the preamble, which suggests a strong commitment to the protection of human, animal and plant life. However, this is undermined by relatively imprecise exemptions such as:

- i. the approval of such substances in "situations when the exposure of humans to the substance is negligible or the substance is necessary for public health reasons" (recital (11)).
- ii. Article 5, concerning exclusion criteria, permits active substances which do not comply with the conditions in Article 16(1) of the proposal (including not having an "unacceptable effect" on human, animal and plant life) to be authorised if it is shown that *not* including them would cause "disproportionate negative impacts when compared with the risk to human health or the environment arising from the use of the substance" (Article 5(1)(c)).
- iii. the requirement of a full in-depth evaluation of an application to renew the authorisation of an active substance only exists where the competent authority that was responsible for the initial evaluation decides to carry out such an evaluation itself. This leaves renewals at a much lower level of protection than initial authorisation.

By contrast, the key elements of the proposal are targeted at facilitating the free movement of biocidal products within the Community. The proposal focuses on the following measures:

- removing the simplified procedures for the evaluation of active substances, in particular low-risk substances;

- simplifying the authorisation procedures for biocidal products, including setting up a centralised system for authorisation, for which the European Chemicals Agency will be competent in carrying out the technical and scientific tasks, and harmonising procedures for mutual recognition of authorisations;
- providing for specific parallel trade rules to minimise the administrative burden on cross-border trade in biocidal products.

All the above measures are aimed at simplifying and harmonising administrative procedures in the authorisation process, which will facilitate cross-border trade in biocidal products.

Further, in paragraph 3.3 of the Explanatory Memorandum, dealing with subsidiarity, the justification given for the EU taking action in this area is the harmonisation of potential "obstacles to trade in biocidal products" resulting from different levels of protection in different Member States. The characterisation of levels of protection as potential "obstacles to trade", even where the level of protection in another Member State could be higher than is currently provided in the Directive, indicates that the facilitation of trade is clearly the dominant aim of this proposal.

Having established that there is one dominant purpose in the proposal and therefore that following the case law it is appropriate to have a single legal basis rather than multiple bases, it is therefore necessary to determine which of the three proposed legal bases is appropriate. A further comparison with the REACH regulation reveals that that measure is based on Article 114 TFEU, but clearly holds the protection of human, animal and plant life in higher regard than the proposal. Neither Article 192 nor Article 168, both of which overwhelmingly concern the protection of human, animal and plant life, is used as a legal basis in REACH. It would therefore be logical that a proposal with a much weaker emphasis on protection, but with a greater emphasis on the free movement of goods within the Union should rely on Article 114 as its legal basis.

Any basis in Article 168 would be weak as the proposal does not satisfy the criteria in Article 168(4)(b) of having as its "direct objective" the protection of public health.

Article 192 is perhaps more applicable; however, the incompatibility of Article 192 and the proposal is clear from the inconsistency between the proposal's dominant aim in facilitating the internal market, and the overriding purpose of Article 192 in terms of protection. Further, Article 191 TFEU requires Union policy in this area to be based on the precautionary principle; but this principle does not appear in the proposal. Article 114 however provides sufficient protection to the same level as the proposal - a "high level of protection" in Article 114(3) corresponds with the "high level of protection" in recital 10 in the preamble and in the Explanatory Memorandum: "The proposal is seeking to improve the existing regulatory framework, without reducing the high level of protection for the environment and human and animal health". Article 114 is therefore the more appropriate legal basis from a protection perspective.

Taking into account the fact that the internal market is the dominant aim of the proposal and the protection aspect of the proposal an incidental or secondary aim, rather than the two aims being "indissociable" and equal in status, it would not be appropriate to condone the use of a

dual legal basis at all in the context of the case law in this area.¹ It would indeed be appropriate to conclude that the legal basis which best corresponds to the dominant aim of the proposal, Article 114, should be retained as the sole legal basis of the proposal.²

V. Conclusion and recommendation

At its meeting of 17 May 2010 the Committee on Legal Affairs accordingly decided, unanimously³, to recommend to you that Article 114 of the Treaty on the functioning of the European Union should be the sole legal basis for the proposal for a regulation in question.

Yours sincerely,

Klaus-Heiner Lehne

¹ Case C-338/01 Commission v Council (2004)

² Case C-91/05 Commission v Council (2008)

³ ³ The following were present for the final vote: Luigi Berlinguer (acting Chair), Raffaele Baldassarre (Vice-Chair), Evelyn Regner (Vice-Chair), Sebastian Valentin Bodu (Vice-Chair), Kurt Lechner (rapporteur), Françoise Castex, Christian Engström, Marielle Gallo, Eva Lichtenberger, Antonio Masip Hidalgo, Bernhard Rapkay, Francesco Enrico Speroni, Cecilia Wikström, Tadeusz Zwiefka.

18.5.2010

OPINION OF THE COMMITTEE ON THE INTERNAL MARKET AND CONSUMER PROTECTION

for the Committee on the Environment, Public Health and Food Safety

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)0267 – C7-0036/2009 – 2009/0076(COD))

Rapporteur (*): Amalia Sartori

(*) Procedure with associated committees – Rule 50 of the Rules of Procedure

SHORT JUSTIFICATION

The purpose of the proposal for a regulation concerning the placing on the market and use of biocidal products is to revise the existing European Union regulatory framework; this is currently provided by Directive 98/8/EC, which would consequently be repealed.

Biocides are products, containing one or more active substances, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any organism which is harmful to human or animal health and to the environment. Biocides, used with care, are part of everyday life in our society, in that they prevent the spread of diseases and promote a high standard of hygiene in a heavily populated environment. Some of these products may be intrinsically hazardous.

The biocides market in the European Union is estimated to be worth some € 900 million annually, and around 90 000 tonnes of products are placed on the market every year. Directive 98/8/EC constitutes the first legislative framework to regulate the placing on the market and use of such products. In this proposal for a regulation the Commission has introduced a series of improvements to several aspects of the regulatory framework, such as the length of the procedures for authorising and evaluating active substances and biocidal products, and the lack of a centralised procedure, of specific rules on parallel trade and of a requirement to share vertebrate animal studies.

The proposal for a regulation under consideration duly responds to the need that was felt for revision and simplification, and addresses the existing problems properly. However, the

rapporteur considers that the proposal could be further improved so as to achieve:

- maximum simplification of the procedures for authorising and evaluating active substances and biocidal products, of research and development activities and of the national tariff system;
- greater harmonisation of the European market and of national regulatory approaches, primarily through a clearer definition of the procedures for mutual recognition, central authorisation and the protection of sensitive data;
- a reduction in the costs, and the abolition, of administrative obstacles, especially for small and medium-sized firms, ensuring that they have appropriate technical, linguistic and administrative support in a system which may be very complex, particularly for those without the requisite experience;
- greater consumer protection, providing an appropriate labelling system which is in keeping with the level of risk and conveys useful and pertinent information with the aim of protecting the health of all types of consumers, especially non-experts.

This is why the rapporteur has proposed a series of amendments to the Commission text which are along the lines described above and which concern matters which are being dealt with under the joint competence of the Committee on the Internal Market and Consumer Protection in accordance with the procedure with associated committees (Rule 50 of the Rules of Procedure). In addition to the changes proposed to Articles 25, 28, 44, 47, 54, 58 and 62, which are matters of joint competence, the rapporteur considered it appropriate to table further improvements to other parts of the text, as well, with the aim of:

- (a) improving the procedures and requirements for access to data, in order to create the conditions for regulating the phenomenon of 'free riders', in particular by tightening up Article 83;
- (b) reducing the time, and hence the cost, involved in the procedures for validating and evaluating applications, for decision-taking by the Commission and the competent authorities, or for renewing authorisations;
- (c) defining more clearly administrative or non-substantive changes to frame formulations or to products authorised under the same frame formulation;
- (d) getting rid of the arbitrary discrimination against those disinfectant products which cannot benefit from the exclusion criteria described in Article 5;
- (e) examining the appropriateness of replacing a product once the requisite experience with it has been obtained;
- (f) improving the procedures for mutual recognition of national authorisations;
- (g) balancing the conditions for parallel trade in identical products based on the same source and the same co-formulants;
- (h) improving the labelling of the items and materials dealt with, drawing a distinction between those which can release a biocidal product and those which cannot do so; defining

more clearly the details to be included on the label, apart from the positioning thereof, in order to provide effective and appropriate information;

(i) bringing the provisions of the regulation into line with the existing legislation, with particular reference to REACH and to the rules on plant protection products and concerning the abolition of the distinction between new and existing data, the provisions relating to research and development and the role of the Agency.

The rapporteur will not include in this opinion the changes needed to adjust to the new system of delegated acts introduced by the Lisbon Treaty, since these will be made by the committee responsible.

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a regulation Recital 11 a (new)

Text proposed by the Commission

Amendment

(11a) In order to achieve the highest level of protection of human and animal health and of the environment, the Commission should submit, within two years of the entry into force of this Regulation, a report to the European Parliament and the Council regarding adequate measures to promote the sustainable use of biocidal products across the different product types. That report may cover issues concerning the training, certification and re-certification of professional users; the provision of dedicated information points for non-professional users; the adoption of national plans for reducing the risks associated with the use of biocidal products; the use of the best technologies available; the requirement to notify the competent authorities of incidents; the use of the requisite equipment and other risk-reduction measures; the development of risk indicators per product category; measures against illegal products; guidelines with regard to the storage; the recycling and disposal of products; soil and air contamination; and use in densely populated areas or in those with a high concentration of food resources. On the basis of this report, the Commission should present, where appropriate, legislative proposals.

Amendment 2

Proposal for a regulation Recital 20

Text proposed by the Commission

Amendment

(20) As products used for the preservation of food or feedstocks by the control of harmful organisms, previously covered by product type 20, are covered by Council Directive 89/107/EEC and Regulation (EC) No 1831/2003 of the European Parliament and of the Council, it is not appropriate to maintain this product type.

deleted

Justification

It is necessary to keep former Directive 98/80/EC's biocidal product type 20 ('Preservatives for food or feedstocks'), but its definition needs to be amended, given that these biocidal products are not preservatives but disinfectants (as a consequence, the older definition led to confusion). For instance, products used to disinfect feed from human pathogens such as Salmonella do not meet the requirements of the feed additives regulations. Indeed, the products do not 'favourably affect the feed' nor enhance its performance.

Amendment 3

Proposal for a regulation Recital 45

Text proposed by the Commission

Amendment

*(45) In view of the benefits for the internal market and for the consumer, it is desirable to establish harmonised rules for parallel trade of **substantially** identical biocidal products that are authorised in different Member States.*

(45) In view of the benefits for the internal market and for the consumer, it is desirable to establish harmonised rules for parallel trading of identical biocidal products which are authorised in different Member States.

Justification

By restricting parallel trade authorisation to identical products based on the same source of active substances and co-formulants, a more reasonable balance is achieved between free trade in goods and a safe market environment. The same approach was used for the placing

of plant protection products on the market.

Amendment 4

Proposal for a regulation

Recital 48

Text proposed by the Commission

(48) 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

(48) Applicants *who* 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 ***or those of 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.

Justification

In the interests of greater clarity it is worthwhile to insert a reference to Directive 98/8/EC, so as not to exclude those who have made investments under the existing regulatory framework.

Amendment 5

Proposal for a regulation

Recital 66

Text proposed by the Commission

(66) Taking into consideration that some products were not previously covered by the Community legislation in the field of biocidal products, it is appropriate to allow for a transitional period for the companies to be prepared to apply the rules concerning in situ generated active substances, treated articles ***and materials*** and ***food contact*** materials.

Amendment

(66) Taking into consideration that some products were not previously covered by the Community legislation in the field of biocidal products, it is appropriate to allow for a transitional period for the companies to be prepared to apply the rules concerning in situ generated active substances ***and*** treated articles and materials.

Justification

Food contact materials should not be within the scope of the Proposal as this would lead to double regulation and assessment. Food contact materials are already regulated by the Food Contact Materials Framework Regulation (EC) No 1935/2004. Should any changes be made to the rules governing food contact materials, they should be addressed through a revision of the food contact legislation, not by extending the scope of the BPR.

Amendment 6

Proposal for a regulation

Article 1 – paragraph – 1 (new)

Text proposed by the Commission

Amendment

-1. This Regulation establishes a framework for achieving the free movement of biocides in the internal market, while ensuring a high level of protection of human and animal health and of the environment.

Amendment 7

Proposal for a regulation

Article 1 – paragraph – 1 a (new)

Text proposed by the Commission

Amendment

1a. The provisions of this Regulation are based on the precautionary principle in order to ensure that the active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the biocidal products to be authorised in their territory.

Amendment 8

Proposal for a regulation
Article 1 a (new)

Text proposed by the Commission

Amendment

Article 1a

Aim

The aim of this Regulation shall be a high level of health and environmental protection. Special attention shall be paid to protecting children, pregnant women and the sick.

Amendment 9

Proposal for a regulation
Article 2 – paragraph 2 – point p a (new)

Text proposed by the Commission

Amendment

(pa) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC¹;

¹ OJ L 338, 13.11.2004, p. 4.

Justification

Food contact materials should not be within the scope of the Proposal as this would lead to double regulation and assessment. Food contact materials are already regulated by the Food Contact Materials Framework Regulation (EC) No 1935/2004. Should any changes be made to the rules governing food contact materials, they should be addressed through a revision of the food contact legislation, not by extending the scope of the BPR.

Amendment 10

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, should normally be a
substance classified as dangerous within
the meaning of Directive 67/548/EEC of 27
***June 1967 on the approximation of the
laws, regulations and administrative
provisions relating to the classification,
packaging and labelling of dangerous
substances***¹ and be 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;

¹ OJ 196, 16.8.1967, p. 1.

Justification

The additional text reflects the definition already included in Directive 98/8/EC and has been inserted, updated in line with the existing legislation, to ensure greater clarity and consistency.

Amendment 11

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

Amendment

(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*;

which was treated with or incorporates one or more biocidal products with the *aim of performing the biocidal function for which it is intended*;

Justification

This amendment broadens the definition of treated articles and materials to include both articles such as paints and varnishes, which contain preserving agents, and articles with external effects, such as mosquito nets, which contain a biocidal product. The assessment is thus a chemical one.

Amendment 12

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 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;

Amendment

(q) 'letter of access' means

an original document, signed by the owner or owners of information *or their representative*, which states that the 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 *for the benefit of a third party*;

Justification

The clarifications inserted into the text of this point are intended to improve the definition of 'letter of access'.

Amendment 13

Proposal for a regulation

Article 3 – paragraph 1 – point s

Text proposed by the Commission

Amendment

s) *'food contact materials' means* **deleted**
any material and article intended to come into contact with food which are covered by Regulation (EC) No 1935/2004;

Justification

Food contact materials should not be within the scope of the Proposal as this would lead to double regulation and assessment. Food contact materials are already regulated by the Food Contact Materials Framework Regulation (EC) No 1935/2004. Should any changes be made to the rules governing food contact materials, they should be addressed through a revision of the food contact legislation, not by extending the scope of the BPR.

Amendment 14

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(ua) 'administrative change' means
a variation to an existing authorisation of a purely administrative nature, which does not involve a reassessment of the risk for public health or the environment or the efficacy of the product;

Justification

The kinds of variation which may be made to an existing authorised biocidal product (change of address, changes to the name of the producer, etc.) should be defined.

Amendment 15

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(ub) 'minor change' means
a variation to an existing authorisation
which cannot be deemed to be an
administrative variation as it requires a
limited reassessment of the risk for public
health or the environment or of the
efficacy of the product, and does not
adversely affect the level of risk for public
health or the environment or the efficacy
of the product;

Justification

The kinds of variation which may be made to an existing authorised biocidal product should be defined.

Amendment 16

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(uc) 'major change' means
a variation to an existing authorisation
which cannot be deemed to be an
administrative change or a minor change.

Justification

The kinds of variation which may be made to an existing authorised biocidal product should be defined.

Amendment 17

Proposal for a regulation Article 3 a (new)

Text proposed by the Commission

Amendment

Article 3a

Prospective applications for inclusion

1. A prospective applicant seeking the inclusion of an active substance in Annex I shall inquire of the Agency whether:

(a) the active substance is included in Annex I;

(b) an application has already been made to have the same active substance included in Annex I;

(c) the same substance is registered pursuant to Regulation (EC) No 1907/2006.

2. The prospective applicant shall forward the following information to the Agency with the application:

(a) the general 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 sections 1.2 and 1.3;

(b) the identity of the active substance as laid down in section 2 of Annex VI to Regulation (EC) No 1907/2006;

(c) which requests for information will require new vertebrate animal studies;

(d) which requests for information will require other new studies.

3. If the same active substance is not included in Annex I or is not registered pursuant to Regulation (EC) No 1907/2006 the Agency shall inform the prospective applicant accordingly, otherwise the Agency shall supply the prospective applicant, without delay, with

the names and addresses of previous applicants and registrants and with the summaries of the studies already supplied.

4. The Agency shall at the same time inform the previous applicant or registrant of the name and address of the prospective applicant seeking inclusion in Annex I. The available vertebrate animal studies shall be shared with the prospective applicant in accordance with Chapter XI of this Regulation.

Justification

The procedures described are necessary in order to avoid duplicating tests on vertebrate animals and to comply with requests for Annex II information. The 'obligation to provide information' under the REACH Regulation is made mutual, as the Agency will have the requisite infrastructure and experience to apply this procedure.

Amendment 18

Proposal for a regulation

Article 4 – paragraph 1

Text proposed by the Commission

1. An active substance shall be included in Annex I for an initial period not exceeding 10 years if the biocidal products containing that active substance fulfil the conditions laid down in point (b) of Article 16(1).

Amendment

1. An active substance shall be included in Annex I for an initial period not exceeding 10 years if ***at least one of*** the biocidal products containing that active substance ***fulfils*** the conditions laid down in point (b) of Article 16(1).

Justification

The proposed addition reflects the concept of inclusion in Annex I more clearly. At the time of inclusion the dossier must be submitted for at least one representative biocidal product the active substance of which meets the conditions laid down.

Amendment 19

Proposal for a regulation

Article 4 – paragraph 3 – introductory part

Text proposed by the Commission

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

Amendment

3. An active substance ***and a statement of the reference source of the active substance, for determining technical equivalence referred to in Article 3(1)(u),*** shall, where appropriate, be included in Annex I together with any of the following conditions:

Justification

To ensure consistency with the information included in the dossier submitted with the application for inclusion, for the purpose of determining technical equivalence it is necessary to specify the source of the active substance to be included. In the interests of greater consistency it is important to link the chemical substance described in Annex I to the data which have supported its inclusion in the annex.

Amendment 20

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

(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;

Amendment

(a) the exposure of humans to that active substance in a biocidal product, under ***prescribed*** conditions of use, is negligible ***or adequately controlled, taking account of the intrinsic hazards presented by the substance,*** in particular where the product is used in closed systems or strictly controlled conditions;

Justification

Exclusion should be decided on the basis of a risk analysis (a combination of hazardousness and exposure). If it is scientifically proven that all the risks associated with the use of these products are properly controlled, the active substances should be authorised.

Amendment 21

Proposal for a regulation

Article 5 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

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

deleted

Justification

The deletion of the provision which discriminates against certain types of product, when there are no scientific grounds for doing so, is a matter of importance. Preventive exclusion is counter-productive for trade, and above all for innovation, since it curtails the range of substances which could potentially be used as biocides in future. Such products, ranging from rodenticides to disinfectants and insecticides, are hugely beneficial, in particular in some regions of Europe, where it is vital to combat rat or insect infestations for hygiene and environmental reasons.

Amendment 22

Proposal for a regulation

Article 5 – paragraph 2 – point d

Text proposed by the Commission

Amendment

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

(d) active substances identified under Article 57(f) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties. ***The scientific criteria for determining endocrine disrupting properties pursuant to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC¹ shall apply.***

¹OJ L 309, 24.11.2009, p. 1.

Justification

Since no criteria exist at present for the approval of endocrine disrupters, these should be

adopted pursuant to Regulation (EC) No 1107/2009 on the placing on the market of plant protection products, which entered into force on 24 November 2009.

Amendment 23

Proposal for a regulation

Article 6 – paragraph 1 – points a and b

Text proposed by the Commission

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

Amendment

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

Justification

Applicants may not be in legitimate possession of all the data in support of the application: it makes sense to provide for the possibility of using a letter of access to the data.

Amendment 24

Proposal for a regulation

Article 7 – paragraph 1

Text proposed by the Commission

1. The applicant shall submit an application to include an active substance in Annex I, or to make subsequent amendments to the conditions of inclusion of an active substance, to the European Chemicals Agency (hereinafter referred to as 'the Agency') ***and inform it of*** the name of the competent authority of the Member State that ***he chooses*** to evaluate ***his*** application. That competent authority (hereinafter referred to as 'the evaluating competent authority') shall be responsible for the evaluation of the application.

Amendment

1. The applicant shall submit an application to include an active substance in Annex I, or to make subsequent amendments to the conditions of inclusion of an active substance, to the European Chemicals Agency (hereinafter referred to as 'the Agency'). ***The Agency shall indicate*** the name of the competent authority of the Member State that ***it has chosen*** to evaluate ***the*** application. That competent authority (hereinafter referred to as 'the evaluating competent authority') shall be responsible for the evaluation of the application.

Justification

Steps must be taken to ensure that certain Member States are not required to deal with a plethora of applications, thereby guaranteeing a balanced division of tasks among the Member States.

Amendment 25

Proposal for a regulation

Article 7 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The Agency shall assign a reference number to each application, which shall be used for all correspondence concerning the application until the active substance is included in Annex I, and a submission date corresponding to the date of receipt by the Agency.

Justification

A reference number assigned to each application would enable the relevant administrative procedure to be clearly identified, thus permitting speedy detection and speedy access, if need be, to the relevant data and information.

Amendment 26

Proposal for a regulation

Article 7 – paragraph 3 – first subparagraph – introductory part

Text proposed by the Commission

Amendment

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

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

Justification

In order to ensure greater consistency with the existing legislation the Agency should keep to the same time limits as those laid down in the REACH Regulation (Article 20) where the validation of applications is concerned.

Amendment 27

Proposal for a regulation

Article 7 – paragraph 4 – subparagraph 2

Text proposed by the Commission

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.

Amendment

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

Justification

Additional time may be allowed for entering all the data in the Community register, but this should not delay the evaluation of applications.

Amendment 28

Proposal for a regulation

Article 7 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Within two months of receipt of an application, the Agency shall register each part of the information in the dossier with a unique identifying code.

Justification

Together with the inclusion of the active principles and the name of the firm in Annex 1, registering each part of the information is a further appropriate and effective means of preventing 'free-riding'. Registering this information will also provide for transparency and data sharing.

Amendment 29

Proposal for a regulation

Article 8 – paragraph 5

Text proposed by the Commission

Amendment

5. On receipt of the opinion of the Agency,

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).

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). ***When the Commission decides to include the active substance in Annex I, the name(s) of the applicant(s) shall be indicated.***

Justification

Including the active principle in Annex I, together with the name of the firm, is an appropriate and effective way of preventing 'free-riding', since it makes it possible to quickly identify the firm which has supported the substance. The inclusion of a substance in Annex I is always the result of an application made by an applicant. In accordance with REACH, the 'no data, no market' principle should also apply to this regulation.

Amendment 30

Proposal for a regulation

Article 8 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. With the decision to include the active substance in Annex I, the Agency shall assign to the substance in question a specific registration number for the substance and for the applicant. The Agency shall without delay inform the applicant of the number and the date of registration. This registration number shall be used in all further correspondence regarding the active substance and for product authorisation as referred to in Chapter IV of this Regulation.

Justification

Including the active principle in Annex I, together with the name of the firm, is an appropriate and effective way of preventing 'free-riding', since it makes it possible to quickly identify the firm which has supported the substance. Only firms which have requested inclusion of an active substance in Annex I are authorised to issue letters of access to the

dossier for that substance. In accordance with REACH, the 'no data, no market' principle should also apply to this regulation.

Amendment 31

Proposal for a regulation

Article 9 – paragraph 1

Text proposed by the Commission

1. ***An active substance fulfilling at least one of the following criteria*** shall be considered ***a candidate*** for substitution in accordance with the procedure referred to in paragraph 2:

(a) ***its acceptable daily intake, acute reference dose or acceptable operator exposure level is significantly lower than those of the majority of the active substances included in Annex I for the same product type;***

(b) ***it meets two of the criteria to be considered as a persistent, bio-accumulative and toxic substance as set out in Annex XIII of Regulation (EC) No 1907/2006;***

(c) ***there are reasons for concern linked to the nature of the critical effects, in particular developmental neurotoxic or immunotoxic effects, which, in combination with the use patterns, amount to use that could still cause concern, even with very restrictive risk management measures;***

(d) ***it contains a significant proportion of non-active isomers;***

Amendment

1. ***Active substances*** shall be considered ***candidates*** for substitution in accordance with the procedure referred to in paragraph 2, ***where:***

(a) ***they are persistent, bio-accumulative and toxic as defined in Annex XIII to Regulation (EC) No 1907/2006;***

(b) ***they are very persistent and bio-accumulative in accordance with the criteria set out in Annex XIII to Regulation (EC) No 1907/2006;***

(c) ***they meet the criteria to be classified, in accordance with Regulation (EC) No 1271/2008, as category 1A or 1B carcinogens, category 1A or 1B mutagens or toxic for reproduction category 1A or 1B;***

(d) ***they are active substances, such as those with endocrine disrupting properties or persistent, bioaccumulative and toxic properties or and very bioaccumulative properties which do not comply with the criteria referred to in points (a) or (b) – for which scientific evidence exists of probable serious effects on public health or the environment giving rise to a level of concern equivalent to that applicable to the substances referred to in points (a) or***

(b).

(e) it is classified or meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, mutagen category 1A or 1B or toxic for reproduction category 1A or 1B;

(f) it is considered to have endocrine disrupting properties that may cause adverse effect on humans on the basis of the assessment of Community or internationally agreed test guidelines or other available data.

Justification

The criteria for identifying active substances which are candidates for substitution should be aligned with the criteria laid down in the REACH Regulation (Article 57) for reasons of harmonisation between the two regulations. As the Agency (ECHA) will have the task of examining whether an active substance meets the criteria, harmonisation between the two regulations is advisable.

Amendment 32

Proposal for a regulation Article 10 – paragraph 3

Text proposed by the Commission

3. Unless otherwise specified in the decision to renew the inclusion of an active substance in Annex I, the renewal shall be *for an unlimited period of time*.

Amendment

3. Unless otherwise specified in the decision to renew the inclusion of an active substance in Annex I, the renewal *of the inclusion* shall be *reviewed every 10 years*.

Amendment 33

Proposal for a regulation Article 12 – paragraph 5 – subparagraph 1a (new)

Text proposed by the Commission

Amendment

In the event that the Commission decides to renew the inclusion of the active substance in Annex I, the name of the

applicant shall be indicated.

Justification

In the interests of greater transparency and data sharing mention should be made of the applicants' names to enable them to be swiftly identified, including in cases where inclusion of an active substance in Annex 1 is being renewed.

Amendment 34

Proposal for a regulation

Article 15 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. Application for authorisation shall be made by, or on behalf of, the person who **shall** be responsible for the placing on the market of a biocidal product in a particular Member State or in the Community.

Amendment

2. Application for authorisation shall be made by, or on behalf of, the person who **will be the holder of the authorisation. This person may be, but is not necessarily, the person** responsible for the placing on the market of a biocidal product in a particular Member State or in the Community.

Justification

The industry needs more flexibility in the supply chain. In fact it is not uncommon that a product is imported in one country and placed on the market under the responsibility of a distributor which is not the holder of the authorisation or, in case of multinational companies, that each individual sister company is responsible for placing the product on the market in their own country. The provision that the holder of the authorisation and the person responsible for placing the product on the market are the same would create a very rigid and unpractical framework for industry to work with.

Amendment 35

Proposal for a regulation

Article 15 – paragraph 2 – subparagraphs 2 and 3

Text proposed by the Commission

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***').

Amendment

Application for authorisation shall be submitted to the ***Agency***.

Application for Community authorisation shall be submitted to the Agency.

When an application for national authorisation in a Member State is submitted, the applicant, in agreement with the Member State concerned, shall identify the evaluating competent authority in the application itself, as laid down in Article 22.

Justification

The 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. The possibility of choosing the evaluating competent authority is an advantage for small and medium-sized enterprises in particular, since they are able to work with their national authorities.

Amendment 36

Proposal for a regulation

Article 15 – paragraph 2 – subparagraph 3 a (new)

Text proposed by the Commission

Amendment

An applicant seeking authorisation for a group of products as part of a frame formulation may submit a single application for authorisation.

Justification

The regulation should make it clear that, where the applicant wishes to obtain authorisation for a frame formulation, he must submit a single application for authorisation to cover all

products to be included in the formulation.

Amendment 37

Proposal for a regulation

Article 16 – paragraph 1 – point a

Text proposed by the Commission

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, ***a registration number is assigned to them in accordance with Article 8(5a)***, and any conditions included in that Annex together with those active substances are complied with;

Justification

In the interests of consistency with the evaluation procedure described in Article 8(5a).

Amendment 38

Proposal for a regulation

Article 16 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The evaluation of the compliance of the biocidal products with the criteria set out in point (b) of paragraph 1 shall be based as far as possible on existing information on the substances of concern contained in the biocidal product in order to keep tests on animals to a minimum, in accordance with the procedures laid down in Directive 1999/45/EC or Regulation (EC) No 1272/2008 on identifying the danger posed by biocidal products and consequent risk assessment.

Justification

The aim is to prevent unnecessary animal testing, by providing a clearer definition of the procedures for comparing existing information, while also complying with the REACH requirement regarding Chemical Safety Report thresholds.

Amendment 39

Proposal for a regulation

Article 16 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The evaluation of the compliance of the biocidal product with the criteria set out in points (b) and (c) of paragraph 1 shall not take into account a substance contained in the biocidal product if it is present in a preparation at a concentration lower than any of the following:

(a) the applicable concentrations laid down in Article 3(3) of Directive 1999/45/EC;

(b) the concentration limit values given in Annex I to Directive 67/548/EEC;

(c) the concentration limit values given in Part B of Annex II to Directive 1999/45/EC;

(d) the concentration limit values given in Part B of Annex III to Directive 1999/45/EC;

(e) the concentration limit values given in an agreed entry in the classification and labelling inventory established under Title V of Regulation (EC) No 1272/2008;

(f) 0.1% weight by weight (w/w), if the substance meets the criteria in Annex XIII to Regulation (EC) No 1907/2006.

Justification

The aim is to avoid unnecessary animal testing by providing a clearer definition of the procedures for comparing existing information, while complying with the requirements of REACH with regard to the Chemical Safety Report thresholds.

Amendment 40

Proposal for a regulation

Article 16 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. The Commission, where necessary in cooperation with the Agency, shall provide all necessary scientific and technical assistance to the competent authorities of the Member States in respect of the authorisation of products, particularly as regards uniform requirements for data, evaluation procedures and decisions by Member States.

Justification

In order to ensure uniform implementation of the regulation throughout the Community, the Commission must provide all necessary scientific and technical assistance to the competent authorities of the Member States in respect of the authorisation of products.

Amendment 41

Proposal for a regulation

Article 17 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The applicant for an authorisation shall, in the circumstances defined in paragraphs 1 and 2, provide the competent authorities with:

(i) the information to be specifically provided at the point of sale;

(ii) specific instructions on the use of protective equipment;

(iii) a brochure on the risks, benefits and responsible use of the product;

(iv) an annual report on incidents, if any.

Justification

The intrinsic characteristics of an active substance, alone, should not determine its suitability for low risk products since the risks may come more from the exposure to the product than from the hazard of the active substance. Given that some biocides are used by non-professionals, it is important to guarantee the safety of these products through better information and precautions regarding their use. Finally, industry needs to be encouraged to focus its research and innovation efforts towards developing low risk products.

Amendment 42

Proposal for a regulation Article 18 – paragraph 3

Text proposed by the Commission

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

Applications for a national authorisation which involve a mutual recognition procedure may be submitted, along with the documents referred to in paragraph 1, to the competent authority in English.

Justification

It is critical that in the case of applications involving subsequent mutual recognition procedures the application and all related documents are accepted in English by the receiving competent authority. This is very important in order to avoid time-consuming and expensive translation procedures for the same documentation in several European languages.

Amendment 43

Proposal for a regulation Article 18 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. The Commission may, where necessary in cooperation with the Agency, provide a non-binding technical and legal

guide available in all official languages of the European Union, intended to facilitate the submission of applications for authorisation under Articles 18, 19 and 20, particularly applications from SME.

Justification

Assistances and guidelines from the Commission may be particularly important for SME as they may not have the necessary resources or experience to adapt to the regulation. The Commission should also ensure that this service is linguistically accessible to SME.

Amendment 44

Proposal for a regulation

Article 20 – paragraph 2 – point e

Text proposed by the Commission

(e) qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge of **which** is essential for proper use of the biocidal product;

Amendment

(e) qualitative and quantitative composition in terms of the active substances and non-active substances, **taking into consideration the concentration limit values given in Article 16, in so far as** knowledge of **these** is essential for proper use of the biocidal product;

Justification

In the interests of consistency with Article 16(2a).

Amendment 45

Proposal for a regulation

Article 20 – paragraph 2 – point g

Text proposed by the Commission

(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 manufacturing sites) **and registration number of the active substance, in accordance with Article 8(5a);**

Justification

To avoid disseminating confidential information, if the manufacturer of the active substance

is authorised through registration in Annex I, the location of the manufacturing site should remain confidential and should not be included in the information linked to the biocidal product authorisation. However, the registration number must be published, in accordance with Article 8(5a).

Amendment 46

Proposal for a regulation

Article 20 – paragraph 3 – point b

Text proposed by the Commission

(b) the permitted alteration of the composition of this reference biocidal product expressed **in** percentage of the non-active substances contained in the biocidal products which are considered to belong to that frame formulation;

Amendment

(b) the permitted alteration of the composition of this reference biocidal product expressed **as a** percentage ***reduction in the active substances or as a percentage alteration*** of the non-active substances contained in the biocidal products which are considered to belong to that frame formulation;

Justification

Paragraph 3b needs to be fully consistent with Article 16(6). The substance of the authorisation must also make provision for this possibility.

Amendment 47

Proposal for a regulation

Article 20 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. In the case of a framework formulation, a single authorisation number shall be assigned to all biocidal products belonging to the frame formulation.

Justification

A new paragraph is needed to stipulate that, in the case of a frame formulation, a single authorisation number should be assigned to all biocidal products belonging to the frame formulation. This is not clear from the existing text of the proposal.

Amendment 48

Proposal for a regulation Article 21 – paragraph 1

Text proposed by the Commission

1. The receiving competent authority or, in the case of evaluation of an application for a Community authorisation, the evaluating competent authority shall perform a comparative assessment as part of the evaluation of an application for ***an authorisation or*** a renewal of an authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 9(1).

Amendment

1. The receiving competent authority or, in the case of evaluation of an application for ***renewal of*** a Community authorisation, the evaluating competent authority shall perform a comparative assessment as part of the evaluation of an application for a renewal of an authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 9(1).

Justification

The comparative assessment should take account first and foremost of whether sufficient experience has been gained in the use of the product. This should be the rule and not the exception. Use of comparative assessment should therefore be confined to the renewal of authorisations for those biocidal products which contain active principles that have been identified as candidates for substitution in accordance with Article 9.

Amendment 49

Proposal for a regulation Article 21 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The comparative assessment shall be carried out for all biocidal products having the same purpose, once they have been in use for at least five years.

Justification

The comparative assessment should take account first and foremost of whether sufficient experience has been gained in the use of the product. Five years is an appropriate period for this purpose.

Amendment 50

Proposal for a regulation

Article 21 – paragraph 1 – subparagraph 1 b (new)

Text proposed by the Commission

Amendment

By way of derogation from paragraph 1, a comparative assessment shall not be required for biocidal products whose use has been shown to be safe.

Justification

To assess whether a product may be removed from the market after being the subject of a comparative evaluation, consideration should always be given in the risk/benefit assessment (see paragraph 3) to the effectiveness of the product and the availability of existing products in sufficient numbers and variety to treat the contamination or infestation concerned. The comparison should focus on biocidal products for which there is an identified risk and where alternatives are needed.

Amendment 51

Proposal for a regulation

Article 21 – paragraph 2

Text proposed by the Commission

Amendment

2. The results of the comparative assessment shall be forwarded, without delay, to the competent authorities of other Member States and the Agency and, in the case of evaluation of an application for a Community authorisation, also to the Commission.

2. The results of the comparative assessment shall be forwarded, without delay, to the competent authorities of other Member States and the Agency and, in the case of evaluation of an application for ***renewal of*** a Community authorisation, also to the Commission.

Justification

Comparative evaluations should apply only to applications for renewal of an authorisation. This should be the rule and not the exception.

Amendment 52

Proposal for a regulation

Article 21 – paragraph 3 – introductory part

Text proposed by the Commission

3. The receiving competent authority or, in the case of a decision on an application for a Community authorisation, the Commission shall prohibit or restrict the placing on the market or use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment weighing up the risks and benefits in accordance with Annex VI demonstrates that all the following criteria are met:

Amendment

3. The receiving competent authority or, in the case of a decision on an application for **renewal of** a Community authorisation, the Commission shall prohibit or restrict the placing on the market or use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment weighing up the risks and benefits in accordance with Annex VI demonstrates that all the following criteria are met:

Justification

Comparative evaluations should apply only to applications for renewal of an authorisation. This should be the rule and not the exception.

Amendment 53

Proposal for a regulation

Article 21 – paragraph 3 – point a

Text proposed by the Commission

(a) for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents significantly lower risk for human or animal health or the environment;

Amendment

(a) for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents significantly lower **or reduced** risk for human or animal health or the environment **and which proves equally effective and involves no significant increase in the risks for any other parameter;**

Justification

As the comparative evaluation should focus on those biocidal products for which there is an identified risk and for which alternatives are needed, any substitute product must be equally efficient and involve a similar level of risk.

Amendment 54

Proposal for a regulation

Article 21 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7a. The Commission shall adopt delegated acts, in accordance with Article [...], specifying the procedure to be followed in the comparative assessment of biocidal products for the purposes of the decision referred to in paragraph 3 and the criteria and algorithms to be used when undertaking such assessment.

Amendment 55

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission

Amendment

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:

(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.

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 authority of the Member State of his choice which shall be responsible for the evaluation of the application (hereinafter 'the evaluating competent authority').

The Agency shall, one month after the receipt of the application, notify the evaluating competent authority that the application is available in the Agency database.

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 56

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 of the receipt of an application, the Agency shall validate the application if:

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

(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 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 57

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 forwarding that information.

The Agency shall, within three weeks of 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 58

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 2.

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 59

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.

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 23 – paragraph 1

Text proposed by the Commission

1. The receiving competent authority shall, within **twelve months** after the validation referred to in Article 22, decide on the application in accordance with Article 16.

Amendment

1. The receiving competent authority shall, within **six months** after the validation referred to in Article 22, decide on the application in accordance with Article 16.

Justification

The active substances used in the biocidal products have already been fully evaluated by their inclusion in Annex I of the regulation. There is no need to provide for such a long evaluation period to authorise a biocidal product based on authorised active substances.

Amendment 61

Proposal for a regulation Article 24 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. The authorisation holder or his representative shall submit an application for renewal of a national authorisation to the receiving competent authority at least **18 months** before the expiry date of the authorisation.

Amendment

1. The authorisation holder or his representative shall submit an application for renewal of a national authorisation to the receiving competent authority at least **12 months** before the expiry date of the authorisation.

Justification

An 18-month period is not necessary to renew a product's authorisation, unless there are new data to be evaluated. 12 months is more appropriate.

Amendment 62

Proposal for a regulation Article 25 – paragraph 5

Text proposed by the Commission

5. The receiving competent authority shall authorise the biocidal product concerned under the same conditions as the reference

Amendment

5. The receiving competent authority shall authorise the biocidal product concerned under the same conditions as the reference

competent authority.

competent authority. ***A single authorisation number shall be used in all the Member States involved.***

Justification

To simplify matters, a single authorisation number should be assigned in all Member States in the case of products for which a mutual recognition procedure has been followed.

Amendment 63

Proposal for a regulation

Article 25 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. The Commission shall adopt delegated acts, in accordance with Article [...], specifying the criteria and procedures for assigning the single authorisation number referred to in paragraph 5 of this Article.

Amendment 64

Proposal for a regulation

Article 27 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

The Commission shall adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

The Commission shall, ***following consultation of the applicant***, adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

Amendment 65

Proposal for a regulation

Article 27 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

This decision shall be taken within three

months of the notification by the competent authority referred to in subparagraph 1. If the Commission requests an opinion from the Agency pursuant to Article 30, the three-month period shall be suspended until the Agency submits its opinion.

Justification

The legislative text should clearly specify the timeframe required for a procedure that can effectively resolve disputes between Member States. Three months is an adequate period of time for the Commission to make a proposal for a decision setting out the grounds for refusing to recognise authorisations or recognising them with restrictions.

Amendment 66

**Proposal for a regulation
Article 28 – paragraph 8**

Text proposed by the Commission

8. The reference competent authority and the competent authorities of the other concerned Member States shall authorise the biocidal product on the basis of the approved assessment report and the summary of the biocidal product characteristics within one month after the end of the period referred to in paragraph 7.

Amendment

8. The reference competent authority and the competent authorities of the other concerned Member States shall authorise the biocidal product on the basis of the approved assessment report and the summary of the biocidal product characteristics within one month after the end of the period referred to in paragraph 7. ***A single authorisation number shall be used in all the Member States involved.***

Justification

To simplify matters, a single authorisation number should be assigned in all Member States in the case of products for which a mutual recognition procedure has been followed.

Amendment 67

**Proposal for a regulation
Article 28 – paragraph 9 – subparagraph 2**

Text proposed by the Commission

The Commission shall adopt a decision on

Amendment

The Commission shall, ***following***

whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

consultation of the applicant, adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

Amendment 68

Proposal for a regulation

Article 28 – paragraph 9 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

This decision shall be taken within three months of the notification by the competent authority referred to in subparagraph 1. If the Commission requests an opinion from the Agency pursuant to Article 30, the three-month period shall be suspended until the Agency submits its opinion.

Justification

The legislative text should clearly specify the timeframe required for a procedure that can effectively resolve disputes between Member States. Three months is an adequate period of time for the Commission to make a proposal for a decision setting out the grounds for refusing to recognise authorisations or recognising them with restrictions.

Amendment 69

Proposal for a regulation

Article 28 – paragraph 11 a (new)

Text proposed by the Commission

Amendment

The Commission shall adopt delegated acts, in accordance with Article [...], specifying the criteria and procedures for assigning the single authorisation number referred to in paragraph 8.

Amendment 70

Proposal for a regulation

Article 29 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The Commission shall adopt a decision on the proposed adjustment of the conditions of the national authorisation to local circumstances in accordance with the procedure referred to in Article 72(3). The competent authority of the concerned Member State shall without delay adopt all appropriate measures to comply with that decision.

Amendment

The Commission shall, ***following consultation of the applicant***, adopt a decision on the proposed adjustment of the conditions of the national authorisation to local circumstances in accordance with the procedure referred to in Article 72(3). The competent authority of the concerned Member State shall without delay adopt all appropriate measures to comply with that decision.

Amendment 71

Proposal for a regulation

Article 29 – paragraph 2 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

Within three months of the notification, the Commission shall submit a proposal for a decision. If the Commission requests an opinion from the Agency pursuant to Article 30, the three-month period shall be suspended until the Agency submits its opinion.

Justification

The legislative text should clearly specify the timeframe required to resolve disputes between Member States. Three months is an adequate period of time for the Commission to make a proposal for a decision setting out the grounds for refusing to recognise authorisations or recognising them with restrictions.

Amendment 72

Proposal for a regulation

Article 33 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) biocidal products designed to be used by consumers in domestic settings, or by professional users, according to conditions and instructions of use which are similar within the European Union, and which meet the criteria listed in Article 33a.

Justification

One of the key objectives of the Union authorisation system is to ensure consistent product safety assessments, equal standards of consumer protection and harmonised implementation of the requirements within all Member States. Biocidal products, which are used in a similar way across the EU, should benefit from the Union authorisation scheme. These products are used in domestic or in professional settings as a pragmatic and cost effective means to protect public health, thereby reducing the burden of infectious diseases. These products have simple and clear use instructions.

Amendment 73

Proposal for a regulation

Article 33 a (new)

Text proposed by the Commission

Amendment

Article 33a

Biocidal products with similar conditions of use

In accordance with point (ba) of Article 33(1), a product shall be considered a biocidal product with similar use conditions if all of the following criteria are met:

(i) it has similar conditions of use across the European Union, according to use instructions;

(ii) it is already placed or is intended to be placed on the market in at least [...] Member States within two years of the

authorisation being granted;

In order to define or adapt the number of Member States referred to in point (ii), the Commission shall adopt delegated acts in accordance with Article [...].

Justification

The criteria are based on the targeted and consistent application and use of those types of products across the EU (number of Member States to be specified), as well as their positive contribution to human and animal safety protection. Annex VI lays down the principles for the evaluation of dossiers for biocidal products to ensure a harmonised high level of protection for humans and the environment. This involves detailed risk assessment of products during their use.

Amendment 74

Proposal for a regulation

Article 35 – paragraph 3 – subparagraph 1

Text proposed by the Commission

3. Within **nine 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.

Amendment

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.

Justification

The nine-month period is too long for the Agency to prepare and submit an opinion which is based on an evaluation already available and carried out by the evaluating competent authority: three months is more appropriate.

Amendment 75

Proposal for a regulation

Article 36 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. The authorisation holder or his representative shall submit an application for renewal of a Community authorisation to the Agency at least **18 months** before

Amendment

1. The authorisation holder or his representative shall submit an application for renewal of a Community authorisation to the Agency at least **12 months** before

the expiry date of the authorisation.

the expiry date of the authorisation.

Justification

An 18-month period is not necessary to renew a product's authorisation, unless there are new data to be evaluated. 12 months is more appropriate.

Amendment 76

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.

Justification

Notification of changes in the source of an active substance used in a biocidal product is required because it could have an impact on the product's safety.

Amendment 77

Proposal for a regulation

Article 41 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

An amendment to an existing authorisation should fall under one of the following categories referred to in points (ua), (ub) and (uc) of Article 3:

(a) Administrative change,

(b) Minor change or

(c) Major change.

Justification

The legislative text should clearly outline the main principles which shall be applied when amending authorisations, although the details of the procedures can be specified in the implementing measures. In particular, it is necessary to specify the types of changes that can be made to existing product authorisations.

Amendment 78

Proposal for a regulation

Article 42 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The criteria and the procedures referred to in paragraph 1 shall be based on, but not limited to, the following principles:

(a) a simplified notification procedure shall be applied for administrative changes to the authorisation;

(b) a reduced evaluation period shall be established for minor changes to the authorisation;

(c) a period of time proportional to the size of the variations requested in the event of significant variations.

Justification

While the details of procedures can be specified in the implementing measures, the legislative text should clearly define the fundamental principles to be applied to the different types of change that may be made to the authorisations for existing products.

Amendment 79

Proposal for a regulation

Article 44 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

1. A competent authority of a Member State (hereinafter referred to as 'Member State of introduction') may grant a parallel trade permit for a biocidal product that is authorised in another Member State (hereinafter referred to as 'Member State of origin') to be placed on the market and used in the Member State of introduction, if it determines that the biocidal product is ***substantially*** identical in composition to a biocidal product already authorised in that Member State (hereinafter referred to as 'the reference product').

1. A competent authority of a Member State (hereinafter referred to as 'Member State of introduction') may grant a parallel trade permit for a biocidal product that is authorised in another Member State (hereinafter referred to as 'Member State of origin') to be placed on the market and used in the Member State of introduction, if it determines that the biocidal product is identical in composition to a biocidal product already authorised in that Member State (hereinafter referred to as 'the reference product').

(This amendment applies to Article 44 as a whole. Adopting it will necessitate corresponding changes throughout.)

Justification

Parallel trade permits should be restricted to identical products based on the same source of active substances and co-formulants in order to achieve a reasonable balance between free trade in goods and a safe market environment.

Amendment 80

Proposal for a regulation Article 44 – paragraph 3

Text proposed by the Commission

3. A biocidal product shall be considered as ***substantially*** identical to the reference product if ***one of the following conditions is met:***

(a) the source of the active substances it contains is the same in terms of manufacturer and location of the production plant;

(b) it is either the same or similar with regard to the non-active substances present and the type of formulation;

(c) it is either the same or equivalent in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.

Amendment

3. A biocidal product shall be considered as identical to the reference product if:

(a) it has been produced by the same manufacturer or a manufacturer associated with him or under licence, on the basis of the same manufacturing process;

(b) it is the same with regard to the specifications and content of the active substances and the type of formulation; and

(c) it is the same or equivalent in the co-formulants present and the packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.

Justification

For the purpose of consistency, the conditions relating a substantially identical product should be replaced with those for an identical product.

Amendment 81

Proposal for a regulation

Article 44 – paragraph 4 – point a a (new)

Text proposed by the Commission

Amendment

(aa) registration number of the active substances contained in the product and, where appropriate, the applicant's letter of access in accordance with Article 50;

Justification

To be consistent with Article 8(5a) and to ensure that the applicant has the document required for access to the data.

Amendment 82

Proposal for a regulation

Article 44 – paragraph 4 – point c

Text proposed by the Commission

Amendment

(c) name and address of the authorisation holder in the Member State of origin;

(c) name and address of the authorisation holder in the Member State of origin ***and, where appropriate, the letter of access in accordance with Article 50;***

Justification

To ensure that the applicant has the document required for access to the data.

Amendment 83

Proposal for a regulation

Article 46

Text proposed by the Commission

Amendment

1. By way of derogation from Article 15, an experiment or a test for the purposes of research or development involving the placing on the market of an unauthorised biocidal product or an active substance intended exclusively for use in a biocidal product may only take place in the case of

1. By way of derogation from Article 15, an experiment or a test for the purposes of research or development involving the placing on the market of an unauthorised biocidal product or an active substance intended exclusively for use in a biocidal product may only take place in the case of

scientific research and development or in the case of product and process-oriented research and development, and under the conditions laid down in the second and third subparagraphs.

In the case of scientific research and development, the person who intends to carry out the experiment or the test shall notify the competent authority prior to the start. The person shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied *and the names and addresses of those persons receiving the biocidal product or active substance*, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The persons concerned shall, if requested, make this information available to the competent authority.

In the case of product and process-oriented research and development, the person who intends to carry out the experiment or the test shall, prior to the placing of the biocidal product or the active substance on the market, notify the information required in the second subparagraph to the competent authority of the Member State where the placing on the market occurs.

2. An unauthorised biocidal product or an active substance for exclusive use in a biocidal product shall not be placed on the market for the purpose of any experiment or test which may involve, or result in, release of the biocidal product into the environment unless the competent authority has assessed the data submitted by the person interested in the placing of such product on the market and issued a *national authorisation* for this purpose which *limits the quantities to be used and the areas to be treated and which* may impose further conditions. *The competent authority shall without delay inform the*

scientific research and development or in the case of product and process-oriented research and development, and under the conditions laid down in the second and third subparagraphs.

In the case of scientific research and development, the person who intends to carry out the experiment or the test shall notify the competent authority prior to the start, *provided that the quantities of active substances or biocidal products that may be released during the experiment or test do not exceed one tonne per year*. The person shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data *and* quantities supplied, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The persons concerned shall, if requested, make this information available to the competent authority.

In the case of product and process-oriented research and development, the person who intends to carry out the experiment or the test shall, prior to the placing of the biocidal product or the active substance on the market, notify the information required in the second subparagraph to the competent authority of the Member State where the placing on the market occurs.

2. An unauthorised biocidal product or an active substance for exclusive use in a biocidal product shall not be placed on the market for the purpose of any experiment or test which may involve, or result in, release of the biocidal product into the environment unless the competent authority has assessed the data submitted by the person interested in the placing of such product on the market and issued a *positive opinion* for this purpose which may impose further conditions. *In the absence of an opinion from the competent authority within 30 days of the notification of the information required in*

Commission and other competent authorities about the issued national authorisation.

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

If the proposed experiments or tests referred to in paragraphs 1 and 2 may have harmful effects on human or animal health or any unacceptable adverse effect on the environment, the competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The competent authority shall without delay inform the Commission and other competent authorities about such measures.

4. The Commission shall adopt measures 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 in accordance with paragraph 2.

Those measures 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).

paragraph 1, the biocidal product or active substance may be placed on the market for the purpose of the notified experiment or test.

3. Where any experiment or test takes place in a Member State other than the Member State where placing on the market of the biocidal product occurs, the applicant shall ***notify*** the competent authority of the Member State in the territory of which the experiments or tests are to be conducted. ***The applicant shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data and quantities supplied, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The applicant shall, if requested, make this information available to the competent authority.***

If the proposed experiments or tests referred to in paragraphs 1 and 2 may have harmful effects on human or animal health or any unacceptable adverse effect on the environment, the competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The competent authority shall without delay inform the Commission and other competent authorities about such measures.

4. The Commission shall adopt measures 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 in accordance with paragraph 2.

Those measures 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).

Amendment 84

Proposal for a regulation Article 47 – paragraph 2

Text proposed by the Commission

2. Treated articles or materials shall be labelled with the following information:

(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;

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

(c) the authorisation number of all biocidal products that were used for the treatment or were incorporated in the articles or materials;

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

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

2. Treated articles or materials *that incorporate one or more biocidal products that might, under normal and foreseeable conditions of use, be released into the environment or come into direct contact with humans*, shall be labelled with the following information:

(a) the name of all active substances that were used *for the treatment* or were incorporated in the articles or materials, *using, where possible, internationally recognised nomenclature*;

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

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

The labelling *may be printed on the treated article or material, on the packaging, on the instructions for use or on the warranty of the treated article or material, provided that it is* clearly visible, easily legible and appropriately durable.

This paragraph shall be without prejudice to labelling or information

requirements laid down in sector specific legislation applicable to treated articles and materials.

Amendment 85

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, *as provided for by Article 50,*

Justification

The first applicant is not necessarily the owner of the information. The option must also be allowed for a second applicant to be or become the co-owner of the information, as a result of sharing or joint development of the information.

Amendment 86

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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

Justification

The first applicant is not necessarily the owner of the information. The option must also be allowed for a second applicant or business to be or become the co-owner of the information, as a result of sharing or joint development of the information.

Amendment 87

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. ***All information contained in*** the list referred to in paragraph 2 shall be entered by the Agency in the Biocides Data Sharing Register, ***identified by a single code and complete with all identifying details and with a link to the identity of the first applicant and of the owner of the information.***

Justification

All parts of the items of information and documents that are on the list must be contained in the register. It is preferable to identify numerically each document sent in order to avoid confusion when titles or corrections to studies with similar names are sent. Linking the items of information to the information owners and applicants will ensure that property rights are respected.

Amendment 88

Proposal for a regulation Article 49 – paragraph 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

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. ***A date of submission shall be assigned separately to each document, identified with the single code pursuant to Article 48(4).***

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.

Justification

Data protection requirements were never unequivocally established by Directive 98/8/EC. As the date on which a dossier is submitted may not be the date of submission of all the information, submission dates are to be assigned individually when each subsequent submission of information is made. Protecting the individual items of information reflects the real situation more faithfully in that each individual item of information is the result of investment by its owner.

Amendment 89

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

Justification

Even if this article represents an improvement in comparison with the provisions of Directive 98/8/EC as regards data protection, there is no justification for distinguishing between new and existing information. This is because national legislative frameworks cover only a small fraction of the biocides market. Where such frameworks exist, some Member States have not in fact applied them. Moreover, eliminating this distinction would bring the provisions of the present Regulation more into line with REACH.

Amendment 90

Proposal for a regulation Article 52 – paragraph 3

Text proposed by the Commission

Amendment

3. Where no such agreement is reached two

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. **An arbitration body within the Agency** shall decide on the proportionate share of **all costs associated with the production and use of the information** that the prospective applicant shall pay to the data owner.

Justification

If it is not possible to reach agreement between the two parties, both parties should inform the Agency, as both are responsible for the failure to agree. In order to ensure that the compulsory sharing of information proceeds in a harmonised manner at EU level, the Commission should establish an arbitration body for the Union.

Amendment 91

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 share the 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.

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 92

Proposal for a regulation

Article 54 – paragraph -1 (new)

Text proposed by the Commission

Amendment

-1. 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 substances referred to in Annex II or are in possession of a letter of access to a dossier which complies with the requirements of Annex II.

Justification

Compliance with the provisions of the Regulation must be guaranteed by official controls by the national competent authorities.

Amendment 93

Proposal for a regulation

Article 54 – paragraph 3 – introductory part

Text proposed by the Commission

Amendment

3. Every ***three years***, starting in 2013, competent authorities shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The report shall

3. Every ***year***, starting in 2013, competent authorities shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The report shall include:

include:

Amendment 94

Proposal for a regulation

Article 54 – paragraph 3 – point b

Text proposed by the Commission

(b) information on any poisonings involving biocidal products.

Amendment

(b) information on any poisonings involving biocidal products ***and the possible health implications for vulnerable groups, such as children, pregnant women or the sick;***

Amendment 95

Proposal for a regulation

Article 54 – paragraph 3 – point b a (new)

Text proposed by the Commission

Amendment

(ba) information on the impact on the environment.

Amendment 96

Proposal for a regulation

Article 54 – paragraph 4

Text proposed by the Commission

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.

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 2019 and every three years thereafter***. The Commission shall submit the report to the European Parliament and the Council.

On the basis of the report, the Commission shall assess the desirability of proposing amendments to this Regulation.

Justification

The Commission report should be the basis for a process of revision with the aim of remedying as much as possible the main difficulties identified.

Amendment 97

Proposal for a regulation

Article 55 – paragraph 2 – point d a (new)

Text proposed by the Commission

Amendment

(da) manufacturers of active substances (names and addresses including location of manufacturing sites);

Justification

Production sites are commercial information with implications for competition and should not be published. Applicants have the right to seek authorisation for many final uses of a product, which however are not necessarily all used, so some of these must be reserved for future use.

Amendment 98

Proposal for a regulation

Article 55 – paragraph 2 – point d b (new)

Text proposed by the Commission

Amendment

(db) the location of the site where a biocidal product is manufactured;

Justification

Production sites are commercial information with implications for competition and should not be published. Applicants have the right to seek authorisation for many final uses of a product, which however are not necessarily all used, so some of these must be reserved for future use.

Amendment 99

Proposal for a regulation

Article 55 – paragraph 2 – point d c (new)

Text proposed by the Commission

Amendment

(dc) date of the authorisation and its date of expiry;

Justification

It is essential that some information contained in authorisations concerning the applicant should be treated in confidence. The date of the authorisation and its date of expiry are also sensitive information and should be protected.

Amendment 100

Proposal for a regulation

Article 55 – paragraph 2 – point d d (new)

Text proposed by the Commission

Amendment

(dd) doses and instructions for use.

Justification

It is essential that some information contained in authorisations concerning the applicant should be treated in confidence. Doses and instructions depend on the type of use, as well as on the intrinsic properties of the product and of the co-formulants, and it is therefore necessary to protect them adequately.

Amendment 101

Proposal for a regulation

Article 58 – paragraph 2 – first subparagraph – introductory part

Text proposed by the Commission

Amendment

2. Labels shall not be misleading and, in any case, shall not mention the indications ***‘low-risk biocidal product’***, ‘non-toxic’, ‘harmless’ or similar indications. In addition, the label must show clearly and indelibly the following information:

2. Labels shall not be misleading and, in any case, shall not mention the indications ‘non-toxic’, ‘harmless’ or similar indications. In addition, the label must show clearly and indelibly the following information:

Justification

Those who place low-risk products on the market should be encouraged and allowed to publicise them appropriately.

Amendment 102

Proposal for a regulation

Article 58 – paragraph 2 – first subparagraph – point e

Text proposed by the Commission

(e) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorisation;

Amendment

(e) directions for use and the dose rate, expressed in metric units ***and/or in a manner which is meaningful and comprehensible to the user***, for each use provided for under the terms of the authorisation;

Justification

The dose must be expressed in a manner which is meaningful and comprehensible to the user. Particularly in the case of non-professional users, a dose in metric units is sometimes hard for users to understand. The dose in metric units should be translated into terms which are significant, comprehensible and appropriate for the consumer if necessary.

Amendment 103

Proposal for a regulation

Article 58 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The Commission shall make available on the internet a list of all active substances available within the internal market.

The persons responsible for the placing on the market of biocidal products shall make available on the internet a list of such products. This website shall serve to increase transparency for consumers and to facilitate an easy and fast collection of data on the properties and conditions of use of these products.

Access to the aforementioned websites shall not be subject to any restriction or condition and their content shall be kept up to date. The relevant website addresses shall be indicated on the labelling of the biocidal products in a visible manner.

Justification

It must be possible for all users to obtain detailed and timely information, in the interests of completeness of the information and to enable consumers to obtain the correct information about the prescribed conditions of use, keeping and treatment of the product. The information on the website should supplement and add detail to the indications on the labelling, so as to ensure that users who require specific information, which can normally be obtained through additional medical consultation, can easily obtain it.

Amendment 104

Proposal for a regulation

Article 59 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Safety data sheets shall contain the following information:

(a) important categories of product whose active substance has been included in Annex I;

(b) the name of at least one Member State where the biocidal product has been authorised;

(c) the authorisation number of the biocidal product as such or present in a treated article or material.

Justification

Consistently with the information requested concerning manufacturers of active substances, safety data sheets accompanying biocidal products too should contain such information to help the supervisory authorities and competent authorities to check the origin of the substances in products placed on the market.

Amendment 105

Proposal for a regulation Article 62 – paragraph 3

Text proposed by the Commission

3. Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health or the environment. In any case, the advertising of a biocidal product shall not mention **‘low-risk biocidal product’**, ‘non-toxic’, ‘harmless’ or any similar indication.

Amendment

3. Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health or the environment. In any case, the advertising of a biocidal product shall not mention ‘non-toxic’, ‘harmless’ or any similar indication.

Justification

Those who place low-risk products on the market should be encouraged and allowed to publicise them appropriately.

Amendment 106

Proposal for a regulation Article 70 – paragraph 2 – point d

Text proposed by the Commission

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

Amendment

(d) ***the fee shall apply only when it is genuinely necessary;*** and

Justification

Fees should relate to the work requested and therefore be proportionate to it. An indiscriminate annual fee is not acceptable, and fees should be paid only when genuinely necessary.

Amendment 107

Proposal for a regulation Article 77 – paragraph 1 – subparagraph 3

Text proposed by the Commission

During the work programme, the

Amendment

During the work programme, the

Commission shall decide pursuant to the procedure laid down in Article 72(4) that an active substance shall be included in Annex I of this Regulation and under which conditions, or, in cases where the requirements of Article 4 are not satisfied or where the requisite information and data have not been submitted within the prescribed period, that such active substance shall not be included in Annex I of this Regulation. The decision shall specify the date on which the inclusion in Annex I becomes effective.

Commission shall decide pursuant to the procedure laid down in Article 72(4) that an active substance shall be included in Annex I of this Regulation and under which conditions, or, in cases where the requirements of Article 4 are not satisfied or where the requisite information and data have not been submitted within the prescribed period, that such active substance shall not be included in Annex I of this Regulation. The decision shall specify the date on which the inclusion in Annex I becomes effective, ***which shall be two years after the adoption of the decision.***

Justification

The legislative text should clearly state the timelines applicable. Two years have previously been agreed upon by the Competent Authorities.

Amendment 108

Proposal for a regulation

Article 77 – paragraph 3 – subparagraph 3

Text proposed by the Commission

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.

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 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

This amendment lays down shorter periods for exclusion from the market, as downstream users of the biocidal product must be informed of their obligations and of the state of revision

of active substances.

Amendment 109

Proposal for a regulation

Article 77 – paragraph 4 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Disposal, storage and use of existing stocks of biocidal products for which the competent authority of the Member State has rejected an application for authorisation submitted under paragraph 3 or has decided not to grant authorisation are allowed until 18 months after such a rejection or a decision.

Amendment 110

Proposal for a regulation

Article 81

Text proposed by the Commission

Amendment

By way of derogation from Article 47, treated articles and materials that incorporate biocidal products which are not authorised in the Community or in at least one Member State and which were available on the market on ... [OJ: insert the date referred to in the first subparagraph of Article 85] may, until the date of a decision granting authorisation to these biocidal products, continue to be placed on the market if the application for authorisation is submitted at the latest by **1 January 2017**. In the case of a refusal to grant an authorisation to place a biocidal product on the market, treated articles and materials that incorporate such biocidal product shall no longer be placed on the market within six months after such decision.

By way of derogation from Article 47, treated articles and materials that incorporate biocidal products which are not authorised in the Community or in at least one Member State and which were available on the market on ... [OJ: insert the date referred to in the first subparagraph of Article 85] may, until the date of a decision granting authorisation to these biocidal products, continue to be placed on the market if the application for authorisation is submitted at the latest by **1 January 2015**. In the case of a refusal to grant an authorisation to place a biocidal product on the market, treated articles and materials that incorporate such biocidal product shall no longer be placed on the market within six months after such decision.

Amendment 111

Proposal for a regulation

Article 81 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Disposal, storage and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission are allowed until 12 months after the date of the decision referred to in the first subparagraph of Article 80(2) or 12 months after the date referred to in the second subparagraph of Article 80(2), whichever is the later.

Amendment 112

Proposal for a regulation

Article 82

Text proposed by the Commission

Amendment

Article 82

deleted

Transitional measures concerning food contact materials

1. Applications for the authorisation of biocidal products which are food contact materials and 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 1 January 2017.

Food contact materials which were available on the market on [OJ: insert the date referred to in the first subparagraph of Article 85] for which an application was submitted in accordance with paragraph 1 may continue to be placed on the market until the date of the decision granting the authorisation or refusing to grant the authorisation. In case of a refusal to grant an authorisation to place

such biocidal product on the market, such biocidal product shall no longer be placed on the market within six months after such decision.

Food contact materials which were available on the market on [OJ: insert the date referred to in the first subparagraph of Article 85] for which an application was not submitted in accordance with paragraph 1 may continue to be placed on the market until six months after the date referred to in paragraph 1.

2. Disposal, storage and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission is allowed until twelve months after the date of the decision referred to in the second subparagraph of paragraph 1 or twelve months after the date referred to in the third subparagraph of paragraph 1, whichever is the later.

Justification

Food contact materials should not be within the scope of the Proposal as this would lead to double regulation and assessment. Food contact materials are already regulated by the Food Contact Materials Framework Regulation (EC) No 1935/2004. Should any changes be made to the rules governing food contact materials, they should be addressed through a revision of the food contact legislation, not by extending the scope of the BPR.

Amendment 113

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

Text proposed by the Commission

Amendment

As from 1 January 2014, all manufacturers of an existing active substance placed on the market for use in biocidal products shall submit to the Agency an application for the inclusion of the substance in Annex I. The competent

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

Justification

Only manufacturers who contribute to the system should be allowed to manufacture and market active substances intended for use in biocidal products. This is the best way of overcoming the 'free rider' problem, by means of appropriate checks on the market for active substances.

Amendment 114

Proposal for a regulation

Article 83 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

***The competent authorities shall adopt the
necessary measures as required by Article
54(2).***

Justification

Member States should be required to establish which biocidal products exist on their market and whether the manufacturer of the active substance has submitted a dossier for Annex I, and proceed accordingly.

Amendment 115

Proposal for a regulation

Article 83 a (new)

Text proposed by the Commission

Amendment

Article 83 a

Reporting

***By ...*, the Commission shall submit
report to the European Parliament and
the Council regarding adequate measures
to promote the sustainable use of biocidal
products across the different product
types. On the basis of this report, the
Commission shall present, where
appropriate, legislative proposals.***

** Two years from the entry into force of this Regulation.*

Amendment 116

Proposal for a regulation

Annex III – Title 1 - point 3.7 – subpoint 1 a (new)

Text proposed by the Commission

Amendment

Storage stability and shelf life will be generally determined based on the stability of the active substance. In the case of readily decomposable active substances, the storage stability and the shelf life may be determined by other valid scientific means, such as extrapolating the analytical data of the active substance from product aging experiments until reaching the efficacy threshold.

Justification

Standard stability tests that are based on the measurements and quantification of the active substance are not appropriate for products containing readily decomposable active substances, such as sodium hypochlorite. These substances are known to decompose beyond accepted guidelines (FAO, WHO limits). Therefore, in such cases, it is more appropriate that the stability and the shelf-life is determined by other means, such as extrapolating the analytical data of the active substance from product aging experiments until reaching the efficacy threshold.

Amendment 117

Proposal for a regulation

Annex V – Main group 4

Text proposed by the Commission

Amendment

Product-type 20: -

Product-type 20: ***Food and feed disinfectants***

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

Justification

It is necessary to keep former Directive 98/80/EC's biocidal product type 20 ('Preservatives for food or feedstocks'), but its definition needs to be amended, given that these biocidal products are not preservatives but disinfectants (as a consequence, the older definition led to confusion). For instance, products used to disinfect feed from human pathogens such as Salmonella do not meet the requirements of the feed additives regulations. Indeed, the products do not 'favourably affect the feed' nor enhance its performance.

PROCEDURE

Title	The placing on the market and use of biocidal products		
References	COM(2009)0267 – C7-0036/2009 – 2009/0076(COD)		
Committee responsible	ENVI		
Opinion by Date announced in plenary	IMCO 14.7.2009		
Associated committee(s) - date announced in plenary	17.12.2009		
Rapporteur Date appointed	Amalia Sartori 28.9.2009		
Discussed in committee	5.11.2009	27.1.2010	18.3.2010
Date adopted	28.4.2010		
Result of final vote	+: 24 -: 3 0: 9		
Members present for the final vote	Cristian Silviu Buşoi, Lara Comi, Anna Maria Corazza Bildt, António Fernando Correia De Campos, Jürgen Creutzmann, Christian Engström, Evelyn Gebhardt, Louis Grech, Małgorzata Handzlik, Malcolm Harbour, Philippe Juvin, Sandra Kalniete, Alan Kelly, Eija-Riitta Korhola, Edvard Kožušník, Kurt Lechner, Toine Manders, Hans-Peter Mayer, Robert Rochefort, Zuzana Roithová, Heide Rühle, Andreas Schwab, Róza Gräfin Von Thun Und Hohenstein, Kyriacos Triantaphyllides, Bernadette Vergnaud, Barbara Weiler		
Substitute(s) present for the final vote	Pascal Canfin, Cornelis de Jong, Anna Hedh, Othmar Karas, Emma McClarkin, Amalia Sartori, Catherine Soullie, Marc Tarabella, Kerstin Westphal		

22.4.2010

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

for the Committee on the Environment, Public Health and Food Safety

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)0267 – C7-0036/2009 – 2009/0076(COD))

Rapporteur: Sajjad Karim

SHORT JUSTIFICATION

Biocidal Products Market and Legal Regulation

The biocidal products market in Europe is estimated at c. €890m per year, comprising around 27% of the global market. Three large companies hold approximately 25% of the European market. It is therefore necessary to balance the concerns of large companies with small and medium-sized enterprises (SMEs).

Directive 98/8/EC, which currently regulates the sector, had the dual aim of improving environmental and health protection. It also provided for a system of mutual recognition of national authorisation procedures in order to allow biocidal products to move across the internal market. However, a range of problems in its 10-year history (such as excessive cost, prohibitive requirements, authorisation time delays, time disparities in evaluations of applications in the different Member States) has led to only one active substance being approved under the current legislative framework with no better expectation in the foreseeable future.

The European Commission proposes a new regulation to streamline procedures and enhance the functioning of the market. The main points include among others: an optional centralised authorisation procedure for "low risk" biocidal products, an improved mutual recognition procedure, a harmonised fee structure for national authorisations and regulation for articles treated with biocidal products.

Your draftsman broadly welcomes the Commission's proposals and widely supports the proposed measures, particularly the emphasis on reducing the burden of the authorisation process. It is, however, important to ensure that the needs of the various stakeholders are addressed and for this reason a range of proposals have been outlined below.

Proposed Amendments

Extended Centralised Authorisation Procedure

The draftsman welcomes the proposals to introduce the option of a centralised authorisation procedure for active substances and biocidal products for producers. The current definition of a "low-risk biocidal product" appears to limit this procedure to an unduly restrictive category of products and the draftsman recommends a partial widening of this category. The review date for the regulation should also be brought forward from 2023 to 2016 to allow for a review and possible expansion of the central authorisation procedure if it is operating effectively.

Assistance to SMEs

More assistance needs to be given to SMEs in an industry dominated by several large industrial producers. For this reason, SMEs need to be exempted from paying an annual fee for placing biocidal products on the market. In addition, Member States should establish helpdesks to supplement the guidance documents provided by the European Chemicals Agency (ECHA).

Streamlining of Deadlines

Throughout the proposal, specific timeframes should be set where possible to allow industry to plan ahead. There should be set timelines for the different stages of evaluation of a dossier. Deadlines should be shortened, where viable, to ensure the greatest possible efficiency in the authorisation process.

Enhancing Research and Development (R&D)

It is appropriate to facilitate greater R&D in an industry critical to the protection of environmental and human health. Under the proposal, experiments/tests which may involve the release of an unauthorised biocidal product into the environment require a national authorisation. A simpler notification procedure should be put in place which still allows the competent authority to issue more stringent conditions, but where burdensome authorisation is not a default option.

Frame Formulations

In the interests of efficiency, the draftsman proposes distinguishing between administrative, minor and major amendments regarding authorisations for frame formulations. Administrative amendments could be processed via a simplified notification procedure; minor amendments could be assessed in a reduced evaluation period; and, for major changes, the evaluation period could be proportionate to the extent of the proposed change. In addition, in order to assist producers, the draftsman recommends that one single authorisation number be provided for all biocidal products which belong to that frame.

Exclusion Criteria

In regard to exclusion criteria, the draftsman felt that excluding certain active substance product types (4 and 14 to 19) from the general authorisation test was unnecessarily restrictive. It should be possible for all product types to be assessed according to the criteria. Banning such products under the plant protection legislation does not justify such a ban (with narrow exceptions) under the biocides legislation because pesticides and biocides have different uses and different levels of exposure.

Language Requirements

It should only be a requirement that product authorisation applications and product labelling are in only one of the official languages of the relevant Member State (if more than one) to avoid an excessive burden for industry.

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a regulation Recital 20

Text proposed by the Commission

Amendment

(20) As products used for the preservation of food or feedstocks by the control of harmful organisms, previously covered by product type 20, are covered by Council Directive 89/107/EEC and Regulation (EC) No 1831/2003 of the European Parliament and of the Council, it is not appropriate to maintain this product type.

deleted

Justification

It is necessary to keep biocidal product type 20 ('Preservatives for food or feedstocks') but its definition needs to be amended, since these biocidal products are not preservatives but disinfectants. For instance, products used to disinfect feed from human pathogens such as Salmonella do not meet the requirements of the feed additives regulations. Neither do they act as preservatives to prevent animal feed from deteriorating. These products must be therefore considered as disinfectant agents.

Amendment 2

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.

Amendment 3

Proposal for a regulation
Recital 31 a (new)

Text proposed by the Commission

Amendment

(31a) In order to help applicants, and in particular SMEs, to comply with the requirements of this Regulation, Member States, in addition to the operational guidance documents provided by the Agency, should establish national helpdesks.

Amendment 4

Proposal for a regulation
Recital 45

Text proposed by the Commission

(45) In view of the benefits for the internal market and for the consumer, it is desirable to establish harmonised rules for parallel trade of ***substantially*** identical biocidal products that are authorised in different Member States.

Amendment

(45) In view of the benefits for the internal market and for the consumer, it is desirable to establish harmonised rules for parallel trade of identical biocidal products that are authorised in different Member States.

Justification

Parallel trade should be confined to identical products which have the same specifications and contain the same active substances and co-formulants.

Amendment 5

Proposal for a regulation

Recital 48

Text proposed by the Commission

(48) 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

(48) 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 those of 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.

Justification

Those who have undertaken investment under the existing legislation must not be excluded.

Amendment 6

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

Amendment

(49) 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.

submitted for the purposes of Directive 98/8/EC.

Justification

In the interests of clarity.

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 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

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 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

procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Article 5a of Decision 1999/468/EC.

Amendment 8

Proposal for a regulation Recital 66

Text proposed by the Commission

(66) Taking into consideration that some products were not previously covered by the Community legislation in the field of biocidal products, it is appropriate to allow for a transitional period for the companies to be prepared to apply the rules concerning in situ generated active substances, treated articles and materials **and food contact materials**.

Amendment

(66) Taking into consideration that some products were not previously covered by the Community legislation in the field of biocidal products, it is appropriate to allow for a transitional period for the companies to be prepared to apply the rules concerning in situ generated active substances, treated articles and materials.

Justification

Food contact materials are already governed by Regulation (EC) No 1935/2004. Such materials should not fall within the scope of the proposal, as that would result in duplication of evaluation and regulation. If gaps in the legislation are discovered, they should be remedied by amending the Regulation on food contact materials.

Amendment 9

Proposal for a regulation Article 2 – paragraph 2 – point p a (new)

Text proposed by the Commission

Amendment

(pa) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food¹.

¹ OJ L 338, 13.11.2004, p. 4.

Justification

Food contact materials are already governed by Regulation (EC) No 1935/2004. Such materials should not fall within the scope of the proposal, as that would result in duplication

of evaluation and regulation. If gaps in the legislation are discovered, they should be remedied by amending the Regulation on food contact materials.

Amendment 10

Proposal for a regulation

Article 3 – paragraph 1 – point f – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

Unless there are other grounds for concern, such a substance shall be a substance classified as hazardous pursuant to Directive 67/548/EEC and be present in the biocidal product in a concentration such as to require it to be regarded as hazardous within the meaning of Directive 1999/45/EC or Regulation (EC) No 1272/2008.

Justification

The definition is already to be found in Directive 98/8/EC, and should be incorporated in the new Regulation in the interests of clarity.

Amendment 11

Proposal for a regulation

Article 3 – paragraph 1 – point k

Text proposed by the Commission

Amendment

(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***;

(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 ***produce the biocidal effect which is their purpose***;

Justification

This amendment extends the definition of treated articles and materials to include both articles such as paints which have been preserved and articles with an external effect, such as mosquito nets. The evaluation is thus a chemical one.

Amendment 12

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 **primary** national or Community authorisation, **or duplicate authorisation or additional authorisation**;

Amendment 13

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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

Amendment 14

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(nb) 'additional authorisation' means an administrative act by which a Member State or the Commission authorises the placing on the market and the use, under a different name, of a biocidal product based on a primary authorisation and on approval by the holder of the primary authorisation;

Amendment 15

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, **provided that, irrespective of these variations,** the level of risk **does not exceed that attached to the reference biocidal products and the efficacy on the target organism corresponds to what is indicated on the label of the product;**

Justification

It is important to establish that the risk potential must not be greater than that of the reference biocidal product and that the efficacy on the target organisms is consistent with the product label.

Amendment 16

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 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;

Amendment

(q) 'letter of access' means an original document, signed by the owner or owners of information **or their representative**, which states that the information may be used by the **designated** competent authorities, the European Chemicals Agency, or the Commission for the purpose of evaluating an active substance or granting an authorisation **to a third party;**

Justification

It is felt necessary to clarify the definition of 'letter of access'.

Amendment 17

Proposal for a regulation

Article 3 – paragraph 1 – point s

Text proposed by the Commission

Amendment

*(s) 'food contact materials' means
any material and article intended to come
into contact with food which are covered
by Regulation (EC) No 1935/2004;*

deleted

Justification

Food contact materials are already governed by Regulation (EC) No 1935/2004. Such materials should not fall within the scope of the proposal, as that would result in duplication of evaluation and regulation. If gaps in the legislation are discovered, they should be remedied by amending the Regulation on food contact materials.

Amendment 18

Proposal for a regulation

Article 3 – paragraph 1 – point t a (new)

Text proposed by the Commission

Amendment

*(ta) 'administrative change' means a
variation to an existing authorisation of a
purely administrative nature, which does
not involve a re-assessment of the risk for
public health or the environment or the
efficacy of the product;*

Justification

It is necessary to define the type of variations that can be made to an existing authorised biocidal product.

Amendment 19

Proposal for a regulation

Article 3 – paragraph 1 – point t b (new)

Text proposed by the Commission

Amendment

(tb) 'minor change' means a variation to an existing authorisation which cannot be deemed to be an administrative variation as it requires a limited re-assessment of the risk for public health or the environment and/or of the efficacy of the product, and does not adversely affect the level of risk for public health or the environment and the efficacy of the product;

Justification

It is necessary to define the type of variations that can be made to an existing authorised biocidal product.

Amendment 20

Proposal for a regulation

Article 3 – paragraph 1 - point t c (new)

Text proposed by the Commission

Amendment

(tc) 'major change' means a variation to an existing authorisation which cannot be deemed to be an administrative change or a minor change;

Justification

It is necessary to define the type of variations that can be made to an existing authorised biocidal product.

Amendment 21

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(ua) 'SMEs' mean small and medium-sized enterprises as defined in the Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises¹.

¹ OJ L 124, 20.5.2003, p. 36.

Justification

Following the example in REACH Regulation, it is better to separately set the definition for SMEs.

Amendment 22

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(ub) 'manufacturer' means:

- with reference to an active substance produced within Community territory or placed on the market, the person who manufactures that active substance or a person resident in the Community who is designated by the manufacturer as his sole representative for the purposes of the present Regulation,

- with reference to an active substance produced outside Community territory, the person resident in the Community who is designated by the manufacturer of the active substance as his sole representative for the purposes of the present Regulation or, if no such person has been designated, the person who imports the biocidal product or the active

*substance in question into the
Community,*

Justification

In view of the new wording of Article 83, it is necessary to define 'manufacturer'. In fact the definition is in line with the provisions of 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 23

Proposal for a regulation

Article 3 a (new – first Article of Chapter II)

Text proposed by the Commission

Amendment

Article 3a

1. Any prospective applicant for inclusion of an active substance in Annex I shall inquire of the Agency whether

- an application for inclusion of the same substance in Annex I has already been submitted or

- the same substance is included in Annex I or

- the same substance is registered pursuant to Regulation (EC) No 1907/2006.

2. Any prospective applicant shall forward the following information to the Agency with the application:

(a) its identity as specified in section 1 of Annex VI to Regulation (EC) No 1907/2006, with the exception of points 1.2 and 1.3;

(b) the identity of the substance as specified in section 2 of Annex VI to Regulation (EC) No 1907/2006;

(c) which requests for information will require new studies involving vertebrate animals which it will have to perform;

(d) which requests for information will

require other new studies which it will have to perform.

3. If the same substance is not included in Annex I or not registered pursuant to Regulation (EC) No 1907/2006, the Agency shall inform the prospective applicant accordingly.

4. If an application for inclusion of the same active substance in Annex I has already been submitted, if the same active substance is already included in Annex I or if it has been registered pursuant to Regulation (EC) No 1907/2006, the Agency shall inform the prospective applicant, without delay, of the name and address of the previous applicants and registrants and the study summaries or robust study summaries of the information, as the case may be, already supplied.

5. The Agency shall at the same time inform the previous applicant or registrant of the name and address of the prospective applicant for inclusion in Annex I. The available studies of vertebrate animals shall be shared with the prospective applicant in accordance with Chapter XI of this Regulation.

Justification

These procedures are necessary in order to avoid duplication of tests on vertebrate animals and to comply with requests for Annex II information. The 'obligation to provide information' under the REACH Regulation is made mutual, as the Agency will have the requisite infrastructure and expertise to adopt this procedure.

Amendment 24

Proposal for a regulation Article 4 – paragraph 1

Text proposed by the Commission

1. An active substance shall be included in Annex I for an initial period not exceeding 10 years if the biocidal products containing

Amendment

1. An active substance shall be included in Annex I for an initial period not exceeding 10 years if *at least one of* the biocidal

that active substance **fulfil** the conditions laid down in point (b) of Article 16(1).

products containing that active substance **fulfils** the conditions laid down in point (b) of Article 16(1).

Justification

At the time of entry in Annex I, the dossier must be submitted for at least one representative biocidal product whose active substance meets the conditions laid down. The proposed change is considered to reflect the concept of entry in Annex I more satisfactorily.

Amendment 25

Proposal for a regulation

Article 4 – paragraph 3 - introductory part

Text proposed by the Commission

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

Amendment

3. An active substance **and a statement of the reference source for the determination of technical equivalence** shall, where appropriate, be included in Annex I together with any of the following conditions:

Justification

It is important to link the chemical substance described in Annex I to the data which have supported its inclusion in the annex. In addition, the isomeric composition is important for the purpose of distinguishing chemical identity.

Amendment 26

Proposal for a regulation

Article 4 – paragraph 3 – point f a (new)

Text proposed by the Commission

Amendment

(fa) indication of the chemical identity as regards stereoisomers.

Justification

It is important to link the chemical substance described in Annex I to the data which have supported its inclusion in the annex. In addition, the isomeric composition is important for the purpose of distinguishing chemical identity.

Amendment 27

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

(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;

Amendment

(a) the exposure of humans to that active substance in a biocidal product, under **prescribed** conditions of use, is negligible **or adequately controlled, taking account of the intrinsic hazards presented by the substance**, in particular where the product is used in closed systems or strictly controlled conditions;

Justification

There are no scientific grounds for discriminating against product types (e.g. PT4 and 14-19). These products are rodenticides, acaricides, molluscicides, disinfectants, piscicides and insecticides and are beneficial, in particular, to people in Southern Europe, where it is vital to combat rat or insect infestations for hygiene reasons. Exclusion should be decided on the basis of a risk analysis (a combination of hazardousness and exposure). If it is scientifically proven that the risks are well controlled, the active substances should be authorised.

Amendment 28

Proposal for a regulation

Article 5 – paragraph 1 – subparagraph 2

Text proposed by the Commission

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

Amendment

deleted

Justification

The scientific rationale for discriminating against particular product types (i.e. PT's 4 and 14-19) is unclear and appears to be arbitrary and therefore unjustly targets these particular product types.

Amendment 29

Proposal for a regulation

Article 5 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Implementing measures adopted in accordance with Regulation (EC) No ... [concerning the placing of plant protection products on the market], which specify the scientific criteria for determining the endocrine-disrupting properties, shall be applied.

Justification

At present no criteria exist for approval of endocrine-disrupters, and it is necessary to draft them. These criteria should be adopted in accordance with Regulation (EC) No 1107/2009 on the placing on the market of plant protection products, which entered into force on 24 November 2009.

Amendment 30

Proposal for a regulation

Article 6 – paragraph 1 – point a

Text proposed by the Commission

Amendment

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

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

Justification

Applicants may not be in legitimate possession of all the data in support of the application.

Amendment 31

Proposal for a regulation

Article 6 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

(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.

Justification

Applicants may not be in legitimate possession of all the data in support of the application.

Amendment 32

Proposal for a regulation

Article 7 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The Agency shall assign a reference number to each application, which shall be used for all correspondence concerning the application until the substance is included in Annex I, and a submission date, which shall be the date of receipt by the Agency.

Amendment 33

Proposal for a regulation

Article 7 – paragraph 3 – introductory part

Text proposed by the Commission

Amendment

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

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

Amendment 34

Proposal for a regulation

Article 7 – paragraph 4 - subparagraph 1

Text proposed by the Commission

Amendment

4. 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.

4. 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 time limit **of up to two months** for the submission of that information.

Justification

A set time limit is needed for the provision of documentation which should be as concise as possible in order to quickly proceed with evaluation.

Amendment 35

Proposal for a regulation

Article 7 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Within two months after the receipt of an application, the Agency shall register each part of the information in the dossier with a unique identifying code.

Amendment 36

Proposal for a regulation

Article 8 – paragraph 2 - subparagraph 1

Text proposed by the Commission

Amendment

2. If, when the dossiers are evaluated, it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, **and** shall inform the Agency thereof.

2. If, when the dossiers are evaluated, it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit ***that shall not exceed six months. In exceptional circumstances and following proper justification, the time limit may be extended by up to a further six months.*** ***The evaluating competent authority*** shall inform the Agency thereof.

Justification

Experience has shown concluding an evaluation procedure could take an unjustifiably long time. It is therefore essential that proper time limits are put in place to avoid loopholes that could protract the procedure unnecessarily. These also bring some certainty to the applicant as to the possible maximum duration of this procedure.

Amendment 37

Proposal for a regulation

Article 8 – paragraph 5 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

When the Commission decides to include the active substance in Annex I, the name(s) of the applicant(s) shall be indicated.

Amendment 38

Proposal for a regulation

Article 8 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. With the decision to include the active substance in Annex I, the Agency shall assign to the substance in question a specific registration number for the substance and for the applicant. The Agency shall without delay inform the applicant of the number and the date of registration. This registration number shall be used in all further correspondence regarding the active substance and for product authorisation as referred to in Chapter IV of this Regulation.

Amendment 39

Proposal for a regulation

Article 9 – paragraph 2

Text proposed by the Commission

Amendment

2. When preparing an opinion on the inclusion or renewal of the inclusion of an active substance in Annex I, the Agency shall examine whether the active substance fulfils any of the criteria listed in paragraph 1 and address the matter in its opinion.

2. When preparing an opinion on the inclusion or renewal of the inclusion of an active substance in Annex I, the Agency shall examine whether the active substance fulfils any of the criteria listed in paragraph 1 and, ***if exposure is not adequately controlled, bearing in mind the intrinsic hazards of the substance, shall*** address the

matter in its opinion.

Justification

The criteria for identifying active substances which are candidates for substitution are aligned with the criteria for substances subject to authorisation as referred to in Regulation (EC) No 1907/2006 for reasons of harmonisation between the two regulations - see Article 57 of Regulation (EC) No 1907/2006. As the Agency (ECHA) will have the task of examining whether an active substance meets the criteria, harmonisation between the two regulations is advisable.

Amendment 40

Proposal for a regulation

Article 11 – paragraph 4 - subparagraph 1

Text proposed by the Commission

4. 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.

Amendment

4. 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 time limit **of up to two months** for the submission of that information.

Justification

A set time limit is needed for the provision of documentation which should be as concise as possible in order to quickly proceed with evaluation.

Amendment 41

Proposal for a regulation

Article 12 – paragraph 5

Text proposed by the Commission

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

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 accordance with the regulatory procedure

with scrutiny referred to in Article 72(4).

with scrutiny referred to in Article 72(4). ***If the Commission decides to renew the inclusion of the active substance in Annex I, mention should be made of the name of the applicant(s).***

Justification

Including the active substance in Annex I, together with the name of the applicant firm, is an appropriate and effective means of preventing free-riding, since it enables the firm which supported the substance to be identified quickly and thereby reducing the administrative burden.

Amendment 42

Proposal for a regulation Article 13 – paragraph 2

Text proposed by the Commission

2. The Commission may consult the Agency on any questions of a scientific or technical nature related to the review of inclusion of an active substance in Annex I. The Agency shall, within ***nine*** months from the request, prepare an opinion and submit it to the Commission.

Amendment

2. The Commission may consult the Agency on any questions of a scientific or technical nature related to the review of inclusion of an active substance in Annex I. The Agency shall, within ***six*** months from the request, prepare an opinion and submit it to the Commission.

Justification

Amendment for sake of consistency since everywhere else in the proposal the limit for issuing an opinion by the Agency at the request of the Commission is six months.

Amendment 43

Proposal for a regulation Article 15 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. Application for authorisation shall be made by, or on behalf of, the person who ***shall be*** responsible for the placing on the market of a biocidal product in a particular Member State or in the Community.

Amendment

2. Application for authorisation shall be made by, or on behalf of, the person ***holding the authorisation, who may or may not be the person*** responsible for the placing on the market of a biocidal product in a particular Member State or in the

Community.

Amendment 44

Proposal for a regulation

Article 15 – paragraph 2 – subparagraph 2

Text proposed by the Commission

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***

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 possibility of choosing the evaluating competent authority is an advantage for small and medium-sized enterprises in particular, since they are able to work with their national authorities.

Amendment 45

Proposal for a regulation

Article 15 – paragraph 2 – subparagraph 3

Text proposed by the Commission

Amendment

Application for ***Community*** authorisation shall be submitted to the Agency.

Application for authorisation shall be submitted to the Agency.

The applicant may, in agreement with a Member State, have his application validated by that Member State and must identify the evaluating competent authority in the application itself, as laid down in Article 22.

Justification

The 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 possibility of choosing the evaluating competent authority is an advantage for small and medium-sized enterprises in particular, since they are able to work with their national authorities.

Amendment 46

Proposal for a regulation

Article 15 – paragraph 2 – subparagraph 3 a (new)

Text proposed by the Commission

Amendment

An applicant seeking authorisation for a group of products as part of a frame formulation may submit a single application for authorisation.

Amendment 47

Proposal for a regulation

Article 16 – paragraph 1 – point a

Text proposed by the Commission

Amendment

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;

a) the active substances included therein are listed in Annex I, ***a registration number is assigned to them in accordance with Article 8(5a)*** and any conditions included in ***Annex I*** together with those active substances are complied with;

Justification

In the interests of consistency with the evaluation procedure described in Article 8(5a).

Amendment 48

Proposal for a regulation

Article 16 – paragraph 1 – point c

Text proposed by the Commission

Amendment

c) the ***nature***, the quantity and the technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or

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;

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;

Justification

The term 'nature' has not been clearly defined. 'Chemical identity' seems a better way of describing the active substance.

Amendment 49

Proposal for a regulation

Article 16 – paragraph 2 – subparagraphs 2 a and 2 b (new)

Text proposed by the Commission

Amendment

The evaluation of the compliance of the biocidal products with the criteria set out in point (b) of paragraph 1 should be based as far as possible on existing information on the substances of concern contained in the biocidal product in order to keep tests on animals to a minimum. In particular, use should be made of the provisions of Directive 1999/45/EC or Regulation (EC) No 1272/2008 on identifying the danger posed by biocidal products and consequent risk evaluation.

The evaluation of the compliance of the biocidal product with the criteria set out in point (b) of paragraph 1 and the requirements set out in point (c) of that paragraph shall not take into account a substance contained in the biocidal product if it is present in a preparation at a concentration lower than any of the following:

(a) the applicable concentrations laid down in Article 3(3) of Directive 1999/45/EC;

(b) the concentration limit values given in

Annex I to Directive 67/548/EEC;

(c) the concentration limit values given in Part B of Annex II to Directive 1999/45/EC;

(d) the concentration limit values given in Part B of Annex III to Directive 1999/45/EC;

(e) the concentration limit given in an agreed entry in the classification and labelling inventory established under Title V of Regulation (EC) No 1272/2008;

(f) 0.1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII to Regulation (EC) No 1907/2006.

Justification

The aim is to prevent unnecessary animal testing while also complying with the REACH requirement regarding Chemical Safety Report thresholds.

Amendment 50

Proposal for a regulation Article 16 – paragraph 6

Text proposed by the Commission

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.*

Amendment

6. In the case of a frame formulation, *the following variations are permitted in respect of one or more reference biocidal products:*

(a) elimination of an active substance in respect of a reference biocidal product with at least two active substances;

(b) reduction in the percentage of the active substances;

(c) elimination of one or more non-active substances;

(d) variation in the percentage

composition of one or more non-active substances;

(e) replacement of one or more non-active substances.

Amendment 51

Proposal for a regulation

Article 16 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. In accordance with the procedure laid down in Article 72(2), the Commission shall provide scientific and technical guidance for the authorisation of products, particularly as regards uniform requirements for data, evaluation procedures and decisions by the Member States.

Justification

The aim is to ensure uniform implementation of the Regulation within Community territory.

Amendment 52

Proposal for a regulation

Article 17

Text proposed by the Commission

Amendment

1. A biocidal product shall be considered a low-risk biocidal product if ***both*** the following conditions ***are*** fulfilled:

(a) for any given environmental compartment, the ratio of the predicted environmental concentration (PEC) to predicted no-effect concentration (PNEC) may be derived and does not exceed 0.1;

(b) for any effect to human health, the margin of exposure (the ratio of no observed adverse effect level (NOAEL) and exposure concentration) is higher

1. A biocidal product shall be considered a low-risk biocidal product if ***at least one of*** the following conditions ***is*** fulfilled:

(a) the biocidal product is not classified for human health or environmental hazards under Regulation (EC) No 1272/2008;

(b) the classification of the biocidal product is not associated with the signal word ‘danger’ on the label required under

than 1,000.

However, a biocidal product shall not be considered a low-risk biocidal product if **at least one of the following conditions is present:**

(a) **it contains one or more active substances which fulfil** the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII of Regulation (EC) No 1907/2006;

(b) **it contains one or more active substances qualified** as endocrine disrupters;

(c) **it contains one or more active substances which have** been classified in accordance with Regulation (EC) No 1272/2008 as or which meets the criteria to be classified as one of the following:

- (i) carcinogenic;
- (ii) mutagenic;
- (iii) neurotoxic;
- (iv) immunotoxic;
- (v) toxic to reproduction;
- (vi) sensitising.

Regulation (EC) No 1272/2008 and under normal and reasonably foreseeable conditions of use of the product without the use of personal protective equipment, the requirements in Article 16(1)(b), (c) and (d) are met;

c) the active substance(s) in the biocidal product are contained in such a way that under normal or reasonably foreseeable conditions of use the exposure is negligible and the product is handled under strictly controlled conditions during all other stages of its lifecycle.

2. However, a biocidal product shall not be considered a low-risk biocidal product if **it contains an active substance or a substance of concern that:**

(a) **fulfils** the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII of Regulation (EC) No 1907/2006;

(b) **is identified** as endocrine disrupters **under Article 57(f) of Regulation (EC) No 1907/2006;**

(c) **has** been classified in accordance with Regulation (EC) No 1272/2008 as, or which meets the criteria to be classified as, one of the following:

- (i) carcinogenic;
- (ii) mutagenic;
- (iii) neurotoxic;
- (iv) immunotoxic;
- (v) toxic to reproduction;
- (vi) sensitising.

2. Notwithstanding paragraph 1, a biocidal product shall be considered a low-risk biocidal product if the active substances in the biocidal product are contained in such way that only a negligible exposure can take place under normal conditions of use and the product is handled under strictly controlled conditions during all other stages of its lifecycle.

3. For a low-risk biocidal product it shall be demonstrated that the potential for the development of resistance in target organisms due to the use of the biocidal product is low.

4. In addition to the active substances referred to in Article 15(2) of Regulation (EC) No 1907/2006, active substances manufactured or imported for use in low-risk biocidal products that are authorised for placing on the market in accordance with Article 15 shall be regarded as being registered and the registration as completed for manufacture or import for use in a low-risk biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of Title II of that Regulation.

3. In addition to the active substances referred to in Article 15(2) of Regulation (EC) No 1907/2006, active substances manufactured or imported for use in low-risk biocidal products that are authorised for placing on the market in accordance with Article 15 shall be regarded as being registered and the registration as completed for manufacture or import for use in a low-risk biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of Title II of that Regulation.

Justification

The proposed by the Commission definition of low-risk biocidal products seems too restrictive and hence limits the occasions where the centralised procedure could apply. The definition is thus extended in order to allow for more products benefitting from Community authorisation while assuring that ECHA will not at first be overwhelmed with the entire range of biocidal products. This could be allowed for at a later stage through an earlier (in 2016) review of the procedure in view of possibly extending it to all products.

Amendment 53

Proposal for a regulation

Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

1. The applicant for **a primary** authorisation shall submit the following

with the application:

documents together with the application:

Amendment 54

Proposal for a regulation

Article 18 – paragraph 2

Text proposed by the Commission

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.

Amendment 55

Proposal for a regulation

Article 18 – paragraph 3

Text proposed by the Commission

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

Justification

The possibility of requiring translations in more than one official language (in cases where there are more than 1 in a given Member State) could place an unnecessary financial and administrative burden on the applicant.

Amendment 56

Proposal for a regulation

Article 18 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. In accordance with the procedure laid down in Article 72(2), the Commission shall provide a standard technical and legal guide and, in particular, assistance with authorisation applications in

accordance with Articles 18, 19 and 20, particularly for SMEs.

Justification

This amendment recognises that assistance and guidelines from the Commission can be particularly important for SME, which may not have the appropriate resources and experience to adapt to the Regulation.

Amendment 57

Proposal for a regulation

Article 20 – paragraph 2 - point e

Text proposed by the Commission

e) qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge *of which* is essential for proper use of the biocidal product;

Amendment

e) qualitative and quantitative composition in terms of the active substances and non-active substances, ***taking into consideration the concentration limit values given in Article 16, in so far as*** knowledge *of these* is essential for proper use of the biocidal product;

Justification

This amendment is necessary to avoid disseminating confidential data; in point (g), provided the manufacturer of the substance is authorised through registration in Annex I, the location of the manufacturing site should remain confidential and should not form part of the biocidal product authorisation.

Amendment 58

Proposal for a regulation

Article 20 – paragraph 2 – point g

Text proposed by the Commission

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 manufacturing sites) ***and registration number of the active substance in accordance with Article 8(5a);***

Justification

In the interests of consistency with the evaluation procedure set out in Article 8(5a).

Amendment 59

Proposal for a regulation

Article 20 – paragraph 3 – point a

Text proposed by the Commission

a) the reference biocidal product within the group of products comprising the frame formulation ***that has the highest allowed concentration of the active substances;***

Amendment

a) the reference biocidal product within the group of products comprising the frame formulation;

Justification

Reference biocidal products are not necessarily defined by the highest concentration. In addition, further to the amendments to Articles 3(1)(p) and 16(6), more than one reference biocidal product may be permitted. The list of accepted variations within a frame formulation is already clearly set out in Article 16(6). Reference to this article will ensure a consistent approach.

Amendment 60

Proposal for a regulation

Article 20 – paragraph 3 – point b

Text proposed by the Commission

b) ***the permitted alteration of the composition of this reference biocidal product expressed in percentage of the non-active substances contained in the biocidal products which are considered to belong to that frame formulation;***

Amendment

b) ***the variations permitted in accordance with Article 16(6).***

Justification

Reference biocidal products are not necessarily defined by the highest concentration. In addition, further to the amendments to Articles 3(1)(p) and 16(6), more than one reference biocidal product may be permitted. The list of accepted variations within a frame formulation is already clearly set out in Article 16(6). Reference to this article will ensure a consistent approach.

Amendment 61

Proposal for a regulation

Article 20 – paragraph 3 – point c

Text proposed by the Commission

Amendment

c) the non-active substances that may be substituted in the authorised biocidal products belonging to that frame formulation. **deleted**

Justification

Reference biocidal products are not necessarily defined by the highest concentration. In addition, further to the amendments to Articles 3(1)(p) and 16(6), more than one reference biocidal product may be permitted. The list of accepted variations within a frame formulation is already clearly set out in Article 16(6). Reference to this article will ensure a consistent approach.

Amendment 62

Proposal for a regulation

Article 21 – paragraph 1

Text proposed by the Commission

Amendment

1. The receiving competent authority or, in the case of evaluation of an application for a Community authorisation, the evaluating competent authority shall perform a comparative assessment ***as part of the evaluation of an application for an authorisation or a*** renewal of an authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 9(1).

1. The receiving competent authority or, in the case of evaluation of an application for a Community authorisation, the evaluating competent authority shall perform a comparative assessment ***for the renewal, in accordance with this regulation,*** of an authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 9(1). ***A comparative assessment shall be required for all biocidal products having the same purpose when sufficient experience has been gained in their use and they have been in use for at least five years.***

Amendment 63

Proposal for a regulation
Article 21 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. By way of derogation from paragraph 1, a comparative assessment shall not be required for biocidal products whose use has been shown to be safe.

Amendment 64

Proposal for a regulation
Article 21 – paragraph 2

Text proposed by the Commission

Amendment

2. The results of the comparative assessment shall be forwarded, without delay, to the competent authorities of other Member States and the Agency and, in the case of ***evaluation of an application for*** a Community authorisation, also to the Commission.

2. The results of the comparative assessment shall be forwarded, without delay, to the competent authorities of other Member States and the Agency and, in the case of ***a renewal of*** a Community authorisation, also to the Commission.

Amendment 65

Proposal for a regulation
Article 21 – paragraph 3

Text proposed by the Commission

Amendment

3. The receiving competent authority or, in the case of a decision on ***an application for*** a Community authorisation, the Commission shall prohibit or restrict the placing on the market or use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment weighing up the risks and benefits in accordance with Annex VI demonstrates that all the following criteria are met:

(a) for the uses specified in the application, ***another authorised biocidal product or a non-chemical control or prevention***

3. The receiving competent authority or, in the case of a decision on ***a renewal of*** a Community authorisation, the Commission shall prohibit or restrict the placing on the market or use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment weighing up the risks and benefits in accordance with Annex VI demonstrates that all the following criteria are met:

(a) for the uses specified in the application, ***other authorised biocidal products already exist which present*** significantly lower risk

method already exists which presents significantly lower risk for human or animal health or the environment;

(b) the biocidal *product or non-chemical control or prevention method* referred to in point (a) *does* not present significant economic or practical disadvantages;

(c) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.

for human or animal health or the environment *and which prove equally effective and involve no significant increase in the risks for any other parameter;*

(b) the biocidal *products* referred to in point (a) *do* not present significant economic or practical disadvantages;

(c) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.

Amendment 66

Proposal for a regulation Article 21 – paragraph 4

Text proposed by the Commission

4. By way of derogation from paragraph 1, a biocidal product containing an active substance that is a candidate for substitution shall be authorised without comparative assessment in cases where it is necessary to acquire experience first through using that product in practice.

Amendment

4. The Commission shall adopt implementing measures which specify the procedure required to define the application for comparative assessment for biocidal products in accordance with the provisions of paragraph 3. These measures shall define the criteria and algorithms to be used for the comparative assessments so as to ensure uniform application throughout the Community. These measures shall be adopted in accordance with the procedures laid down in Article 72(3).

Justification

In the interests of uniform application of the comparative assessment of biocidal products, the Commission should draw up implementing measures.

Amendment 67

Proposal for a regulation

Article 21 a (new) – to be inserted at the end of Chapter IV

Text proposed by the Commission

Amendment

Article 21a

1. The person responsible for the placing of a biocidal product on the market, or his representative, shall submit an application for a national authorisation or 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 three weeks after the receipt of the application, notify the evaluating competent authority that the application is available in the Agency database.

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.

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

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 fails to submit the information required within the deadline and inform the applicant and the evaluating competent authority thereof.

In such cases a part of the fee paid to the Agency in accordance with 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 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.

Justification

The ECHA should perform the initial validation of all applications throughout the Community, so that the evaluating competent authorities can concentrate on the actual assessment of applications. Currently, where evaluating competent authorities consider both the administrative and scientific aspects of applications, there have been inconsistencies in their approach. The Agency must abide by the same deadlines as those laid down under REACH (Article 20) for validating the application.

Amendment 68

Proposal for a regulation Article 23 – paragraph 1

Text proposed by the Commission

1. The receiving competent authority shall, within **twelve** months after the validation referred to in Article 22, decide on the application in accordance with Article 16.

Amendment

1. The receiving competent authority shall, within ~~six~~ months after the validation referred to in Article 22, decide on the application in accordance with Article 16.

Justification

Given the fact that, before being included in Annex I to the regulation, active substances used in biocidal products are already subject to lengthy assessment, it is felt that the period of twelve months provided for in the proposal for a regulation is too long for the authorisation of a biocidal product based on authorised active substances.

Amendment 69

Proposal for a regulation

Article 23 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. If the ingredients contained in the biocidal product have already been registered for use in biocidal products in accordance with Regulation (EC) No 1907/2006, the evaluating competent authority shall not carry out a further assessment.

Justification

To avoid unnecessary duplication of effort.

Amendment 70

Proposal for a regulation

Article 23 – paragraph 3

Text proposed by the Commission

Amendment

3. If it appears that additional information is necessary in order to carry out a full evaluation of the application, the receiving competent authority shall request the applicant to submit such information. The twelve-month period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received.

3. If it appears that additional information is necessary in order to carry out a full evaluation of the application, the receiving competent authority shall request the applicant to submit such information ***within a specified time limit that shall not exceed six months. In exceptional circumstances and following proper justification, the time limit may be extended by up to a further six months.*** The twelve-month period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date

the information is received.

Justification

Experience has shown concluding an evaluation procedure could take an unjustifiably long time. It is therefore essential that proper time limits are put in place to avoid loopholes that could protract the procedure unnecessarily. These also bring some certainty to the applicant as to the possible maximum duration of this procedure.

Amendment 71

Proposal for a regulation

Article 24 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. The authorisation holder or his representative shall submit an application for renewal of a national authorisation to the receiving competent authority at least **eighteen** months before the expiry date of the authorisation.

Amendment

1. The authorisation holder or his representative shall submit an application for renewal of a national authorisation to the receiving competent authority at least **twelve** months before the expiry date of the authorisation.

Justification

Unless there are new data to be assessed, eighteen months are not required to renew a product authorisation. A twelve month period is more appropriate.

Amendment 72

Proposal for a regulation

Article 25 – paragraph 3

Text proposed by the Commission

3. The receiving competent authority may require a translation of the national authorisation and application into one **or several** of the official languages of the Member State where that competent authority is situated.

Amendment

3. The receiving competent authority may require a translation of the national authorisation and application into one of the official languages of the Member State where that competent authority is situated.

Justification

The possibility of requiring translations in more than one official language (in cases where

there are more than 1 in a given Member State) could place an unnecessary financial and administrative burden on the applicant.

Amendment 73

Proposal for a regulation

Article 25 – paragraph 5 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

In the event of mutual recognition, a single authorisation number shall be used in all Member States involved.

Justification

In the case of a mutual recognition procedure, a single authorisation number should be used in all Member States. The Commission should be responsible for adopting implementing measures to introduce a single number.

Amendment 74

Proposal for a regulation

Article 25 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. In the case of mutual recognition procedures, the Commission shall adopt implementing measures laying down the criteria and procedures for assigning a single authorisation number in all Member States concerned.

Justification

In the case of a mutual recognition procedure, a single authorisation number should be used in all Member States. The Commission should be responsible for adopting implementing measures to introduce a single number.

Amendment 75

Proposal for a regulation

Article 27 – paragraph 1 – subparagraph 2

Text proposed by the Commission

The Commission shall adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

Amendment

After consulting the applicant, the Commission shall adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

Justification

Provision is needed in the regulation for a deadline for settling disputes between Member States. A period of three months is thought to be adequate to enable the Commission to draw up a proposal for a decision to refuse to recognise or to restrict the authorisation.

Amendment 76

Proposal for a regulation

Article 27 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

Within three months of receiving the notification, the Commission shall make a proposal for a decision. Should the Commission ask the Agency for an opinion under the procedure set out in Article 30, the three-month period shall be suspended until the Agency has forwarded its opinion.

Justification

The regulation should set out the time period for the resolution of disputes between Member States. Three months would seem to be appropriate timing for the Commission to draw up a proposal for a decision on the refusal, or restriction, of authorisation.

Amendment 77

Proposal for a regulation

Article 28 – paragraph 9 – subparagraph 2

Text proposed by the Commission

The Commission shall adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

Amendment

Within three months following the notification, the Commission shall, after consultation with the applicant, adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3). Should the Commission ask the Agency for an opinion under the procedure set out in Article 30, the three-month period shall be suspended until the Agency has forwarded its opinion.

Justification

The legislative text should clearly state the timelines applicable in order to have an efficient system in place to resolve disputes between Member States. Three months is an adequate timing for the Commission to make a proposal for a decision on the grounds justifying the refusal to recognise or restrict authorisations.

Amendment 78

Proposal for a regulation

Article 28 – paragraph 9 – subparagraph 3

Text proposed by the Commission

If the Commission decision ***dismisses*** the grounds presented for refusing or restricting the national authorisation the competent authority that ***proposed to refuse to recognise the authorisation, or to restrict the authorisation,*** shall without delay ***authorise the biocidal product concerned in accordance with the*** national authorisation ***issued by the reference competent authority.***

Amendment

If the Commission decision ***confirms*** the grounds presented for refusing or restricting the subsequent authorisation, the competent authority that ***had previously authorised the biocidal product*** shall without delay ***review its*** national authorisation ***to comply with that decision.***

If the Commission decision confirms the initial national authorisation, the competent authority that proposed to refuse to recognise a national authorisation, or to recognise the national

authorisation subject to certain conditions, shall without delay authorise the biocidal product concerned in accordance with the initial authorisation.

Justification

This current wording only presents the option whereby the Commission dismisses the grounds for refusal but not the case where the Commission agrees with these, as is correctly presented in paragraph 2 of Article 27 - same wording has been applied here as well.

Amendment 79

Proposal for a regulation

Article 29 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The Commission shall adopt a decision on the proposed adjustment of the conditions of the national authorisation to local circumstances in accordance with the procedure referred to in Article 72(3). The competent authority of the concerned Member State shall without delay adopt all appropriate measures to comply with that decision.

Amendment

The Commission shall, ***after consultation with the applicant***, adopt a decision on the proposed adjustment of the conditions of the national authorisation to local circumstances in accordance with the procedure referred to in Article 72(3). The competent authority of the concerned Member State shall without delay adopt all appropriate measures to comply with that decision.

Justification

The regulation should set out the time period for the resolution of disputes between Member States. Three months would seem to be appropriate timing time for the Commission to draw up a proposal for a decision on the refusal, or restriction, of authorisation.

Amendment 80

Proposal for a regulation

Article 29 – paragraph 2 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

Within three months of receiving the notification, the Commission shall make a proposal for a decision. Should the Commission ask the Agency for an

opinion under the procedure set out in Article 30, the three-month period shall be suspended until the Agency has forwarded its opinion.

Justification.

The regulation should set out the time period for the resolution of disputes between Member States. Three months would seem to be appropriate timing time for the Commission to draw up a proposal for a decision on the refusal, or restriction, of authorisation.

Amendment 81

Proposal for a regulation Article 33

Text proposed by the Commission

Amendment

1. The Community authorisation may be granted to <i>the following categories</i> of biocidal products:	The Community authorisation may be granted to <i>any category</i> of biocidal products.
<i>(a) biocidal products containing one or more new active substances;</i>	
<i>(b) low-risk biocidal products.</i>	
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.	
<i>Those measures, 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).</i>	

Justification

A centralised authorisation system has clear benefits for the functioning of the internal market by ensuring consistent assessments and a harmonised implementation of the requirements in all Member States, driving best practices and same standards of consumer protection across Europe. The Community authorisation procedure should therefore extend to all product categories instead of only a small minority of products (low risk biocidal products and products with new active substances).

Amendment 82

Proposal for a regulation Article 34

Text proposed by the Commission

Amendment

Article 34

Deleted

Submission and validation of application

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 fails to complete his application within the deadline and inform the applicant and the evaluating competent authority thereof. In such cases a part of the fee paid to the Agency in accordance with 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.

Justification

Under the new Article 22, the submission and validation of applications for national and Community authorisations are governed by the same rules. This renders superfluous Article 22 of the original proposal.

Amendment 83

Proposal for a regulation Article 35 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Should the ingredients contained in the biocidal product have already been registered, in conformity with Regulation (EC) No 1907/2006, for use in biocidal

products, the evaluating competent authority shall not duplicate that evaluation.

Justification

Aims to avoid an unnecessary duplication of effort.

Amendment 84

Proposal for a regulation

Article 35 – paragraph 2 - subparagraph 1

Text proposed by the Commission

2. If, when the dossiers are evaluated, it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a *specified* time limit, *and* shall inform the Agency thereof.

Amendment

2. If, when the dossiers are evaluated, it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a time limit *that shall not exceed six months. In exceptional circumstances and following proper justification, the time limit may be extended by up to a further six months. The evaluating competent authority* shall inform the Agency thereof.

Justification

Experience has shown concluding an evaluation procedure could take an unjustifiably long time. It is therefore essential that proper time limits are put in place to avoid loopholes that could protract the procedure unnecessarily. These also bring some certainty to the applicant as to the possible maximum duration of this procedure.

Amendment 85

Proposal for a regulation

Article 35 – paragraph 3 – subparagraph 1

Text proposed by the Commission

3. Within *nine* months from the receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the

Amendment

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.

authorisation of the biocidal product.

Justification

Nine months is too long a period for the Agency to prepare and submit an opinion based on an already-available evaluation conducted by the evaluating competent authority. Three months is a more appropriate length of time.

Amendment 86

Proposal for a regulation

Article 35 – paragraph 5

Text proposed by the Commission

Amendment

5. If the decision referred to in paragraph 4 refuses to grant a Community authorisation to a biocidal product because it does not fulfil the criteria for a low-risk biocidal product in accordance with Article 17, the applicant may apply, if relevant, for a Community authorisation in accordance with point (a) of Article 33(1) or a national authorisation in accordance with Chapter V.

deleted

Justification

This paragraph requires deletion as Community authorisation is being requested for all types of biocide.

Amendment 87

Proposal for a regulation

Article 36 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

1. The authorisation holder or his representative shall submit an application for renewal of a Community authorisation to the Agency at least *18 months* before the expiry date of the authorisation.

1. The authorisation holder or his representative shall submit an application for renewal of a Community authorisation to the Agency at least *12 months* before the expiry date of the authorisation.

Justification

12 months would be a more appropriate length of time for the renewal of an authorisation.

Amendment 88

Proposal for a regulation

Article 37 – paragraph 2 - subparagraph 1

Text proposed by the Commission

2. If the evaluating competent authority that carried out the initial evaluation of the application for Community authorisation decides that a full evaluation of the application is not necessary, it shall, within **twelve** months after the validation, prepare and submit to the Agency a recommendation on the renewal of the authorisation.

Amendment

2. If the evaluating competent authority that carried out the initial evaluation of the application for Community authorisation decides that a full evaluation of the application is not necessary, it shall, within **six** months after the validation, prepare and submit to the Agency a recommendation on the renewal of the authorisation.

Justification

In Article 12.2 for renewal of inclusion of active substance in Annex I, when full evaluation is not necessary it is required that the evaluating authority issues a recommendation for renewal in 6 months not 12.

Amendment 89

Proposal for a regulation

Chapter VII a (new) – Article 37 a (new)

Text proposed by the Commission

Amendment

CHAPTER VIIa

Article 37a

1. Holders of, or applicants for, a primary authorisation may submit to the Agency a request for a duplicate authorisation for the same biocidal product.

2. Applicants for a duplicate authorisation must forward the following items and information with their application:

(a) the authorisation number for the primary authorisation or, in the case of

an application for primary authorisation, the application number;

(b) the qualitative and quantitative composition in terms of active substances and non-active substances, taking into account the concentration limits given in Article 16, insofar as knowledge of this is essential for appropriate use of the biocidal product;

(c) the application doses and instructions for use;

(d) categories of users.

3. The Agency shall validate the application on the basis of the rules laid down in Article 22.

4. If the Agency considers the application to be complete, on the basis of the validation under paragraph 3, it shall inform forthwith the applicant, the evaluating competent authority granting the primary authorisation or, in the case of duplication of a Community authorisation, the Commission.

5. In the case of existing primary authorisations, the evaluating competent authority or, in the case of duplication of a Community authorisation, the Commission, shall decide on the application within one month of the validation. In the case of pending applications for authorisation, the evaluating competent authority or, in the case of duplication of a Community authorisation, the Commission, must decide on the application within one month of the granting of the primary authorisation.

6. Should additional information appear to be required to enable the identity of the biocidal product to be established, the evaluating competent authority or, in the case of duplication of a Community authorisation, the Commission, shall request that information from the applicant. The one-month period referred

to in paragraph 5 shall be suspended from the date of issue of the request until the date the information is received.

7. As soon as the evaluating competent authority or, in the case of duplication of a Community authorisation, the Commission, has authorised the duplication of a primary authorisation, it shall assign to it a specific authorisation number and record the administrative act in the Community Register of Biocidal Products.

8. Notwithstanding the information submitted pursuant to paragraph 2, in the case of duplicate authorisations the terms and conditions for the placing on the market and use of the biocidal product agreed in the primary authorisation must be applied.

Amendment 90

Proposal for a regulation

Article 37 b (new – second article in the new Chapter VIIa)

Text proposed by the Commission

Amendment

Article 37b

1. An additional authorisation may be granted on the basis of a primary authorisation.

2. Applicants wishing to apply for an additional authorisation must send the application for authorisation to the Agency.

3. Applicants for an additional authorisation must forward the following items and information with their application:

(a) the authorisation number for the primary authorisation or, in the case of a pending application, the application number;

- (b) the name and address of the applicant;*
- (c) written approval from the holder of the authorisation;*
- (d) the qualitative and quantitative composition in terms of active substances and non-active substances, taking into account the concentration limits given in Article 16, insofar as knowledge of this is essential for appropriate use of the biocidal product;*
- (e) the application doses and instructions for use;*
- (f) categories of users.*

4. The Agency shall validate the application on the basis of the rules laid down in Article 22.

5. If the Agency considers the application to be complete, on the basis of the validation under paragraph 4, it shall inform forthwith the applicant, the evaluating competent authority granting the primary authorisation or, in the case of addition of a Community authorisation, the Commission.

6. In the case of existing primary authorisations, the evaluating competent authority or, in the case of addition of a Community authorisation, the Commission, shall decide on the application within one month of the validation. In the case of pending applications for authorisation, the evaluating competent authority or, in the case of addition of a Community authorisation, the Commission, must decide on the application within one month of the granting of the primary authorisation.

7. Should additional information appear to be required to enable the identity of the biocidal product to be established, the evaluating competent authority or, in the case of addition of a Community authorisation, the Commission, shall

request that information from the applicant. The one-month period referred to in paragraph 6 shall be suspended from the date of issue of the request until the date the information is received.

8. As soon as the evaluating competent authority or, in case of addition of a Community authorisation, the Commission, has authorised the addition of a primary authorisation, it shall assign to it a specific authorisation number and record the administrative act in the Community Register of Biocidal Products.

9. Notwithstanding the information submitted pursuant to paragraph 3, in the case of additional authorisations the terms and conditions for the placing on the market and use of the biocidal product agreed in the primary authorisation must be applied.

Amendment 91

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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

Justification

Notification of any change in the origin of an active substance used in a biocidal product is being requested as this can have an impact on the safety of the product.

Amendment 92

Proposal for a regulation

Article 39 - paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The cancellation or amendment of a primary authorisation shall apply to

duplicate and additional authorisations based on that authorisation.

Amendment 93

Proposal for a regulation Article 40 - paragraph 1

Text proposed by the Commission

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.

Amendment

The competent authority that has granted *an* 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 *duplicate or additional* Community authorisation, it shall be submitted to the Agency.

Amendment 94

Proposal for a regulation Article 41 - paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The amendment of a primary authorisation at the request of the holder of the primary authorisation shall apply to duplicate and additional authorisations based on that authorisation.

Amendment 95

Proposal for a regulation Article 41 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. An amendment to an existing authorisation shall, in accordance with Article 3, constitute either:

- a) an administrative change;*
- b) a minor change; or*
- c) a major change.*

Justification

The legislative text should clearly outline the main principles which shall be applied when amending authorisations, although the details of the procedures can be specified in the implementing measures. In particular, it is necessary to specify the types of changes that can be made to existing product authorisations.

Amendment 96

Proposal for a regulation

Article 42 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The criteria and procedures referred to in the first paragraph of this article shall be based, non-exclusively, on the following principles for which a simplified notification procedure has been requested:

- (a) administrative changes to the authorisation;*
- (b) changes to the biocidal product within the range permitted under an existing authorised frame formulation;*
- (c) placing on the market of a new biocidal product within the limits of an existing authorised frame formulation;*
- (d) changes in a biocidal product which do not adversely alter the level of the risk or efficacy of the product.*

Amendment 97

Proposal for a regulation

Article 44 – paragraph 1 – subparagraph 3

Text proposed by the Commission

The application shall be accompanied by all the information necessary to demonstrate that the biocidal product is ***substantially*** identical to the reference product as defined in paragraph 3.

Amendment

The application shall be accompanied by all the information necessary to demonstrate that the biocidal product is identical to the reference product as defined in paragraph 3.

Justification

Parallel trade should be confined to identical products which have the same specifications and contain the same active substances and co-formulants.

Amendment 98

Proposal for a regulation

Article 44 – paragraph 3

Text proposed by the Commission

3. A biocidal product shall be considered as ***substantially*** identical to the reference product if ***one of*** the following conditions ***is*** met:

a) ***the source of the active substances it contains is the same in terms of manufacturer and location of the production plant;***

b) it is ***either*** the same ***or similar*** with regard to the ***non-active*** substances present and the type of formulation;

c) it is either the same or equivalent in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.

Amendment

3. A biocidal product shall be considered as identical to the reference product if ***all*** the following conditions ***are*** met:

a) ***it has been manufactured by the same company or one of its associate companies or under licence, following the same production process;***

b) it is the same with regard to the ***specifications, the active*** substances present and the type of formulation;

c) it is either the same or equivalent, ***as regards the co-formulants it contains and the format, materials and form of its packaging,*** in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.

Justification

Parallel trade should be confined to identical products which have the same specifications and contain the same active substances and co-formulants.

Amendment 99

Proposal for a regulation

Article 44 – paragraph 4 – point a a (new)

Text proposed by the Commission

Amendment

aa) the registration numbers of the active substances contained in the product and a letter of access in accordance with Article 50 from the relevant applicant under Chapter II of this Regulation;

Justification

The application for a parallel trade licence must also contain the number of registrations for the active substances.

Amendment 100

Proposal for a regulation

Article 44 – paragraph 4 – point c

Text proposed by the Commission

Amendment

c) name and address of the authorisation holder in the Member State of origin;

c) name and address of the authorisation holder in the Member State of origin ***and a letter of access in accordance with Article 50 from the holder of the authorisation;***

Justification

The application for a parallel trade licence must also contain information relating to the letter of access, as indicated in Article 50.

Amendment 101

Proposal for a regulation

Article 46 – paragraph 1

Text proposed by the Commission

1. By way of derogation from Article 15, an experiment or a test for the purposes of research or development involving the placing on the market of an unauthorised biocidal product or an active substance intended exclusively for use in a biocidal product may only take place in the case of scientific research and development or in the case of product and process-oriented research and development, and under the conditions laid down in the second and third subparagraphs.

In the case of scientific research and development, the person who intends to carry out the experiment or the test shall notify the competent authority prior to the start. The person shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied ***and the names and addresses of those persons receiving the biocidal product or active substance***, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The persons concerned shall, if requested, make this information available to the competent authority.

In the case of product and process-oriented research and development, the person who intends to carry out the experiment or the test shall, prior to the placing of the biocidal product or the active substance on the market, notify the information required in the second subparagraph to the competent authority of the Member State where the placing on the market occurs.

Amendment

1. By way of derogation from Article 15, an experiment or a test for the purposes of research or development, ***including product- and process-oriented research and development activities***, involving the placing on the market of an unauthorised biocidal product or an active substance intended exclusively for use in a biocidal product may only take place in the case of scientific research and development or in the case of product and process-oriented research and development, and under the conditions laid down in the second and third subparagraphs.

In the case of scientific research and development, ***including product and process-oriented research and development***, the person who intends to carry out the experiment or the test shall notify the competent authority prior to the start. The person shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data ***and*** quantities supplied, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The persons concerned shall, if requested, make this information available to the competent authority.

Amendment 102

Proposal for a regulation

Article 46 – paragraph 1 – subparagraph 2

Text proposed by the Commission

In the case of scientific research and development, the person who intends to carry out the experiment or the test shall notify the competent authority prior to the start. The person shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied ***and the names and addresses of those persons receiving the biocidal product or active substance***, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The persons concerned shall, if requested, make this information available to the competent authority.

Amendment

In the case of scientific research and development, ***including product and process-oriented research and development***, the person who intends to carry out the experiment or the test shall notify the competent authority prior to the start. The person shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data ***and*** quantities supplied, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The persons concerned shall, if requested, make this information available to the competent authority.

Justification

According to the proposal, in order to proceed with an experiment or test for the purposes of R&D, an unauthorised biocidal product which may involve release of the product into the environment requires a national authorisation before the test/experiment can be done. This clearly constitutes a significant barrier to innovation, as it implies a very long waiting period before the test can be carried out. Thus, whilst maintaining the need for a prior evaluation by the competent authority, a 30 day period should be set to assess if the proposed test/experiment raises any concerns.

Amendment 103

Proposal for a regulation

Article 46 – paragraph 3 - subparagraph 1

Text proposed by the Commission

3. Where any experiment or test takes place in a Member State other than the Member State where placing on the market of the biocidal product occurs, the applicant shall ***obtain experiment or test***

Amendment

3. Where any experiment or test takes place in a Member State other than the Member State where placing on the market of the biocidal product occurs, the applicant shall ***notify*** the competent

authorisation from the competent authority of the Member State in the territory of which the experiments or tests are to be conducted.

authority of the Member State in the territory of which the experiments or tests are to be conducted. ***The applicant shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data and quantities supplied, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The applicant shall, if requested, make this information available to the competent authority.***

Justification

The rules on conducting tests/experiments on the territory of a Member State, other than the one on whose market the biocidal products shall be placed, should be same as those in paragraph one of the same article.

Amendment 104

Proposal for a regulation

Article 47 – paragraph 2 - subparagraph 1

Text proposed by the Commission

2. Treated articles or materials shall be labelled with the following information:
- (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;
- (b) where relevant, the biocidal property attributed to treated articles ***or materials***;
- (c) the authorisation number of all biocidal products that were used for the treatment or were incorporated in the***

Amendment

2. Treated articles or materials shall be labelled with the following information:
- (a) the ***names, using wherever possible common nomenclature (e.g. INCI), of all active substances that were used to treat the articles or materials or that were incorporated in the articles or materials, where relevant, and of all active substances which are intended to be released under normal or foreseeable conditions of use from the treated article or material, unless labelling requirements or alternative means to meet information requirements already exist under sector-specific legislation;***
- (b) where relevant, the biocidal property attributed to treated articles;

articles or materials;

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

(c) only for treated articles and where relevant, any hazard statement or precautionary statement set out in the authorisation for the biocidal product where relevant, and for all active substances intended to be released by the article or material treated in normal or foreseeable conditions of use.

Justification

The labelling provisions for treated articles and materials should not overlap with existing requirements under sectoral legislation.

Amendment 105

Proposal for a regulation

Article 47 – paragraph 2 – subparagraphs 2 and 3

Text proposed by the Commission

The labelling shall be clearly visible, easily legible **and** appropriately durable.

Amendment

The labelling shall be clearly visible, easily legible, appropriately durable **and** printed **on the article or material**, on the packaging, on the instructions for use or on the warranty of the treated article or material **in the national language or languages of the Member State on whose market the treated article or material is to be placed**.

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.

Justification

It should be clarified that treated articles and materials, as with other products, should always be labelled in the national language or languages of the Member State on whose market the product is placed. (The rapporteur has amended his proposed Amendment 37 of his draft opinion to take account of Member States with more than one national language.)

Amendment 106

Proposal for a regulation
Article 47 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The person responsible for placing treated articles or materials on the market shall have a letter of certification issued by the holder of the authorisation in respect of all biocidal products that have been used for the treatment or that have been inserted into the articles or materials.

Justification

Any person placing articles or materials treated with biocides on the market should also have a letter of certification listing all the biocides which have been used in the articles and materials.

Amendment 107

Proposal for a regulation
Article 48 – paragraph 1 – point a

Text proposed by the Commission

Amendment

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,***

a) the subsequent applicant has written agreement in the form of a letter of access ***in accordance with the requirements of Article 50,***

Justification

The first applicant is not necessarily the data owner. Provision should also be made for cases in which a second applicant or company is or becomes joint owner of data as a result of the sharing or joint compilation of the data.

Amendment 108

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 data.

Justification

The first applicant is not necessarily the data owner. Provision should also be made for cases in which a second applicant or company is or becomes joint owner of data as a result of the sharing or joint compilation of the data.

Amendment 109

Proposal for a regulation

Article 48 – paragraph 4

Text proposed by the Commission

Amendment

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

4. Every element of information in the list referred to in paragraph 2, ***identified by a unique code***, shall be entered by the Agency in the Biocides Data Sharing Register, ***including all the identifying details and linked to the identity of the first applicant and data owner(s).***

Justification

The Register should contain every element of information and documents in the list. A numerical identification is preferable for every document sent in order to avoid any confusion wherever titles or corrections of studies with similar names are sent. There should also be a link to the data owner to ensure that ownership rights are respected.

Amendment 110

Proposal for a regulation

Article 49 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

Information protected under Directive 98/8/EC or under this Article or for which the protection period expired under

An individual date of submission shall be assigned to each document, as identified by the unique code under Article 48(4).

Directive 98/8/EC or under this Article shall not be protected again.

Justification

Directive 98/8/EC did not clearly lay down data protection requirements. The date of submission of the dossier may not be the date of submission of all the information. This is why each submission should be assigned a date.

Amendment 111

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 whether they are technically equivalent in the light of the reference source. If the assessment confirms the fact, the competent authority of the Agency shall*** communicate the name and contact details of the owner of the information to the prospective applicant.

Justification

Before studies give rise to the sharing of data, appropriate checks should be carried out on technical equivalence. Otherwise, there is no way of establishing whether the data available are applicable to the subsequent applicant.

Amendment 112

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

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 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.

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 information protection periods under Article 49 have not ended, the competent authority or the Agency may agree that a subsequent applicant for authorisation may share the data provided by the first applicant in accordance with Article 52,*** 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.

Justification

If an applicant wishes to share data, the similarity and technical equivalence must be demonstrated even if the data protection period has not ended.

Amendment 113

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 2016**. The Commission shall submit the report to the European Parliament and the Council.

Amendment 114

Proposal for a regulation Article 55 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. Disclosure of the following information shall be deemed to undermine the

Amendment

2. Disclosure of the following information shall be deemed to undermine the

protection of the commercial interests of the concerned person:

- a) details of the full composition of a biocidal product;
- b) the precise use, function or application of a substance or mixture;
- c) the precise tonnage of the substance or mixture manufactured or placed on the market;
- d) links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product.

protection of the commercial interests of the concerned person ***and may not be disclosed publicly:***

- a) details of the full composition of a biocidal product;
- b) the precise use, function or application of a substance or mixture;
- c) the precise tonnage of the substance or mixture manufactured or placed on the market;
- d) links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;

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

(db) the location of a biocidal product's manufacturing site;

(dc) the date of issue of an authorisation and the expiry date;

(dd) doses and instructions for use.

Justification

(dc) Information to be considered confidential because it is commercially sensitive should also include the date of issue of an authorisation and the expiry date, doses, instructions for use and the location of the manufacturing site of a biocidal product or active substance.

Amendment 115

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

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

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.

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.

Justification

This article should apply not just to active substances but also to biocidal products.

Amendment 116

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:

deleted

i) in scientific research and development;

ii) in product and process orientated research and development.

Justification

Information on R&D should remain confidential.

Amendment 117

Proposal for a regulation

Article 58 – paragraph 2 – point e

Text proposed by the Commission

Amendment

e) directions for use and the dose rate, expressed *in metric units*, for each use provided for under the terms of the authorisation;

e) directions for use and the dose rate, expressed *in a manner that is meaningful and comprehensible to users*, for each use provided for under the terms of the authorisation;

Justification

The dose rate expressed in metric units is not comprehensible for non-professional users and is therefore difficult for users to understand. Instead, the dose rate should be expressed on the label in a manner that is meaningful and comprehensible to the end user.

Amendment 118

Proposal for a regulation
Article 58 – paragraph 3

Text proposed by the Commission

3. Member States **may** require that biocidal products placed on the market of their territories are labelled in their national language or languages.

Amendment

3. Member States **shall** require that biocidal products placed on the market of their territories are labelled in their national language or languages.

Justification

Products in general should always be labelled in the national language or languages of the Member State on whose market the product is placed. (The rapporteur has amended his proposed Amendment 39 of his draft opinion to take account of Member States with more than one national language.)

Amendment 119

Proposal for a regulation
Article 58 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Biocidal products which include nanomaterials or which have been manufactured by means of the nanotechnology shall be clearly labelled as such.

Justification

Biocidal products which include nanomaterials are covered by the Regulation. But the impact of these substances on health and the environment is largely unknown at present. Consumers must be informed correctly.

Amendment 120

Proposal for a regulation

Article 66 – paragraph 2 – point d

Text proposed by the Commission

(d) providing advice and assistance to applicants for the inclusion of an active substance in Annex I or for a Community authorisation;

Amendment

(d) providing advice and assistance to applicants, ***and in particular to SMEs***, for the inclusion of an active substance in Annex I or for a Community authorisation;

Justification

It should be noted that SMEs will more often be in a position to require assistance with their applications and this should be provided whenever possible by Commission, Agency and Member States.

Amendment 121

Proposal for a regulation

Article 70 – paragraph 2 – point a

Text proposed by the Commission

(a) a reduced fee shall be set for ***small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises***;

Amendment

(a) a reduced fee shall be set for ***SMEs, this in no way alters the responsibility of the evaluating competent authority for carrying out an accurate evaluation within the meaning of the Regulation***;

Justification

Definition for SMEs has been separately set in a new amendment to Article 3 on definitions.

Amendment 122

Proposal for a regulation

Article 70 – paragraph 2 – point d

Text proposed by the Commission

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

Amendment

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

Justification

While the annual fee will help sustain the continuous financing of ECHA, SMEs should be exempt from that in order not to place unnecessary financial burden on them.

Amendment 123

Proposal for a regulation Article 75 a (new)

Text proposed by the Commission

Amendment

Article 75a

National helpdesks in Member States

Member States shall establish national helpdesks to provide advice to applicants, in particular to SMEs, and any other interested parties on their respective responsibilities and obligations under this Regulation and in addition to any assistance provided by the Agency under Article 66(2)(d).

Amendment 124

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 with effect from 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

The aim is to shorten the deadlines since downstream users should be aware of their obligations and of the state of revision of active substances.

Amendment 125

Proposal for a regulation Article 82

Text proposed by the Commission

Amendment

Article 82

deleted

Transitional measures concerning food contact materials

1. Applications for the authorisation of biocidal products which are food contact materials and 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 1 January 2017.

Food contact materials which were available on the market on [OJ: insert the date referred to in the first subparagraph of Article 85] for which an application was submitted in accordance with paragraph 1 may continue to be placed on the market until the date of the decision granting the authorisation or refusing to grant the authorisation. In case of a refusal to grant an authorisation to place such biocidal product on the market, such biocidal product shall no longer be placed on the market within six months after such decision.

Food contact materials which were available on the market on [OJ: insert the date referred to in the first subparagraph of Article 85] for which an application was not submitted in accordance with paragraph 1 may continue to be placed on the market until six months after the date referred to in paragraph 1.

2. Disposal, storage and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission is allowed until twelve months after the date of the decision referred to in the second subparagraph of paragraph 1 or twelve months after the date referred to in the third subparagraph of paragraph 1, whichever is the later.

Justification

Food contact materials are already governed by Regulation (EC) No 1935/2004. Such materials should not fall within the scope of the proposal, as that would result in duplication of evaluation and regulation. If gaps in the legislation are discovered, they should be remedied by amending the Regulation on food contact materials.

Amendment 126

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

Text proposed by the Commission

Amendment

From 1 January 2014 all manufacturers of an existing active substance placed on the market for use in biocidal products shall submit to the Agency a request to include the substance in Annex I. Competent authorities shall carry out official controls in accordance with Article 54(1).

Justification

Only companies which contribute to the system should be authorised to manufacture and market active substances for use in biocidal products. This is the best way to deal with the problem of free riders, through appropriate supervision of the market in active substances. Member States should be required to establish what biocidal products exist on the market and whether the manufacturer of the active substance has submitted a file under Annex I, and take appropriate action.

Amendment 127

Proposal for a regulation
Article 83 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

Competent authorities shall take the necessary measures in accordance with Article 54(2).

Justification

Only companies which contribute to the system should be authorised to manufacture and market active substances for use in biocidal products. This is the best way to deal with the problem of free riders, through appropriate supervision of the market in active substances. Member States should be required to establish what biocidal products exist on the market and whether the manufacturer of the active substance has submitted a file under Annex I, and take appropriate action.

Amendment 128

Proposal for a regulation
Annex III - first part (Data requirements for biocidal products) - point 1 a (new)

Text proposed by the Commission

Amendment

1a. The information shall, as far as possible, be taken from existing data in order to minimise animal tests. The provisions of Directive 1999/45/EC and Regulation (EC) No 1272/2008 shall, in particular, be applied.

Justification

To avoid unnecessary animal tests.

Amendment 129

Proposal for a regulation
Annex III – Title 1 – point 2.2

Text proposed by the Commission

Amendment

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

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

impurities, adjutants, inert components

taking into account the concentration limits laid down in Article 16

Justification

To bring the provision into line with the amendments to Article 16(2a) and (2b)(new).

Amendment 130

Proposal for a regulation

Annex V – Main Group 4 – Product type 20

Text proposed by the Commission

Amendment

Product-type 20: -

Product-type 20: ***Food and feed disinfectants***

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

Justification

It is necessary to keep biocidal product type 20 ('Preservatives for food or feedstocks') but its definition needs to be amended since these products are not preservatives but disinfectants. For example, products used to disinfect feed from human pathogens such as Salmonella do not meet the requirements of the feed additives regulations. Neither do they act as preservatives to prevent feed from deteriorating. These products must be therefore considered as disinfectant agents.

PROCEDURE

Title	The placing on the market and use of biocidal products						
References	COM(2009)0267 – C7-0036/2009 – 2009/0076(COD)						
Committee responsible	ENVI						
Opinion by Date announced in plenary	ITRE 14.7.2009						
Rapporteur Date appointed	Sajjad Karim 17.9.2009						
Discussed in committee	10.11.2009 27.1.2010						
Date adopted	7.4.2010						
Result of final vote	<table> <tr> <td>+: </td><td>37</td></tr> <tr> <td>–: </td><td>5</td></tr> <tr> <td>0: </td><td>7</td></tr> </table>	+:	37	–:	5	0:	7
+:	37						
–:	5						
0:	7						
Members present for the final vote	Jean-Pierre Audy, Zigmantas Balčytis, Jan Březina, Maria Da Graça Carvalho, Giles Chichester, António Fernando Correia De Campos, Pilar del Castillo Vera, Lena Ek, Ioan Enciu, Adam Gierek, Norbert Glante, Fiona Hall, Jacky Hénin, Edit Herczog, Sajjad Karim, Arturs Krišjānis Kariņš, Bogdan Kazimierz Marcinkiewicz, Marisa Matias, Judith A. Merkies, Jaroslav Paška, Aldo Patriciello, Miloslav Ransdorf, Herbert Reul, Michèle Rivasi, Jens Rohde, Paul Rübig, Amalia Sartori, Francisco Sosa Wagner, Konrad Szymański, Patrizia Toia, Evžen Tošenovský, Ioannis A. Tsoukalas, Claude Turmes, Niki Tzavela, Vladimir Urutchev, Adina-Ioana Vălean, Alejo Vidal-Quadras						
Substitute(s) present for the final vote	Lara Comi, Rachida Dati, Jolanta Emilia Hibner, Yannick Jadot, Oriol Junqueras Vies, Marian-Jean Marinescu, Ivari Padar, Markus Pieper, Mario Pirillo, Silvia-Adriana Țicău, Lambert van Nistelrooij, Hermann Winkler						

PROCEDURE

Title	The placing on the market and use of biocidal products		
References	COM(2009)0267 – C7-0036/2009 – 2009/0076(COD)		
Date submitted to Parliament	12.6.2009		
Committee responsible Date announced in plenary	ENVI 14.7.2009		
Committee(s) asked for opinion(s) Date announced in plenary	ITRE 14.7.2009	IMCO 14.7.2009	
Associated committee(s) Date announced in plenary	IMCO 17.12.2009		
Rapporteur(s) Date appointed	Christa Klač 15.9.2009		
Legal basis disputed Date of JURI opinion	JURI 17.5.2010		
Discussed in committee	4.11.2009	23.2.2010	28.4.2010
Date adopted	22.6.2010		
Result of final vote	+: –: 0:	47 5 6	
Members present for the final vote	János Áder, Elena Oana Antonescu, Pilar Ayuso, Paolo Bartolozzi, Sandrine Bélier, Milan Cabrnoch, Martin Callanan, Nessa Childers, Esther de Lange, Anne Delvaux, Edite Estrela, Elisabetta Gardini, Gerben-Jan Gerbrandy, Julie Girling, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Dan Jørgensen, Karin Kadenbach, Christa Klač, Holger Krahmer, Jo Leinen, Corinne Lepage, Peter Liese, Linda McAvan, Radvilė Morkūnaitė-Mikulėnienė, Gilles Pargneaux, Andres Perello Rodriguez, Sirpa Pietikäinen, Mario Pirillo, Pavel Poc, Vittorio Prodi, Frédérique Ries, Oreste Rossi, Richard Seeber, Theodoros Skylakakis, Bogusław Sonik, Catherine Soullie, Glenis Willmott, Sabine Wils, Marina Yannakoudakis		
Substitute(s) present for the final vote	Margrete Auken, João Ferreira, Christofer Fjellner, Matthias Groote, Rebecca Harms, Marisa Matias, Judith A. Merkies, Miroslav Mikolášik, Bill Newton Dunn, James Nicholson, Alojz Peterle, Rovana Plumb, Michail Tremopoulos, Gionmmaria Uggias, Thomas Ulmer, Marita Ulvskog, Anna Záborská		
Date tabled	30.7.2010		