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Committee on Industry, Research and Energy

2009/0076(COD)

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

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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	*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***, 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.	(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	*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 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	*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 should be	(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***

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

Justification

In the interests of clarity.

Amendment 7

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	(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.	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 Article 5a of Decision 1999/468/EC.

Amendment 8

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, 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 food[1].
	[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	*Amendment*
(n) 'authorisation' means national ***authorisation*** or Community authorisation;	(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	*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 specifications ***where such permitted variations do not adversely affect*** the level of risk ***or the***	(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***

efficacy of these products;	***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	*Amendment*
(q) 'letter of access' means	(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;	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	***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 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 enterprises[1].
	[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	*Amendment*
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).	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

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	*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 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	*Amendment*
(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) 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	*Amendment*
Point (c) shall not apply to active substances for product types 4 and 14 to 19.	***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	*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 41

Proposal for a regulation
Article 12 – paragraph 5

Text proposed by the Commission	*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).	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). ***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	*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 43

Proposal for a regulation
Article 15 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	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	***deleted***

competent authority of that Member State (hereinafter referred to as 'the receiving competent authority').

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 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	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;

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	*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 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:	1. A biocidal product shall be considered a low-risk biocidal product if ***at least one of*** the following conditions ***is*** 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;***	(a) ***the biocidal product is not classified for human health or environmental hazards under Regulation (EC) No 1272/2008;***
(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 than 1,000.***	(b) ***the classification of the biocidal product is not associated with the signal word 'danger' on the label required under 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.
However, a biocidal product shall not be considered a low-risk biocidal product if ***at least one of the following conditions is present***:	***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) ***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) ***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) ***it contains one or more active substances qualified*** as endocrine disrupters;	(b) ***is identified*** as endocrine disrupters ***under Article 57(f) of Regulation (EC) No 1907/2006***;
(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) ***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;	(i) carcinogenic;
(ii) mutagenic;	(ii) mutagenic;
(iii) neurotoxic;	(iii) neurotoxic;
(iv) immunotoxic;	(iv) immunotoxic;
(v) toxic to reproduction;	(v) toxic to reproduction;
(vi) sensitising.	(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	*Amendment*
1. The applicant for ***an*** authorisation shall submit the following documents together with the application:	1. The applicant for ***a primary*** authorisation shall submit the following documents together with the application:

Amendment 54

Proposal for a regulation
Article 18 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The application for authorisation shall be accompanied by the fees payable under Article 70.	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	*Amendment*
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.	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	*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 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	*Amendment*
g) manufacturers of the active substances (names and addresses including location of manufacturing sites);	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	*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 60

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 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:	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, ***another authorised biocidal product or a non-chemical control or prevention***	(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;	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 ***product or non-chemical control or prevention method*** referred to in point (a) ***does*** not present significant economic or practical disadvantages;	(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.	(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	*Amendment*
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.***	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	*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 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	*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 ***eighteen*** months before the expiry date of the authorisation.	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	*Amendment*
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.	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	*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).	***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 time 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	*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).	***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	*Amendment*
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***.	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	*Amendment*
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.	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 ***the following categories*** of biocidal products:	The Community authorisation may be granted to ***any category*** of biocidal products.
(a) biocidal products containing one or more new active substances;	
(b) low-risk biocidal products.	
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.	
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).	

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	*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 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	*Amendment*
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	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	*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 ***twelve*** months after the validation, prepare and submit to the Agency a recommendation on the renewal of the authorisation.	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	*Amendment*
The competent authority that has granted ***the national*** authorisation ***or in case of Community authorisation, the Commission,*** shall cancel the authorisation at the request of its holder, who shall state the reasons for such request. If such a request concerns a Community authorisation, it shall be submitted to the Agency.	The competent authority that has granted ***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	*Amendment*
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.	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	*Amendment*
3. A biocidal product shall be considered as ***substantially*** identical to the reference product if ***one of*** the following conditions ***is*** met:	3. A biocidal product shall be considered as identical to the reference product if ***all*** the following conditions ***are*** met:
a) ***the source of the active substances it contains is the same in terms of manufacturer and location of the production plant***;	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 ***either*** the same ***or similar*** with regard to the ***non-active*** substances present and the type of formulation;	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 in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.	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	*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 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.	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, 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 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.
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 102

Proposal for a regulation
Article 46 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
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 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	*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 ***obtain 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

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	*Amendment*
2. Treated articles or materials shall be labelled with the following information:	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;	(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 ***or materials***;	(b) where relevant, the biocidal property attributed to treated articles;
(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.	***(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	*Amendment*
The labelling shall be clearly visible, easily legible ***and*** appropriately durable***.***	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	*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 communicate the name and contact details of the owner of the information to the prospective applicant.	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	*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	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	*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 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	*Amendment*
2. Disclosure of the following information shall be deemed to undermine the	2. Disclosure of the following information shall be deemed to undermine the

protection of the commercial interests of the concerned person:	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;	a) details of the full composition of a biocidal product;
b) the precise use, function or application of a substance or mixture;	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;	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.	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	*Amendment*
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	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	*Amendment*
3. Member States ***may*** require that biocidal products placed on the market of their territories are labelled in their national language or languages.	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	*Amendment*
(d) providing advice and assistance to applicants for the inclusion of an active substance in Annex I or for a Community authorisation;	(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	*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 ***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	*Amendment*
(d) an annual fee shall be paid by persons placing biocidal products on the market; and	(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. The 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, adjutants, 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	+: 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 Ţicău, Lambert van Nistelrooij, Hermann Winkler