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Committee on the Environment, Public Health and Food Safety

2009/0076(COD)

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AMENDMENTS
102 - 230

Draft recommendation for second reading
Christa Klaß
(PE467.347v01-00)

The placing on the market and use of biocidal products

Council position at first reading
(05032/2/2011 – C7-0333/2010 – 2009/0076(COD))

AM_Com_LegRecomm

Amendment 102
Julie Girling

Council position
Recital 9

Council position	*Amendment*
(9) This Regulation should apply to biocidal products that, in the form in which they are supplied to the user, consist of, contain or generate one or more active substances***. It therefore should not apply to devices within industrial plants that generate biocidal products in situ***.	(9) This Regulation should apply to biocidal products that, in the form in which they are supplied to the user, consist of, contain or generate one or more active substances.

Or. en

Justification

In line with the definition of a biocidal product, the Regulation should apply to in-situ generation of biocidal products, whether generated by mixing chemical precursors or by other means such as electrolysis. Fumigation is a hazardous activity in which biocidal products are often generated in situ. Deletion of the second sentence in Recital 9 also removes the implication that biocides used for fumigation in industrial plants are outside scope.

Amendment 103
Dan Jørgensen

Council position
Recital 9

Council position	*Amendment*
(9) This Regulation should apply to biocidal products that, in the form in which they are supplied to the user, consist of, contain or ***generate*** one or more active substances***. It therefore should not apply to devices within industrial plants that generate biocidal products in situ***.	(9) This Regulation should apply to biocidal products that, in the form in which they are supplied to the user, consist of, ***or*** contain ***one*** or ***more active substances or precursors for*** one or more active substances.

Or. en

Justification

It should be clear that the physical devices / equipment generating an active substance in situ in itself is not included in the scope of this Regulation. If the present text is maintained all the machines/devices that are not within an industrial plant are defined as biocidal products and therefore have to be evaluated for any harmful effects on human or animal health or unacceptable effects or the environment.

Amendment 104
Michèle Rivasi

Council position
Recital 13

Council position	*Amendment*
(13) The active substances in the Union list should be regularly examined to take account of developments in science and technology. Where there are ***serious*** indications that an active substance used in biocidal products or treated articles does not meet the requirements of this Regulation, the Commission should be able to review the approval of the active substance.	(13) The active substances in the Union list should be regularly examined to take account of developments in science and technology. Where there are ***significant*** indications that an active substance used in biocidal products or treated articles does not meet the requirements of this Regulation, the Commission should be able to review the approval of the active substance.

Or. en

(To be coherent with parts of amendment 74 from first reading.)

Justification

The Commission should review the approval of an active substance as soon as there are significant indications of non-compliance, not only when there are serious indications.

Amendment 105
Christa Klaß

Council position
Recital 21

Council position	*Amendment*
(21) Processing aids are covered by	(21) Processing aids are covered by

existing Union legislation, in particular Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition and Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. Therefore, it is appropriate to exclude them from the scope of this Regulation.

existing Union legislation, in particular Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition and Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. ***Wine processing products are covered by Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions[1].*** Therefore, it is appropriate to exclude them from the scope of this Regulation.

_____

[1] OJ. L 193, 24.7.2009, p. 1.

Or. de

Justification

Products for wine processing as referred to in Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions should be excluded from the scope of the regulation by analogy with processing aids.

Amendment 106
Dan Jørgensen

Council position
Recital 28

Council position	*Amendment*
(28) To encourage the use of products with a more favourable environmental or human health profile, it is appropriate to provide for simplified authorisation procedures for such biocidal products***. Once authorised in at least one Member State, those products***	(28) To encourage the use of products with a more favourable environmental or human health profile, it is appropriate to provide for simplified authorisation procedures for such biocidal products.

should be allowed to be made available on the market in all Member States without the need for mutual recognition, under certain conditions.

Or. en

Justification

We do not support that a national authorisation granted in accordance with Chapter IVA – the simplified authorisation procedure – can be placed on the market in all Member States without the need for mutual recognition. Instead we suggest that products authorised under the simplified procedure should have a Union authorisation with a lower fee.

Amendment 107
Jolanta Emilia Hibner, Bogusław Sonik

Council position
Recital 29

Council position	*Amendment*
(29) To identify biocidal products which are eligible for simplified authorisation procedures, it is appropriate to establish a specific list of the active substances that those products may contain. That list should, initially, contain substances identified as presenting a low risk under Regulation (EC) No 1907/2006 or Directive 98/8/EC, substances identified as food additives, pheromones and other substances considered to have low toxicity, such as weak acids, alcohols and vegetable oils used in cosmetics and food.	(29) To identify biocidal products which are eligible for simplified authorisation procedures, it is appropriate to establish a specific list of the active substances that those products may contain. That list should, initially, contain substances identified as presenting a low risk under Regulation (EC) No 1907/2006 or Directive 98/8/EC, substances identified as food additives, pheromones and other substances considered to have low toxicity, such as weak acids, alcohols***, aversive agents*** and vegetable oils used in cosmetics and food.

Or. en

Justification

Referring to Recital 29 of the Regulation, there is no category that can include denatonium benzoate. Therefore, we propose to add one more group 'aversive agents'. It is a narrow group of substances used in cosmetics in very low concentrations, in which are not harmful to human and the environment.

Amendment 108
Rolandas Paksas

Council position
Recital 52

Council position	*Amendment*
(52) To enable consumers to make informed choices, to facilitate enforcement and to provide an overview of their use, treated articles should be appropriately labelled.	(52) To enable consumers to make informed choices, to facilitate enforcement and to provide an overview of their use, treated articles should be appropriately labelled. ***Detailed labelling should take place only where it is useful to the consumer. All known information should be kept in databanks and on the internet and made available to consumers, particularly when they need to call on the aid of professionals (e.g. poison centres, doctors etc.)***

Or. lt

Amendment 109
Rolandas Paksas

Council position
Recital 62

Council position	*Amendment*
(62) The costs of the procedures associated with the operation of this Regulation need to be recovered from those making biocidal products available on the market and those seeking to do so in addition to those supporting the approval of active substances. To promote the smooth operation of the internal market, it is appropriate to establish certain common principles applicable both to fees payable to the Agency and to Member States' competent authorities, including the need to take into account, as appropriate, the specific needs of SMEs.	(62) The costs of the procedures associated with the operation of this Regulation need to be recovered from those making biocidal products available on the market and those seeking to do so in addition to those supporting the approval of active substances. To promote the smooth operation of the internal market, it is appropriate to establish certain common principles applicable both to fees payable to the Agency and to Member States' competent authorities, including the need to take into account, as appropriate, the specific needs of SMEs. ***In particular, fees should be as transparent as possible and***

	should reflect the various steps and procedures needing to be taken in the course of the assessment. They should also be proportionate to the amount of work required and should only be levied where necessary.

Or. lt

Amendment 110
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 1 – paragraph 1

Council position	*Amendment*
1. The purpose of this Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products***, whilst ensuring a high level of protection of both human and animal health and the environment***. The provisions of this Regulation are underpinned by the precautionary principle, ***the aim of which is*** to ***safeguard*** the ***health of*** humans, ***animals*** and the environment.	1. The purpose of this Regulation is to ***ensure a high level of protection of both human and animal health and the environment and to*** improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products. The provisions of this Regulation are underpinned by the precautionary principle, ***in order*** to ***ensure that active substances or products placed on*** the ***market do not have harmful effects on*** humans, ***non-target species*** and the environment. ***Special attention shall be paid to protecting children, pregnant women and the sick.***

Or. en

(Reinstatement of amendment 341 from first reading.)

Justification

It should be clear that the purpose of protecting both human and animal health and the environment is at an equal level as the purpose of the functioning of the internal market, and not just an ancillary purpose.

Amendment 111
Nessa Childers

Council position
Article 2 – paragraph 2 – introductory part

Council position	*Amendment*
2. ***Subject to any explicit provision to the contrary in this*** Regulation ***or other Union legislation, this Regulation*** shall not apply to biocidal products or treated articles that are within the scope of the following instruments:	2. ***This*** Regulation shall not apply to ***those functions of*** biocidal products or treated articles that are within the scope of the following instruments ***for the purposes of these instruments***:

Or. en

Amendment 112
Françoise Grossetête

Council position
Article 2 – paragraph 2 – point j a (new)

Council position	*Amendment*
	j (a) 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.

Or. fr

Justification

Materials and articles intended to come into contact with food, including any biocidal products linked to such materials, are already covered by Regulation (EC) No 1935/2004. In order to avoid duplication of assessment and legislation, and to avoid legal uncertainty concerning the interaction of two assessment systems, materials and articles intended to come into contact with food should be excluded from the scope of the regulation. Regulation (EC) No 1935/2004 guarantees a sufficient level of safety and, where there is a need to amend the rules governing materials and articles intended to come into contact with food, such amendments should be made by means of a revision of Regulation (EC) No 1935/2004, and

not by extending the scope of this regulation on biocidal products.

Amendment 113
Julie Girling

Council position
Article 2 – paragraph 2 – point j a (new)

Council position	*Amendment*
	(j a) 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.

Or. en

Justification

Food contact materials are already regulated by Regulation 1935/2004, including biocides. In order to avoid dual assessments and double legislation, as well as assuring legal certainty, food contact materials should be excluded from the scope of this regulation. Regulation 1935/2004 provides a sufficient level of safety, and should any changes be required to the rules governing food contact materials, these should be addressed through revision of Regulation 1935/2004, and not by extending the scope of the biocidal products regulation.

Amendment 114
Michèle Rivasi

Council position
Article 2 – paragraph 2 – subparagraph 2

Council position	*Amendment*
Notwithstanding point (i), this Regulation shall apply to biocidal products that are intended to be used both as biocidal products and plant protection products.	***deleted***

Or. en

Justification

New text from Council. There is a separate regulation for plant protection products. This regulation cannot replace it, otherwise there risks to be double standards in light of the slightly diverging provisions of the two regulations.

Amendment 115
Nessa Childers

Council position
Article 2 – paragraph 2 – subparagraph 2

Council position	*Amendment*
Notwithstanding point (i), this Regulation shall apply to biocidal products that are ***intended*** to be used both as biocidal ***products*** and ***plant protection products***.	Notwithstanding point (i), this Regulation shall apply to biocidal products that are to be used both as biocidal ***product*** and ***for a purpose within the scope of one of these instruments***.

Or. en

Amendment 116
Christa Klaß

Council position
Article 2 – paragraph 5 – point b

Council position	*Amendment*
(b) processing aids that are used as biocidal products.	b) processing aids ***and wine processing products*** that are used as biocidal products.

Or. de

Justification

Products for wine processing as referred to in Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions should be excluded from the scope of the regulation by analogy with processing aids.

Amendment 117
Horst Schnellhardt

Council position
Article 2 – paragraph 8

Council position	*Amendment*
(8) Member States may allow for exemptions from this Regulation in specific cases for certain biocidal products, on their own or in a treated article, where necessary in the interests of defence.	(8) Member States may allow for exemptions from this Regulation in specific cases for certain biocidal products, on their own or in a treated article, where necessary in the interests of defence ***or of animal disease control***.

Or. de

Justification

To secure effective animal disease control in the event of an outbreak or suspected outbreak of an animal disease it is crucial to have substances to combat the pathogen, which may in some cases also be dangerous to humans, available quickly and in sufficient quantities. Crisis planning documents list substances particularly suited to this purpose, such as caustic lime, sodium hydroxide, formaldehyde and various organic acids, which have proved their value over many decades in combating animal diseases.

Amendment 118
Miroslav Ouzký

Council position
Article 3 – paragraph 1 – point a

Council position	*Amendment*
(a) 'biocidal product' means any substance, mixture or article, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the ***primary*** intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action;	(a) 'biocidal product' means any substance, mixture or article, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention, ***except in the case of articles, where primary intention is required,*** of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action;

Or. en

Justification

While 'primary' is relevant for articles because of the large variety of items having multiple functions, in the case of substances and mixtures, it is appropriate to delete the word 'primary'. The wording 'primary intention' could introduce a loophole for certain types of applications, such as cleaning, disinfecting, etc.

Amendment 119
Kathleen Van Brempt

Council position
Article 3 – paragraph 1 – point a

Council position	*Amendment*
(a) 'biocidal product' means any substance, mixture or article, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the ***primary*** intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action;	(a) 'biocidal product' means any substance, mixture or article, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action; ***A treated article that has a primary biocidal function shall be considered as a biocidal product.***

Or. en

Justification

The reference to 'primary intention' for all biocidal products could introduce a loophole for certain types of applications, in the sense that a number of products would fall outside the scope of the regulation. For example, a disinfecting product could be interpreted as having primarily a cleaning action, and only secondarily a disinfecting one. Splitting the definition into two parts avoids to extend the tension between 'primary – secondary function' to all biocidal products and limits it to treated articles.

Amendment 120
Dan Jørgensen

Council position
Article 3 – paragraph 1 – point a

Council position	*Amendment*
(a) ***'***biocidal ***product'*** means ***any substance***, ***mixture*** or ***article***, in the form in which ***it is*** supplied to the user, consisting of, containing or ***generating*** one or more active substances, with the ***primary*** intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action;	(a) ***'***biocidal ***products'*** means ***substances***, ***mixtures*** or ***articles***, in the form in which ***they are*** supplied to the user, consisting of, containing or ***being the precursor for*** one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action;

Or. en

Justification

We find that all treated materials and articles that emit a biocide in order to control harmful organisms in their surroundings shall still be considered biocidal products.

Amendment 121
Michèle Rivasi

Council position
Article 3 – paragraph 1 – point (f) – subparagraph 2 – indent 1

Council position	*Amendment*
– a substance classified as dangerous according to Directive 67/548/EEC, and present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, or	– a substance classified as dangerous ***or meeting the criteria to be classified as dangerous*** according to Directive 67/548/EEC, and present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, or

Or. en

(Reinstatement of the Commission text.)

Justification

Where there is no harmonised classification, companies have to classify their substances themselves. It is therefore important to also refer to "meeting the criteria for classification", and not just to the actual classification. This is the standard approach and had also been followed by the Commission in its proposal.

Amendment 122
Michèle Rivasi

Council position
Article 3 – paragraph 1 – point (f) – subparagraph 2 – indent 2

Council position	*Amendment*
– a substance classified as hazardous according to Regulation (EC) No 1272/2008, and present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation;	– a substance classified as hazardous ***or meeting the criteria for classification as hazardous*** according to Regulation (EC) No 1272/2008, and present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation;

Or. en

(Reinstatement of the Commission text.)

Justification

Where there is no harmonised classification, companies have to classify their substances themselves. It is therefore important to also refer to "meeting the criteria for classification", and not just to the actual classification. This is the standard approach and had also been followed by the Commission in its proposal.

Amendment 123
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 3 – paragraph 1 – point (f) - subparagraph 2 – indent 2 a (new)

Council position	*Amendment*
	- a substance which fulfils the criteria for

being a POP under Regulation (EC) No 850/2004, or which 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;

Or. en

(Reinstatement of amendment 99 from first reading.)

Justification

Non-active substances that are a POP, PBT or vPvB should be considered a substance of concern.

Amendment 124
Dan Jørgensen

Council position
Article 3 – paragraph 1 – point s

Council position	*Amendment*
(s) 'biocidal product family' means a group of biocidal products having similar uses, the active substances of which have the same specifications**,** and presenting specified variations in their composition which do not adversely affect the level of risk or significantly reduce the efficacy of the products;	(s) 'biocidal product family' means a group of biocidal products having similar uses, the active substances of which have the same specifications ***or a change in the quantities of one or more of the non-active substances*** and presenting specified variations in their composition which do not adversely affect the level of risk or significantly reduce the efficacy of the products;

Or. en

Justification

The change of the definition is made in order to bring it in accordance with Article 20(2)(e) and to underline that also the non-active substances should be evaluated and specified in a product family. With the wording in the Council common position an applicant can change any non active substance in a formulation and this might result in a significant higher risk to human health and the environment. If e.g. a change in the composition of a fixative in a wood preservative is made then this might result in a higher leaching rate of the active substances

from the treated wood to the environment and therefore result in a higher environmental risk.

Amendment 125
Pilar Ayuso, Andres Perello Rodriguez, Cristina Gutiérrez-Cortines

Council position
Article 3 – paragraph 1 – point aa

Council position	*Amendment*
(aa) 'nanomaterial' means nanomaterial as defined in Commission Recommendation 20../…/EC of … … … concerning the definition of nanomaterials;	(aa) 'nanomaterial' means nanomaterial as defined in Commission Recommendation 20../…/EC of … … … concerning the definition of nanomaterials; ***The Commission shall regularly review and update the definition in light of latest advances in technical and scientific development.***

Or. en

Justification

In light of the many on-going researches and developments in the area of nanotechnology, the definition will need to be regularly reviewed to encompass latest EU and International scientific experience and acquired knowledge.

Amendment 126
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 3 – paragraph 1 – point aa

Council position	*Amendment*
(aa) **'**nanomaterial**'** means ***nanomaterial as defined in*** Commission Recommendation 20../…/EC of … … ***…*** concerning the definition of nanomaterials***;***	(aa) ***"***nanomaterial***"*** means ***any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above***

the order of 100 nm but retain properties that are characteristic of the nanoscale. Properties that are characteristic of the nanoscale include:

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

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

No later than six months after the adoption of Recommendation 20../…/EC of … … concerning the definition of nanomaterials ***, the Commission shall make a legislative proposal to include the definition in this Regulation.***

Or. en

(Partial reinstatement of amendment 34 of first reading.)

Justification

The definition of nanomaterials is an essential element of the regulation and thus needs to be adopted by the legislator. The discussions over the definition have been highly controversial within the Commission and the outcome is unclear. It is thus inappropriate to give the Commission a "carte blanche" for whatever definition they come up with.

Amendment 127
Julie Girling

Council position
Article 3 – paragraph 1 – point ad

Council position	*Amendment*
(ad) 'major change' means an amendment of an existing authorisation ***which is neither an administrative change nor*** a ***minor change***;	(ad) 'major change' means an amendment of an existing authorisation ***requiring*** a ***full or substantial re-evaluation of the risk assessment of the biocidal product or biocidal product family***;

Or. en

Justification

The Council text is inexact, it is important to define "major change" more precisely.

Amendment 128
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 4 – paragraph 1

Council position	*Amendment*
1. An active substance shall be ***approved*** for an initial period not exceeding 10 years if at least one biocidal product containing that active substance ***may be expected to meet*** the ***criteria*** laid down in point (b) of Article 18(1) taking into account the factors set out in Article 18(2) and (5).	1. An active substance shall be ***included in Annex -I*** for an initial period not exceeding 10 years if at least one biocidal product containing that active substance ***fulfils*** the ***conditions*** laid down in point (b) of Article 18(1) taking into account the factors set out in Article 18(2) and (5). ***An active substance referred to in Article 5 may only be included in Annex I for an initial period of 5 years.*** *(Note: This amendment applies throughout the text. If adopted, reference to "approval of an active substance" is to be replaced by reference to "inclusion of an active substance in Annex -I", reference to "approval" by "inclusion in Annex -I", reference to "approved" by "included in Annex -I" etc. throughout the text.)*

Or. en

(Reinstatement of amendment 39 from first reading.)

Justification

Active substances should continue to be included in an Annex to the Regulation. The approach proposed by Council would deprive Parliament of its control rights, which is not acceptable. Moreover, it is inconsistent with the analogous provision in Article 27 for the inclusion of active substances under the simplified procedure, which would continue to be adopted by way of delegated acts. Active substances that fall under Article 5 should have a shorter period for the inclusion in Annex I.

Amendment 129
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 5 – paragraph 1 – point d

Council position	*Amendment*
(d) active substances identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties***;***	(d) active substances ***which, on the basis of the assessment of Union or internationally agreed test guidelines or other peer-reviewed scientific data and information, including a review of the scientific literature, reviewed by the Agency, are considered as having endocrine-disrupting properties that may cause adverse effect in humans, or which are*** identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties***.***

Or. en

(Reinstatement of part of amendment 44 from first reading.)

Justification

It is not sufficient to refer to the candidate list of REACH to determine endocrine disrupters, as this is not a comprehensive scientific process, but one led by political priorities. So far, only one substance has been proposed to be identified pursuant to Art. 57(f). Endocrine disrupters should also be those that are identified on the basis of agreed test guidelines or other available information reviewed by the Agency in line with the provisions of the PPP regulation (Annex II, point 3.6.5).

Amendment 130
Cristian Silviu Buşoi

Council position
Article 5 – paragraph 2 – subparagraph 1 – introductory part

Council position	*Amendment*
Without prejudice to Article 4(1), active substances referred to in paragraph 1 ***of this Article*** may be ***approved*** if ***it is shown***	***The*** active substances referred to in paragraph 1 may be ***included in Annex I only*** if at least one of the following

that at least one of the following conditions is met:	conditions is met:

Or. en

Justification

The amendment reinstates the Parliament's position in first reading and provides for more clarity. Risk mitigation measures are needed in order to protect human health, as well as the environment.

Amendment 131
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 5 – paragraph 2 – subparagraph 1 – point a

Council position	*Amendment*
(a) the risk to humans or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, ***in particular where*** the product is used in closed systems or ***strictly controlled*** conditions;	(a) the risk to humans or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, ***meaning that*** the product is used in closed systems or ***under other*** conditions ***excluding contact with humans***;

Or. en

(Reinstatement of part of amendment 44 from first reading.)

Justification

The term "negligible exposure" should be clearly defined to avoid any loopholes. The wording chosen here comes from the PPP regulation (Annex II, point 3.6.3).

Amendment 132
Cristian Silviu Buşoi

Council position
Article 5 – paragraph 2 – subparagraph 1 – point a

Council position	*Amendment*
(a) the ***risk to*** humans or the environment	(a) the ***exposure of*** humans or ***to*** the

from exposure to the active substance in a biocidal product, under ***realistic worst case*** conditions of use, is negligible, ***in particular where*** the product is used in closed systems or ***strictly controlled*** conditions;	environment to the active substance in ***question in*** a biocidal product, under ***normal*** conditions of use, is negligible, ***meaning that*** the product is used in closed systems or ***under other*** conditions ***excluding contact with humans***;

Or. en

Justification

The amendment reinstates the Parliament's position in first reading and provides for more clarity. Risk mitigation measures are needed in order to protect human health, as well as the environment.

Amendment 133
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 5 – paragraph 2 – subparagraph 1 – point b

Council position	*Amendment*
(b) the active substance is ***essential*** to prevent or ***to*** control a serious danger to public or animal health or the environment***;*** or	(b) ***it is shown by evidence that*** the active substance is ***necessary*** to prevent or control a serious danger to public or animal health or ***to*** the environment***, to food and feed safety,*** or ***to the public interest and that there are no effective alternative substances or technologies available.*** ***The use of any biocidal product containing active substances included in Annex I pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment is minimised.*** ***Member State authorising a biocidal product containing an active substance included in Annex I pursuant to this paragraph shall draw up a substitution plan concerning the control of the serious danger by other means including non-chemical methods, which are as effective as the biocidal product concerned and***

shall without delay transmit that plan to the Commission. The use of the biocidal product with the active substance concerned shall be restricted to those Member States where the serious danger has to be prevented or, if it occurs, controlled.

Or. en

(Reinstatement of part of amendment 44 from first reading. Linked to the amendment deleting Article 5(2)(c) and the last subparagraph - should be voted together.)

Justification

The Council wording only suggests taking the availability of alternatives "into account". This is far too vague. It is unacceptable to grant a derogation for an active substance that should normally be excluded from approval, when safer alternatives are available. Any such derogation should be subject to a number of conditions: risk mitigation, minimisation of exposure, substitution plan, and limitation of the use of the biocidal product to the Member State where the serious danger is.

Amendment 134
Cristian Silviu Buşoi

Council position
Article 5 – paragraph 2 – subparagraph 1 – point b

Council position	*Amendment*
(b) the active substance is ***essential*** to prevent or ***to*** control a serious danger to public or animal health or the environment***;*** or	(b) ***it is shown by evidence that*** the active substance is ***necessary*** to prevent or control a serious danger to public or animal health or ***to*** the environment***, to food and feed safety,*** or ***to the public interest and that there are no effective alternative substances or technologies available.*** ***The use of any biocidal product containing active substances included in Annex I pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment is minimised.***

Or. en

Justification

The amendment reinstates the Parliament's position in first reading and provides for more clarity. Risk mitigation measures are needed in order to protect human health, as well as the environment.

Amendment 135
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 5 – paragraph 2 – subparagraph 1 – point c

Council position	*Amendment*
(c) not approving the active substance would cause disproportionate negative impacts for society when compared with the risk to human health or the environment arising from the use of the substance.	***deleted***

Or. en

(Partial reinstatement of amendment 44 of first reading. Linked to the new amendment on Article 5(2)(b))

Justification

This clause is no longer necessary if the amendment to Article 5(2)(aa) is adopted. There should always be an assessment whether there is no safer alternative available.

Amendment 136
Cristian Silviu Buşoi

Council position
Article 5 – paragraph 2 – subparagraph 1 – point c

Council position	*Amendment*
(c) not approving the active substance would cause disproportionate negative impacts for society when compared with the risk to human health or the environment arising from the use of the	***deleted***

substance.

Or. en

Justification

The amendment reinstates the Parliament's position in first reading and provides for more clarity. Risk mitigation measures are needed in order to protect human health, as well as the environment.

Amendment 137
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 5 – paragraph 2 – subparagraph 2

Council position	*Amendment*
When deciding whether an active substance may be approved in accordance with the first subparagraph, the availability of suitable and sufficient alternative substances or technologies shall also be taken into account.	***deleted***

Or. en

(Partial reinstatement of amendment 44 of first reading. Linked to the new amendment on Article 5(2)(b).)

Justification

The Council wording only suggests to take the availability of alternatives "into account". This is far too vague, and could still allow a derogation for an active substance that should normally be excluded from approval despite the availability of safer alternatives.

Amendment 138
Françoise Grossetête

Council position
Article 5 – paragraph 3 – subparagraph 1

Council position	*Amendment*
The Commission shall ***be empowered to***	***No later than 31 December 2013,*** the

adopt delegated acts in accordance with Article 82 specifying scientific criteria for the determination of endocrine disrupting properties.	Commission shall adopt delegated acts in accordance with Article 82 specifying scientific criteria for the determination of endocrine disrupting properties.

Or. fr

Justification

The date by which the Commission is to adopt scientific criteria for the determination of endocrine disrupting properties should be specified.

Amendment 139
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 5 – paragraph 3 – subparagraph 1

Council position	*Amendment*
The Commission shall ***be empowered to*** adopt delegated acts in accordance with Article 82 ***specifying*** scientific criteria for the determination of endocrine disrupting properties.	***No later than 13 December 2013, the*** Commission shall adopt delegated acts in accordance with Article 82 ***specific*** scientific criteria for the determination of endocrine disrupting properties.

Or. en

(Partial reinstatement of amendment 44 of first reading.)

Justification

The Commission should not merely be empowered to adopt scientific criteria for endocrine disrupters, but actually be obliged to do so. There should be a clear deadline for the Commission to do so.

Amendment 140
Cristian Silviu Buşoi

Council position
Article 5 – paragraph 3 – subparagraph 1

Council position	*Amendment*
The Commission shall ***be empowered to*** adopt delegated acts in accordance with Article 82 specifying scientific criteria for	***No later than 13 December 2013, the*** Commission shall adopt delegated acts in accordance with Article 82 specifying

the determination of endocrine disrupting properties.	scientific criteria for the determination of endocrine disrupting properties.

Or. en

Justification

While it is important to establish at EU level criteria for the determination of endocrine disrupting properties, the introduction of an interim definition may cause uncertainty and confusion. It can lead to the exclusion of an active substance which could eventually be approved according to the final criteria adopted by the Commission. It is also needed to fix an appropriate deadline for the development of such criteria. The proposed date is in accordance with Regulation 1107/2009.

Amendment 141
Cristian Silviu Buşoi

Council position
Article 5 – paragraph 3 – subparagraph 2

Council position	*Amendment*
Pending the adoption of those criteria, active substances that are classified in accordance with the provisions of Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as, carcinogen category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties.	***deleted***

Or. en

Justification

While it is important to establish at EU level criteria for the determination of endocrine disrupting properties, the introduction of an interim definition may cause uncertainty and confusion. It can lead to the exclusion of an active substance which could eventually be approved according to the final criteria adopted by the Commission. It is also needed to fix an appropriate deadline for the development of such criteria. The proposed date is in accordance with Regulation 1107/2009.

Amendment 142
Cristian Silviu Buşoi

Council position
Article 5 – paragraph 3 – subparagraph 3

Council position	*Amendment*
Substances such as those that are classified in accordance with the provisions of Regulation (EC) No 1272/2008 as, or that meet the criteria to be classified as, toxic for reproduction category 2 and that have toxic effects on the endocrine organs, may be considered as having endocrine-disrupting properties.	***deleted***

Or. en

Justification

While it is important to establish at EU level criteria for the determination of endocrine disrupting properties, the introduction of an interim definition may cause uncertainty and confusion. It can lead to the exclusion of an active substance which could eventually be approved according to the final criteria adopted by the Commission. It is also needed to fix an appropriate deadline for the development of such criteria. The proposed date is in accordance with Regulation 1107/2009.

Amendment 143
Michèle Rivasi

Council position
Article 6 – paragraph 2 – subparagraph 1 – point a

Council position	*Amendment*
(a) the data are not necessary ***owing to the*** exposure associated with the proposed uses;	(a) the data are not necessary ***as all relevant*** exposure associated with the proposed uses ***can be ruled out***;

Or. en

(Reinstatement of amendment 47 of first reading.)

Justification

The Council wording is ambiguous. Such data waiving should only occur if all relevant exposure ban be ruled out.

Amendment 144
Rovana Plumb

Council position
Article 7 – paragraph 2 – subparagraph 3

Council position	*Amendment*
Upon receipt of the fees payable under Article 79(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the exact date of the acceptance of the application and its unique identification code.	Upon receipt of the fees payable under Article 79(1) ***and (2)***, the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the exact date of the acceptance of the application and its unique identification code.

Or. ro

Justification

The Council text fails to take account of the fact that Article 79 has been modified so as to subdivide the fees into agency fees and evaluating authority fees. The aim of this amendment is to ensure a more consistent and coherent text.

Amendment 145
Rovana Plumb

Council position
Article 7 – paragraph 3 – subparagraph 2 a (new)

Council position	*Amendment*
	As soon as possible after the agency has accepted an application, the evaluating competent authority shall inform the applicant of the fees payable under Article 79(2). It shall reject the application if the applicant fails to pay the fees within 60 days.

Or. ro

Justification

The aim of this amendment is to clarify the text and ensure greater consistency (both within the text itself and with other legislative acts).

Amendment 146
Rovana Plumb

Council position
Article 7 – paragraph 4 – subparagraph 3

Council position	*Amendment*
The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Agency accordingly. In such cases, part of the fee paid in accordance with Article 79 shall be reimbursed.	The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Agency accordingly. In such cases, part of the fee paid in accordance with Article 79***(1) and (2)*** shall be reimbursed.

Or. ro

Justification

The aim of this amendment is to clarify the text and ensure greater consistency (both within the text itself and with other legislative acts).

Amendment 147
Daciana Octavia Sârbu, Claudiu Ciprian Tănăsescu

Council position
Article 8 – paragraph 2

Council position	*Amendment*
2. Where 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	2. Where 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 accordingly. As specified in the second subparagraph of Article 6(2), the evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to permit a determination of whether an active substance meets the criteria referred to in Article 5(1) or 10(1). The 365-day period referred to in paragraph 1 of this Article shall be suspended from the date of issue of the request until the date the information is received. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances.

limit, and shall inform the Agency accordingly. ***Where such additional information includes animal testing, the applicant shall be advised by experts from the Agency or competent authorities regarding suitable alternative methods and testing strategies to replace, reduce or refine the use of vertebrate animals.*** As specified in the second subparagraph of Article 6(2), the evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to permit a determination of whether an active substance meets the criteria referred to in Article 5(1) or 10(1). The 365-day period referred to in paragraph 1 of this Article shall be suspended from the date of issue of the request until the date the information is received. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances.

Or. en

Amendment 148
Michèle Rivasi

Council position
Article 8 – paragraph 3

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

of its conclusions.

Or. en

(Reinstatement of amendment 57 from first reading.)

Justification

Cumulative effects to be considered should not be limited to the use of products with the same active substance, but also include products with other substances with similar effects.

Amendment 149
Michèle Rivasi

Council position
Article 9 – paragraph 1

Council position	*Amendment*
1. The Commission shall, on receipt of the opinion of the Agency referred to in Article 8(4), ***either:***	1. The Commission shall, on receipt of the opinion of the Agency referred to in Article 8(4), ***adopt, by means of delegated acts in accordance with Article 82, a decision on the inclusion of the active substance in Annex -I, including the conditions of the inclusion, the dates of inclusion and of expiry of inclusion, or on the non-inclusion of the active substance in Annex I.***
(a) adopt an implementing Regulation providing that an active substance is approved, and under which conditions, including the dates of approval and of expiry of the approval; or	
(b) n cases where the requirements of Article 4(1) or, where applicable, Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, adopt an implementing decision that an active substance is not approved.	
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).	

Or. en

Justification

Amendment of new text by Council, adding certain elements to am 17 by the rapporteur. The approval of active substances should be done by delegated act to ensure the control rights of Parliament. It should include the conditions and relevant dates of inclusion and expiry of inclusion. There should also be a decision in its own right if a substance is not included in Annex -I to have a record of all decisions.

Amendment 150
Michèle Rivasi

Council position
Article 10 – paragraph 1 – point a a (new)

Council position	*Amendment*
	(a a) it meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser;

Or. en

(Reinstatement of amendment 65 of first reading.)

Justification

Active substances that are respiratory sensitisers should also be candidates for substitution.

Amendment 151
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 10 – paragraph 1 – point c a (new)

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

Or. en

(Reinstatement of the text of the Commission proposal.)

Justification

This is a fall-back amendment to the amendment by the same authors to Article 5(1)(d). If a comprehensive definition of endocrine disrupters is adopted in that Article, the content of this amendment is covered by the reference to Art. 5(1) in Art. 10(1)(a). If endocrine disrupters are not properly covered under the exclusion criteria, they should be so at least as candidates for substitution.

Amendment 152
Corinne Lepage

Council position
Article 10 – paragraph 1 – point d

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

Or. en

Justification

Reinstatement of first reading.

Amendment 153
Michèle Rivasi

Council position
Article 10 – paragraph 1 – point d

Council position	*Amendment*
(d) there are reasons for concern linked to	(d) there are reasons for concern linked to

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

Or. en

(Reinstatement of the text of the Commission proposal.)

Justification

Developmental neurotoxic or immunotoxic effects should be highlighted specifically, in line with the regulation on plant protection products.

Amendment 154
Holger Krahmer

Council position
Article 10 – paragraph 1 – point e

Council position	*Amendment*
(e) it contains a significant proportion of non-active isomers or impurities.	***deleted***

Or. en

Justification

The level of non-active isomers or impurities is not directly related to the hazard or risk of the active substance, but rather depends on the manufacturing process. Therefore, it should not be part of the substitution criteria. Reinstating first reading Amendment 64.

Amendment 155
Andres Perello Rodriguez, Pilar Ayuso, Cristina Gutiérrez-Cortines

Council position
Article 10 – paragraph 3

Council position	*Amendment*
3. Prior to submitting its opinion on the approval or renewal of the approval of an active substance to the Commission, the Agency shall make publicly available, without prejudice to Articles 65 and 66, information on potential candidates for substitution during a period of no more than ***60*** days, during which time interested third parties may submit relevant information, including information on available substitutes. The Agency shall take due account of the information received when finalising its opinion.	3. Prior to submitting its opinion on the approval or renewal of the approval of an active substance to the Commission, the Agency shall make publicly available, without prejudice to Articles 65 and 66, information on potential candidates for substitution during a period of no more than ***90*** days, during which time interested third parties may submit relevant information, including information on available substitutes. The Agency shall take due account of the information received when finalising its opinion.

Or. en

Justification

The proposed period of 90 days is a more appropriate timing for industry and other third parties to provide information on potential candidates for substitution.

Amendment 156
Nessa Childers

Council position
Article 12 – paragraph 2

Council position	*Amendment*
2. In the light of scientific and technical progress, the conditions specified for the active substance referred to in Article 4(3) shall be reviewed and, where appropriate, amended.	2. In the light of scientific and technical progress ***using agreed technical methods and guidance documents available at the time of application for renewal***, the conditions specified for the active substance referred to in Article 4(3) shall be reviewed and, where appropriate, amended.

Or. en

Amendment 157
Michèle Rivasi

Council position
Article 12 – paragraph 3

Council position	*Amendment*
3. Unless ***otherwise*** specified in the decision to renew the approval of an active substance, the renewal shall be for ***fifteen*** years for all product-types to which the approval applies.	3. Unless ***more strictly*** specified in the decision to renew the approval of an active substance, the renewal shall be for ***ten*** years for all product-types to which the approval applies.

Or. en

(Reinstatement of amendment 71 from first reading.)

Justification

The Council wording is ambiguous, it would also allow for a renewal for a period exceeding 15 years. Science is developing fast, and ad hoc reviews occur only very rarely. As such, a renewal should not exceed 10 years to ensure a proper reassessment every ten years at the latest.

Amendment 158
Nessa Childers

Council position
Article 14 – paragraph 1 – subparagraph 1

Council position	*Amendment*
On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for approval or, as appropriate, the previous renewal, the evaluating competent authority shall, within 90 days of the Agency accepting an application in accordance with Article 13(3), decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all ***product-types*** for which renewal is requested.	On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for approval or, as appropriate, the previous renewal, the evaluating competent authority shall, within 90 days of the Agency accepting an application in accordance with Article 13(3), decide whether, in the light of current scientific knowledge ***using agreed technical methods and guidance documents available at the time of application for renewal***, a full evaluation

	of the application for renewal is necessary taking account of all ***product types*** for which renewal is requested.

Or. en

Amendment 159
Rovana Plumb

Council position
Article 14 – paragraph 2 – subparagraph 2 a (new)

Council position	*Amendment*
	As soon as possible after the agency has accepted an application, the evaluating competent authority shall inform the applicant of the fees payable under Article 79(2). It shall reject the application if the applicant fails to pay the fees within 60 days.

Or. ro

Justification

The aim of this amendment is to clarify the text and ensure greater consistency (both within the text itself and with other legislative acts).

Amendment 160
Michèle Rivasi

Council position
Article 14 – paragraph 4

Council position	*Amendment*
4. The Commission shall, on receipt of the opinion of the Agency, adopt***:***	4. The Commission shall, on receipt of the opinion of the Agency, adopt***, by means of delegated acts in accordance with Article 82, a decision on the renewal of the inclusion of the active substance in Annex -I for one or more product-types, or of the non-renewal of inclusion. In the event that the inclusion is renewed, the decision shall state the conditions of renewal and***

	the dates of renewal and of expiry of inclusion.
(a) an implementing Regulation providing that the approval of an active substance is renewed for one or more product-types, and under which conditions; or	
(b) an implementing decision that the approval of an active substance is not renewed.	
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).	
Article 9(2) shall apply.	

Or. en

Justification

Amendment of new text by Council, adding certain elements to am 20 by the rapporteur. The renewal of active substances should be done by delegated act to ensure the control rights of Parliament. It should include the conditions and relevant dates of inclusion and expiry of inclusion. There should also be a decision in its own right if the inclusion of a substance in Annex -I is not renewed to have a record of all decisions.

Amendment 161
Michèle Rivasi

Council position
Article 15 – paragraph 1 – subparagraph 1

Council position	*Amendment*
The Commission may review the approval of an active substance for one or more product-types at any time where there are ***serious*** indications that the conditions laid down in Article 4(1) or, where relevant, Article 5(2) are no longer met. The Commission may also review the approval of an active substance for one or more product-types at the request of a Member State if there are indications that the use of the active substance in biocidal products or treated articles raises ***serious*** concerns	The Commission may review the approval of an active substance for one or more product-types at any time where there are ***significant*** indications that ***any of*** the conditions laid down in Article 4(1) or, where relevant, Article 5(2) are no longer met. The Commission may also review the approval of an active substance for one or more product-types at the request of a Member State if there are indications that the use of the active substance in biocidal products or treated articles raises

about the safety of such biocidal products or treated articles.	***significant*** concerns about the safety of such biocidal products or treated articles. ***The Commission may also review inclusion where there are significant indications that the objectives of Article 4(1)(a)(iv), Article 4(1)(b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may not be achieved.***

Or. en

(Reinstatement of amendment 74 from first reading in a modified form.)

Justification

The Commission should review the approval of an active substance as soon as there are significant indications of non-compliance, not only when there are serious indications. Non-compliance with the relevant provisions of the water framework directive should also trigger a review.

Amendment 162
Michèle Rivasi

Council position
Article 15 – paragraph 1 – subparagraph 3

Council position	*Amendment*
On duly justified imperative grounds of urgency the Commission shall adopt ***immediately applicable implementing*** acts in accordance with the procedure referred to in Article ***81(4)***.	On duly justified imperative grounds of urgency the Commission shall adopt ***delegated*** acts in accordance with the procedure referred to in Article ***83***.

Or. en

Justification

Amendment to new text by the Council. While it is important to maintain an urgency procedure, urgent decisions about renewals should be taken via delegated acts, not implementing acts.

Amendment 163
Julie Girling

Council position
Article 17 – paragraph 1 a (new)

Council position	*Amendment*
	1 a. In situ devices shall not be made available on the market unless the biocidal product that they generate is authorised in accordance with this Regulation and the in situ device complies with any relevant conditions of that authorisation.

Or. en

Justification

To enable biocidal products generated by an in situ device to be addressed in the Regulation (recital 9), they should be subject to a separate prohibition on making devices that generate biocidal products in situ available on the market, unless the biocidal product they generate is authorised. This is achieved by the proposed new Article 17(1a).

Amendment 164
Holger Krahmer

Council position
Article 17 – paragraph 2 – subparagraph 2

Council position	*Amendment*
Applications for ***national*** authorisation ***in a Member State*** shall be submitted to ***the competent authority of that Member State (‘***the ***receiving competent authority’)***.	Applications for authorisation shall be submitted to the ***Agency***.

Or. en

Justification

One important point of the modifications envisaged by the proposed regulation is the simplification and centralisation of applications. Therefore, the possibility to submit all applications (both national and Union authorisations) directly to the Agency should be maintained. Partial reinstatement of first reading Amendment 81.

Amendment 165
Dan Jørgensen

Council position
Article 17 – paragraph 6

Council position	*Amendment*
6. The authorisation holder shall ***notify*** each competent authority that has granted a national authorisation for a biocidal product family of each product within the biocidal product family before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission.	6. The authorisation holder shall ***submit an application to*** each competent authority that has granted a national authorisation for a biocidal product family of each product within the biocidal product family before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission.

Or. en

Justification

In the new regulation there is the possibility to change the composition of the biocidal products within a product family and therefore it is appropriate that the Competent Authority do have the possibility to refuse a product if they do not consider that the product is covered by the risk assessment performed for the product family.

Amendment 166
Corinne Lepage

Council position
Article 17 – paragraph 6

Council position	*Amendment*
6. The authorisation holder shall notify each competent authority that has granted a national authorisation for a biocidal product family of each product within the	6. The authorisation holder shall notify each competent authority that has granted a national authorisation for a biocidal product family of each product within the

biocidal product family before placing it on the market***, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations***. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission.	biocidal product family ***at least 30 days*** before placing it on the market. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission.

Or. en

Justification

The notification should be made at least 30 days in advance to allow a real market monitoring. The notification of products belonging to a biocidal product family aims to know all products that are placed on the market, as well as their exact composition. The notification of each product within the biocidal product family is therefore needed.

Amendment 167
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 18 – paragraph 1 – point e a (new)

Council position	*Amendment*
	(e a) where nanomaterials are used in that product, the risk to the environment and to health has been assessed separately

Or. en

(Reinstatement of amendment 88 from first reading.)

Justification

Nanomaterials can have very different characteristics to the same substances in normal form. The risks posed by nanomaterials in biocidal products must therefore be investigated separately.

Amendment 168
Holger Krahmer, Christa Klaß

Council position
Article 18 – paragraph 2 – point b a (new)

Council position	*Amendment*
	(b a) The evaluation of the compliance of the biocidal product with the criteria set out in points (b) and (c) of paragraph 1 shall not take into account a substance contained in the biocidal product if it is present in a preparation at a concentration lower than any of the concentrations mentioned in points (a) to (f) of Article 14(2) of Regulation (EC) No 1907/2006;

Or. en

Justification

This Amendment would ensure the alignment to provisions for the Chemical Safety Report threshold under the REACH regulation. Reinstating first reading Amendment 9.

Amendment 169
Julie Girling

Council position
Article 18 – paragraph 2 – point d

Council position	*Amendment*
(d) cumulative ***and synergistic*** effects.	(d) cumulative effects.

Or. en

Justification

It is important to differentiate cumulative effects (same substance in different products and uses) from synergistic effects (different substances in one mixture).

Amendment 170
Julie Girling

Council position
Article 18 – paragraph 2 – point d a (new)

Council position	*Amendment*
	(d a) synergistic effects.

Or. en

Justification

It is important to differentiate cumulative effects (same substance in different products and uses) from synergistic effects (different substances in one mixture).

Amendment 171
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 18 – paragraph 5

Council position	*Amendment*
5. Notwithstanding paragraphs 1 and 4, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met, ***or may be authorised for making available on the market for use by the general public when the criteria referred to in paragraph 4(c) are met,*** where ***not authorising*** the biocidal product ***would result in disproportionate negative impacts for society when compared*** to ***the risks*** to ***human*** or animal health or to the environment ***arising from*** the use of ***the*** biocidal product ***under*** the ***conditions laid down in*** the ***authorisation***.	5. Notwithstanding paragraphs 1 and 4, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met, where ***it is shown by evidence that*** the biocidal product ***is necessary*** to ***prevent or control a serious danger*** to ***public*** or animal health or to the environment***, to food and feed or to*** the ***public interest and that there are no effective alternative products or technologies available.***
	The use of ***any*** biocidal product ***authorised pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and*** the ***environment is minimised.***
	A Member State authorising a biocidal

product authorised pursuant to this paragraph shall draw up a substitution plan concerning the ***control of*** the ***serious danger by other means including non-chemical methods, which are as effective as the biocidal product concerned and shall without delay transmit that plan to the Commission***. ***The use of any biocidal product authorised pursuant to this paragraph shall be restricted to those Member States where the serious danger has to be prevented or, if it occurs, controlled.***

Or. en

Justification

Amendment to new text by the Council. The same conditions as adopted in first reading for the derogations from the cut-off criteria for active substances should apply in analogy for any derogations from the cut-offs for biocidal products. There should be no derogation for general use for products authorised for professional use only.

Amendment 172
Miroslav Ouzký

Council position
Article 19 – paragraph 1 – introductory part

Council position	*Amendment*
1. ***The applicant*** for ***an*** authorisation shall ***submit*** the following documents ***together with the application***:	1. ***An application*** for authorisation shall ***contain*** the following documents:

Or. en

Amendment 173
Miroslav Ouzký

Council position
Article 19 – paragraph 1 – point a – point i

Council position	*Amendment*
(i) a dossier or letter of access for the biocidal product satisfying the requirements set out in Annex III;	(i) a dossier or ***a*** letter of access ***to a dossier*** for the biocidal product satisfying the requirements set out in Annex III;

Or. en

Justification

According to Art. 21 (1), the authorisation includes also stipulates the terms and conditions relating to the placing on the market and use of the biocidal product. The latter circumscribes the authorisation of the product that should be used in compliance with it. The terms and conditions of the authorisation should be drafted and submitted by the applicant and should be handled by the competent authorities together with the summary of product characteristics during the whole procedure.

Amendment 174
Miroslav Ouzký

Council position
Article 19 – paragraph 1 – point a – point ii a (new)

Council position	*Amendment*
	(ii a) a proposal for the terms and conditions of the authorisation referred to in Article 21 (1);

Or. en

Justification

According to Art. 21 (1), the authorisation includes also stipulates the terms and conditions relating to the placing on the market and use of the biocidal product. The latter circumscribes the authorisation of the product that should be used in compliance with it. The terms and conditions of the authorisation should be drafted and submitted by the applicant and should be handled by the competent authorities together with the summary of product characteristics during the whole procedure.

Amendment 175
Jolanta Emilia Hibner, Bogusław Sonik

Council position
Article 19 – paragraph 1 – point a – point iii

Council position	*Amendment*
(iii) a dossier or a letter of access for the biocidal product satisfying the requirements set out in Annex II for each active substance in the biocidal product;	(iii) a dossier or a letter of access for the biocidal product satisfying the requirements set out in Annex II for each active substance in the biocidal product, ***other than active substances listed in Annex I;***

Or. en

Justification

In case of products containing both the active substances approved and listed in Annex I, submitting of data required in Annex II for active substances listed in Annex I should not be required, because these active substances are regarded as not posing the risk and is impossible, because such data do not exist, as being not required for inclusion of these substances into Annex I. The amendment is necessary for legal certainty, that biocidal products authorized according to Chapters VI, VII and VIII may contain also active substances included into Annex I.

Amendment 176
Miroslav Ouzký

Council position
Article 19 – paragraph 1 – point a – point iii a (new)

Council position	*Amendment*
	(iii a) a dossier or a letter of access to a dossier satisfying the requirements set out in Annex II if the active substance is listed in category 6 of Annex I;

Or. en

Justification

This sub point concerns active substances that could be included in low-risk biocidal products. It is in line with Article 95.

Amendment 177
Miroslav Ouzký

Council position
Article 19 – paragraph 1 – point b – point i a (new)

Council position	*Amendment*
	(i a) a proposal for the terms and conditions of the authorisation referred to in Article 21 (1);

Or. en

Amendment 178
Dan Jørgensen

Council position
Article 19 – paragraph 2 a (new)

Council position	*Amendment*
	2 a. For applications for Union authorisations submitted under Article 42, the summary of the characteristics of the biocidal product referred to in point (ii) of paragraph(1)(a) of this Article shall be provided in one official language of the Union accepted by the evaluating competent authority at the time of application. The Agency shall transmit that summary to the Commission in all official languages within 30 days of the submission of the opinion referred to in Article 43(3).

Or. en

Justification

Products authorised at the level of the Union will have access to the markets of all Member States. It is therefore important that the summary of product characteristics is available in all official languages. The costs of providing such translations should be borne by the applicant.

Amendment 179
Holger Krahmer, Christa Klaß

Council position
Article 21 – paragraph 2 – point e

Council position	*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 ***biocidal products; and in*** the ***case of a*** biocidal product ***family, the quantitative composition shall indicate a minimum and maximum percentage for each active and non-active substance, where the minimum percentage indicated for certain substances may be 0 %***;	(e) qualitative and quantitative composition in terms of the active substances and non-active substances, ***taking account*** of ***the concentration limits in Article 18(2b) and in so far as this information*** is ***required*** for proper use of the biocidal product;

Or. en

Justification

This Amendment would ensure the alignment to provisions for the Chemical Safety report threshold under the REACH Regulation. Partial reinstatement of first reading Amendment 117

Amendment 180
Christa Klaß

Council position
Article 21 – paragraph 2 – point g

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

Or. de

Justification

This information is covered by data protection law.

Amendment 181
Cristian Silviu Buşoi

Council position
Article 21 – paragraph 2 – point g

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

Or. en

Justification

Name of active substances supplier is confidential business information that should not be disclosed in order to protect commercial interests.

Amendment 182
Françoise Grossetête

Council position
Article 22 – paragraph 1

Council position	*Amendment*
1. The receiving competent authority or, in the case of an evaluation of an application for a Union authorisation, the evaluating competent authority, shall perform a comparative assessment as part of the ***evaluation of an application for authorisation or for*** renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1).	1. The receiving competent authority or, in the case of an evaluation of an application for a Union authorisation, the evaluating competent authority, shall perform a comparative assessment as part of the renewal ***pursuant to this Regulation*** of authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1). ***Comparative assessment shall be carried out on all biocidal products used for the same purpose provided that sufficient (at least five years') experience of their use exists.***

Or. fr

Justification

The request for comparative assessment should take into account first of all – as a rule, not as an exception – sufficient experience of use. The request for comparative assessment should accordingly be restricted to the renewal of authorisations for products containing an active substance identified as a candidate for substitution in accordance with Article 9.

Amendment 183
Françoise Grossetête

Council position
Article 22 – paragraph 1 a (new)

Council position	*Amendment*
	1 a. By derogation from paragraph 1, comparative assessment shall not be carried out on biocidal products which have been shown to be safe in use.

Or. fr

Justification

Comparative assessment should concentrate on biocidal products with an identified risk and for which alternatives are needed.

Amendment 184
Françoise Grossetête

Council position
Article 22 – paragraph 2

Council position	*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 Union 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 ***renewal of*** a Union authorisation, also to the Commission.

Or. fr

Justification

The request for comparative assessment should take into account first of all – as a rule, not as an exception – sufficient experience of use. The request for comparative assessment should accordingly be restricted to the renewal of authorisations for products containing an active substance identified as a candidate for substitution in accordance with Article 9.

Amendment 185
Françoise Grossetête

Council position
Article 22 – paragraph 3 – introductory part

Council position	*Amendment*
3. The receiving competent authority or, in the case of a decision on ***an application for*** a Union authorisation, the Commission shall prohibit or restrict the making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment in accordance with Annex VI ('comparative assessment') demonstrates that both of the following criteria are met:	3. The receiving competent authority or, in the case of a decision on ***the renewal of*** a Union authorisation, the Commission shall prohibit or restrict the making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment in accordance with Annex VI ('comparative assessment') demonstrates that both of the following criteria are met:

Or. fr

Justification

The request for comparative assessment should take into account first of all – as a rule, not as an exception – sufficient experience of use. The request for comparative assessment should accordingly be restricted to the renewal of authorisations for products containing an active substance identified as a candidate for substitution in accordance with Article 9.

Amendment 186
Françoise Grossetête

Council position
Article 22 – paragraph 3 – point a

Council position	*Amendment*
(a) for the uses specified in the application, ***another*** authorised biocidal ***product or a non-chemical control or prevention method*** already ***exists*** which ***presents*** a significantly lower overall risk for human and animal health and the environment, ***is*** sufficiently effective and ***presents*** no other significant economic or practical disadvantages;	(a) for the uses specified in the application, ***other*** authorised biocidal ***products*** already ***exist*** which ***present*** a significantly lower overall risk for human and animal health and the environment, ***are*** sufficiently effective and ***present*** no other significant economic or practical disadvantages;

Or. fr

Justification

The request for comparative assessment should take into account first of all – as a rule, not as an exception – sufficient experience of use. The request for comparative assessment should accordingly be restricted to the renewal of authorisations for products containing an active substance identified as a candidate for substitution in accordance with Article 9.

Amendment 187
Michèle Rivasi

Council position
Article 22 – paragraph 3 a (new)

Council position	*Amendment*
	3 a. The Commission shall, on the basis of paragraph 3, be empowered to adopt delegate acts in accordance with Article 82 defining the criteria and algorithms to be used in comparative assessments to ensure that there is a uniform application throughout the Union.

Or. en

(Partial reinstatement of amendment 124 from first reading.)

Justification

It is important that Member States follow the same methodology in comparative assessments.

Amendment 188
Holger Krahmer

Council position
Article 22 – paragraph 6

Council position	*Amendment*
6. Notwithstanding Article 17(4), and without prejudice to paragraph 4 of this Article, an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted for ***a period*** not exceeding five years and renewed for a ***period*** not exceeding five years.	6. Notwithstanding Article 17(4), and without prejudice to paragraph 4 of this Article, an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted for ***periods*** not exceeding five years and renewed for a ***periods*** not exceeding five years.

Or. en

Justification

This Amendment makes the text more precise. Reinstatement of first reading Amendment 126

Amendment 189
Miroslav Ouzký

Council position
Article 22 – paragraph 7

Council position	*Amendment*
7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, ***that*** cancellation or amendment of the authorisation shall take effect ***five years after that decision. However, where*** the ***approval*** of ***the active substance which is a candidate for substitution expires on an earlier date, the cancellation of the authorisation shall take effect on that earlier date***.	7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, ***the*** cancellation or amendment of the authorisation shall take effect ***in accordance with*** the ***provisions*** of ***Chapter VIII***.

Or. en

Justification

It is more appropriate to refer to Chapter VIII, which regulates the cancellation, review and amendment of authorisations.

Amendment 190
Michèle Rivasi

Council position
Article 22 – paragraph 7

Council position	*Amendment*
7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or amendment of the authorisation shall take effect ***five*** years after that decision. However, where the approval of the active substance which is a candidate for substitution expires on an earlier date, the cancellation of the authorisation shall take effect on that earlier date.	7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or amendment of the authorisation shall take effect ***three*** years after that decision. However, where the approval of the active substance which is a candidate for substitution expires on an earlier date, the cancellation of the authorisation shall take effect on that earlier date.

Or. en

(Reinstatement of amendment 128 from first reading.)

Justification

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

Amendment 191
Julie Girling

Council position
Article 23

Council position	*Amendment*
The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter and, in	The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter and, in

particular, Articles 21(2) and 22(3).	particular, Articles ***18(2)(d) and (da),*** 21(2) and 22(3).

Or. en

Justification

There is neither a currently agreed scientific definition for the concept of cumulative or synergistic effects, nor an agreed methodology. These definitions and methodologies need to be adopted by the Commission via technical guidance notes, prior to entry into force of the Regulation.

Amendment 192
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 24 – paragraph 1 – point b a (new)

Council position	*Amendment*
	(b a) the biocidal product does not contain a nanomaterial;

Or. en

(Reinstatement of amendment 103 of first reading.)

Justification

In light of the current lack of appropriate risk assessment of nanomaterials, they should not qualify for the simplified authorisation procedure.

Amendment 193
Rovana Plumb

Council position
Article 25 – paragraph 2 – subparagraph 2

Council position	*Amendment*
The evaluating competent authority shall inform the applicant of the fees payable under Article 79 and shall reject the application if the applicant fails to pay the fees within ***30*** days. It shall inform the applicant accordingly.	The evaluating competent authority shall inform the applicant of the fees payable under Article 79***(2)*** and shall reject the application if the applicant fails to pay the fees within ***60*** days. It shall inform the applicant accordingly.

Or. ro

Justification

The aim of this amendment is to clarify the text and ensure greater consistency (both within the text itself and with other legislative acts).

Amendment 194
Rovana Plumb

Council position
Article 25 – paragraph 2 – subparagraph 3

Council position	*Amendment*
Upon receipt of the fees payable under Article 79, the evaluating competent authority shall accept the application and inform the applicant accordingly.	Upon receipt of the fees payable under Article 79***(2)***, the evaluating competent authority shall accept the application and inform the applicant accordingly.

Or. ro

Justification

The aim of this amendment is to clarify the text and ensure greater consistency (both within the text itself and with other legislative acts).

Amendment 195
Dan Jørgensen

Council position
Article 26 – paragraph 1

Council position	*Amendment*
1. ***A*** biocidal product ***authorised in accordance with Article 25 may be made available*** on the market in ***all*** Member States ***without*** the ***need for mutual recognition***. ***However,*** the authorisation ***holder shall notify each*** Member State	1. ***If an authorisation holder wishes to place the*** biocidal product on the market in ***other*** Member States ***they shall apply for an Union authorisation to*** the ***Agency***. ***The application shall contain*** the ***evaluation and*** authorisation ***already given***

before placing the biocidal product on the ***market within the territory*** of ***that Member State*** and shall ***use*** the ***official language*** or ***languages*** of ***that Member State in*** the product***'s labelling, unless that Member State provides otherwise***.

in one Member State***, including*** the ***confirmation according to article 41 that the*** biocidal product ***would have similar conditions of use across the Union.***

On receipt of an application for authorisation for a product already authorised according to Article 25, the Agency shall prepare an opinion

on the ***authorisation*** of ***the biocidal product*** and ***submit it to the Commission.***

The opinion

shall ***contain at least*** the ***following elements:***

(a) a statement on whether the conditions laid down in Article 24 are fulfilled

b) where relevant, details of any terms

or ***conditions which should be imposed on the placing on the market or use*** of the ***biocidal*** product***;***

(c) the final assessment report on the biocidal product

Or. en

Amendment 196
Dan Jørgensen

Council position
Article 26 – paragraph 2 – subparagraph 1

Council position	*Amendment*
Where a Member State other than that of the ***evaluating competent authority considers that*** a biocidal product ***authorised*** in accordance with Article ***25*** has ***not been notified or labelled*** in ***accordance with paragraph 1 of this*** Article ***or does not meet*** the ***requirements of Article 24,*** it ***may refer*** that ***matter*** to	***On receipt*** of the ***opinion of the Agency, the Commission shall adopt*** a ***decision on the Union authorisation of the*** biocidal product in accordance with ***the examination procedure referred to in*** Article ***81(3). As soon as the Commission*** has ***granted a Union authorisation, it shall enter the information referred to*** in

the ***coordination group established*** in accordance with Article ***34***(1)***. Article 34(3) and Article 35 shall apply mutatis mutandis***.	Article ***29(4) in*** the ***Register for Biocidal Products.***
	A Member State shall inform the Commission if it ***decides*** that ***the Union authorisation is adjusted*** to the ***different circumstances*** in ***that Member State in*** accordance with ***the grounds laid down in*** Article ***36***(1).

Or. en

Amendment 197
Dan Jørgensen

Council position
Article 26 – paragraph 2 – subparagraph 2

Council position	*Amendment*
Where a Member State has valid reasons to consider that a biocidal product authorised in accordance with Article 25 does not meet the criteria laid down in Article 24 and a decision pursuant to Articles 34 and 35 has not yet been taken, that Member State may provisionally restrict or prohibit the use or sale of that product on its territory.	***deleted***

Or. en

Justification

We do not support that a national authorisation granted in accordance with the simplified authorisation procedure – can be placed on the market in all Member States without the need for mutual recognition. Instead we suggest that products authorised under the simplified procedure should have a Union authorisation with a lower fee.

Amendment 198
Jolanta Emilia Hibner, Bogusław Sonik

Council position
Article 27 – paragraph 1 a (new)

Council position	*Amendment*
	1 a. Without prejudice to paragraph 1, active substances fulfilling the criteria laid down in paragraph 2 of this Article may be included in Annex I if they are authorised as food additives in accordance with Regulation (EC) No 1333/2008

Or. en

Justification

This amendment will allow to put into Annex I commonly used food additive substances (e.g. acidic acid), which do not comply with the exclusion criteria listed in Art. 27/2 (e.g. skin corrosivity). Acetic acid and propionic acid could be therefore placed, with proposed restrictions, as category 1 Annex I substances.

Amendment 199
Miroslav Ouzký

Council position
Article 30 – paragraph 3 – point a

Council position	*Amendment*
(a) ***a list*** to all relevant data that ***it*** has generated since the initial authorisation or, as appropriate, previous renewal; and	(a) ***without prejudice*** to ***Article 20 (1),*** all relevant data ***required under Article 19*** that has generated since the initial authorisation or, as appropriate, previous renewal***, or a letter of access to such data***; and

Or. en

Justification

References made to Article 19 and 20 make the text more precise. In order to obtain data protection, it is required that the data is actually submitted. The possibility to submit a letter of access should be included in this provision for cases when the data owner is different from the applicant wishing to seek a renewal.

Amendment 200
Rovana Plumb

Council position
Article 30 – paragraph 4 – subparagraph 1

Council position	*Amendment*
The receiving competent authority shall inform the applicant of the fees payable under Article 79 and shall reject the application if the applicant fails to pay the fees within ***30*** days. It shall inform the applicant accordingly.	The receiving competent authority shall inform the applicant of the fees payable under Article 79***(2)*** and shall reject the application if the applicant fails to pay the fees within ***60*** days. It shall inform the applicant accordingly.

Or. ro

Justification

The aim of this amendment is to clarify the text and ensure greater consistency (both within the text itself and with other legislative acts).

Amendment 201
Rovana Plumb

Council position
Article 30 – paragraph 4 – subparagraph 2

Council position	*Amendment*
Upon receipt of the fees payable under Article 79, the receiving competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.	Upon receipt of the fees payable under Article 79***(2)***, the receiving competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

Or. ro

Justification

The aim of this amendment is to clarify the text and ensure greater consistency (both within the text itself and with other legislative acts).

Amendment 202
Nessa Childers

Council position
Article 30 – paragraph 5 – subparagraph 1

Council position	*Amendment*
On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for authorisation or, as appropriate, the previous renewal, the receiving competent authority shall, within 90 days of accepting an application in accordance with paragraph 4, decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product types for which renewal is requested.	On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for authorisation or, as appropriate, the previous renewal, the receiving competent authority shall, within 90 days of accepting an application in accordance with paragraph 4, decide whether, in the light of current scientific knowledge ***using agreed technical methods and guidance documents available at the time of application for renewal***, a full evaluation of the application for renewal is necessary taking account of all product types for which renewal is requested.

Or. en

Amendment 203
Cristian Silviu Buşoi

Council position
Article 32 – paragraph 1 – subparagraph 1 – point a

Council position	*Amendment*
(a) a translation of the national authorisation granted by the reference Member State, into ***such*** official languages of the Member State concerned ***as it may require***; and	(a) a translation of the national authorisation granted by the reference Member State, into ***English or one of the*** official languages of the Member State concerned; and

Or. en

Justification

The possibility to submit application for mutual recognition in sequence in English facilitates the handling of these demands in each Member State concerned, as the Parliament proposed it in first reading Art. 32 (3).

Amendment 204
Mario Pirillo

Council position
Article 32 – paragraph 2 – subparagraph 2

Council position	*Amendment*
Within 90 days of validating the application, and subject to Articles 34, 35 and 36, the Member States concerned shall agree on the summary of biocidal product characteristics and shall record their agreement in the Register for Biocidal Products.	Within 90 days of validating the application, and subject to Articles 34, 35 and 36, the Member States concerned shall agree on the summary of biocidal product characteristics ***together with the terms*** and ***conditions of the authorisation;*** shall ***authorise the biocidal product accordingly and shall*** record their agreement in the Register for Biocidal Products. ***A single authorisation number shall be used in all Member States concerned.***

Or. en

Justification

According to Article 21(1), the authorisation includes not only the summary of biocidal product characteristics, but it stipulates also the terms and conditions relating to the placing on the market and use of the biocidal products in question. A single authorisation number should facilitate the administrative management of applications for mutual recognition.

Amendment 205
Cristian Silviu Buşoi, Romana Jordan Cizelj

Council position
Article 32 – paragraph 2 – subparagraph 2

Council position	*Amendment*
Within 90 days of validating the	Within 90 days of validating the

application, and subject to Articles 34, 35 and 36, the Member States concerned shall agree on the summary of biocidal product characteristics and shall record their agreement in the Register for Biocidal Products.	application, and subject to Articles 34,35 and 36, the Member States concerned shall agree on the summary of biocidal product characteristics ***included in the national authorisation granted by the reference Member State*** and shall record their agreement in the Register for Biocidal Products. ***Without prejudice to Articles 34, 35, and 36, if agreement is not reached within the 90 day period referred to in the second subparagraph, each Member State which agrees to the biocidal product characteristics referred to in the first subparagraph may register its agreement in the Register of Biocidal Products and authorise the product in conformity with the summary of biocidal product characteristics to which it agreed.***

Or. en

Justification

Consistency between Regulation 1107/2009 and this one is essential. Given that the provisions on zonal authorisation in Regulation 1107/2009 on PPP exclude the possibility for one Member State to delay the authorisation procedure in the other Member States once the Draft Inclusion by the Rapporteur has been finalised, the same principle should apply within the Biocides Regulation. This will allow avoiding unnecessary delays which could jeopardise the benefits of the mutual recognition process.

Amendment 206
Miroslav Ouzký

Council position
Article 32 – paragraph 3

Council position	*Amendment*
3. The procedure shall be closed after all the Member States concerned have agreed on the summary of biocidal product characteristics and recorded their agreement in the Register for Biocidal Products.	3. The procedure shall be closed after all the Member States concerned have agreed on the summary of biocidal product characteristics ***together with the terms*** and ***conditions of the authorisation, and*** recorded their agreement in the Register

for Biocidal Products.

Or. en

Justification

According to Art. 21 (1), the authorisation includes also stipulates the terms and conditions relating to the placing on the market and use of the bioc. product in question. The latter circumscribes the authorisation of the product which should be used in compliance with it. Therefore, in case of mutual recognition, the Member States concerned should agree not only on the summary of bioc. product characteristics, but also on the terms and conditions of authorisation.

Amendment 207
Cristian Silviu Buşoi, Romana Jordan Cizelj

Council position
Article 32 – paragraph 3

Council position	*Amendment*
3. The procedure shall be closed after all the Member States concerned have agreed on the summary of biocidal product characteristics and recorded their agreement in the Register for Biocidal Products.	3. The procedure ***referred to in the second subparagraph*** shall be closed after all the Member States concerned have agreed on the summary of biocidal product characteristics ***included in the national authorisation granted by the reference Member State*** and recorded their agreement in the Register for Biocidal Products.

Or. en

Justification

Consistency between Regulation 1107/2009 and this one is essential. Given that the provisions on zonal authorisation in Regulation 1107/2009 on PPP exclude the possibility for one Member State to delay the authorisation procedure in the other Member States once the Draft Inclusion by the Rapporteur has been finalised, the same principle should apply within the Biocides Regulation. This will allow avoiding unnecessary delays which could jeopardise the benefits of the mutual recognition process.

Amendment 208
Cristian Silviu Buşoi, Romana Jordan Cizelj

Council position
Article 32 – paragraph 4

Council position	*Amendment*
4. Within 30 days of closure of the procedure***, each of the*** Member States concerned shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics.	4. Within 30 days of closure of the procedure ***referred to in paragraph 3*** Member States concerned shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics.

Or. en

Justification

Consistency between Regulation 1107/2009 and this one is essential. Given that the provisions on zonal authorisation in Regulation 1107/2009 on PPP exclude the possibility for one Member State to delay the authorisation procedure in the other Member States once the Draft Inclusion by the Rapporteur has been finalised, the same principle should apply within the Biocides Regulation. This will allow avoiding unnecessary delays which could jeopardise the benefits of the mutual recognition process.

Amendment 209
Cristian Silviu Buşoi

Council position
Article 33 – paragraph 2 – point c a (new)

Council position	*Amendment*
	(c a) the proposed terms and conditions of the authorisation referred to in Article 21 (1) in English.

Or. en

Justification

Since the terms and conditions of authorisation constitute an important part of the authorisation, it should be proposed and added to the application by the applicant.

Amendment 210
Cristian Silviu Buşoi, Romana Jordan Cizelj

Council position
Article 33 – paragraph 5 a (new)

Council position	*Amendment*
	5 a. Without prejudice to Articles 34, 35, and 36, if agreement is not reached within the 90 day period referred to in paragraph 5 each Member State which agrees to the summary biocidal product characteristics referred to in paragraph 4 may register its agreement and authorise the product in conformity with the summary of biocidal product characteristics to which it agreed.

Or. en

Justification

Consistency between Regulation 1107/2009 and this one is essential. Given that the provisions on zonal authorisation in Regulation 1107/2009 on PPP exclude the possibility for one Member State to delay the authorisation procedure in the other Member States once the Draft Inclusion by the Rapporteur has been finalised, the same principle should apply within the Biocides Regulation. This will allow avoiding unnecessary delays which could jeopardise the benefits of the mutual recognition process.

Amendment 211
Mario Pirillo

Council position
Article 33 – paragraph 6

Council position	*Amendment*
6. The procedure shall be closed after all the Member States concerned have agreed the summary of biocidal product characteristics and recorded their agreement in the Register for Biocidal Products.	6. The procedure shall be closed after all the Member States concerned have agreed the summary of biocidal product characteristics ***together with the terms*** and ***conditions of the authorisation, and*** recorded their agreement in the Register for Biocidal Products. ***A single authorisation number shall be used in all the Member States concerned.***

Or. en

Amendment 212
Cristian Silviu Buşoi, Romana Jordan Cizelj

Council position
Article 33 – paragraph 7

Council position	*Amendment*
7. Within 30 days of closure of the procedure, ***the reference Member State and*** each of the Member States concerned shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics.	7. Within 30 days of closure of the procedure, each of the ***remaining*** Member States concerned shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics.

Or. en

Justification

Consistency between Regulation 1107/2009 and this one is essential. Given that the provisions on zonal authorisation in Regulation 1107/2009 on PPP exclude the possibility for one Member State to delay the authorisation procedure in the other Member States once the Draft Inclusion by the Rapporteur has been finalised, the same principle should apply within the Biocides Regulation. This will allow avoiding unnecessary delays which could jeopardise the benefits of the mutual recognition process.

Amendment 213
Dan Jørgensen

Council position
Article 36 – title

Council position	*Amendment*
Derogations ***from mutual recognition***	Derogations

Or. en

Amendment 214
Dan Jørgensen

Council position
Article 36 – paragraph 1 – subparagraph 1 – introductory part

Council position	*Amendment*
By way of derogation from ***Article*** 31(2), any of the Member States concerned may ***propose to*** refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of:	By way of derogation from ***Articles 26,*** 31(2) ***and 41(1)***, any of the Member States concerned may refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of:

Or. en

Amendment 215
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 36 – paragraph 1 – subparagraph 1 – introductory part

Council position	*Amendment*
By way of derogation from Article 31(2), any of the Member States concerned may ***propose to*** refuse to grant an authorisation or ***to*** adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of:	By way of derogation from Article 31(2), any of the Member States concerned may refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of:

Or. en

(Amendment to be coherent with amendment 342 from first reading.)

Justification

Member States should be allowed to derogate from mutual recognition in justified cases, and not just make a proposal to do so..

Amendment 216
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 36 – paragraph 1 – subparagraph 1 – point c

Council position	*Amendment*
(c) the protection of health and life of humans, animals or plants;	(c) the protection of health and life of humans, ***particularly of vulnerable groups, or of*** animals or plants;

Or. en

(Partial reinstatement of amendment 343 from first reading)

Justification

It should be clarified that the protection of vulnerable groups is included amongst the grounds to derogate from mutual recognition.

Amendment 217
Esther de Lange, Christa Klaß

Council position
Article 36 – paragraph 1 – subparagraph 1 – point e a (new)

Council position	*Amendment*
	(e a) implementation of other Union legislation, and in particular Directive 98/83/EC.

Or. en

Justification

Member States should be able to request a derogation from the Commission to allow national policies that relate to the implementation of other Union legislation, such as national policies that ensure drinking water quality to continue to exist.

Amendment 218
Michèle Rivasi

Council position
Article 36 – paragraph 1 – subparagraph 1 – point e a (new)

Council position	*Amendment*
	(e a) implementation of other relevant Union legislation, and in particular Directive 98/83/EC.

Or. en

Justification

Member States should be allowed to derogate from mutual recognition so as to safeguard national implementation of Union legislation. This is particular relevant for the Drinking Water Directive 98/83/EC, for which different national conditions may result in stricter national laws to comply with Union legislation.

Amendment 219
Dan Jørgensen

Council position
Article 36 – paragraph 1 – subparagraph 2

Council position	*Amendment*
Any of the Member States concerned may, in particular, ***propose*** in accordance with the first subparagraph ***to*** refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or 10(1) applies.	Any of the Member States concerned may, in particular, in accordance with the first subparagraph refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or 10(1) applies.

Or. en

Amendment 220
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 36 – paragraph 1 – subparagraph 2

Council position	*Amendment*
Any of the Member States concerned may,	Any of the Member States concerned may,

in particular, ***propose*** in accordance with the first subparagraph ***to*** refuse to grant an authorisation or ***to*** adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or 10(1) applies.	in particular, in accordance with the first subparagraph***,*** refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or 10(1) applies.

Or. en

(Amendment to be coherent with amendment 342 from first reading.)

Justification

Member States should always be allowed to deviate from mutual recognition for substances covered by Article 5 or 10(1).

Amendment 221
Dan Jørgensen

Council position
Article 36 – paragraph 2 – subparagraph 1

Council position	*Amendment*
The Member State concerned shall ***communicate to*** the ***applicant a detailed statement*** of ***the grounds for seeking a derogation pursuant to paragraph 1*** and ***shall seek to reach an agreement with the applicant on the proposed derogation***.	The Member State concerned shall ***without delay inform*** the ***other Member States and the Commission*** of ***any decision taken in this respects*** and ***its justification***.

Or. en

Amendment 222
Dan Jørgensen

Council position
Article 36 – paragraph 2 – subparagraph 2 – introductory part

Council position	*Amendment*
If the Member State concerned is unable to reach agreement with the applicant or	***deleted***

receives no reply from the applicant within 60 days of that communication it shall inform the Commission. In that case, the Commission:

(a) may ask the Agency for an opinion on scientific or technical questions raised by the applicant or the Member State concerned;

(b) shall adopt a decision on the derogation in accordance with the examination procedure referred to in Article 81(3).

Or. en

Amendment 223
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 36 – paragraph 2 – subparagraph 2 – introductory part

Council position	*Amendment*
If the Member State concerned is unable to reach agreement with the applicant or receives no reply from the applicant within 60 days of that communication it shall inform the Commission. ***In that case, the Commission:***	If the Member State concerned is unable to reach agreement with the applicant or receives no reply from the applicant within 60 days of that communication it shall ***without delay*** inform ***other Member States and*** the Commission ***of any decision taken in this respect and its justification***.

Or. en

(Reinstatement of amendment 342 from first reading. Linked to the deletion of the rest of this paragraph)

Justification

While it is acceptable to try to reach an agreement on national derogation with the applicant, in case no such agreement is found, the Member State should be free to derogate from mutual recognition as long as it provides a proper justification on the basis of the grounds listed in the first paragraph of this Article.

Amendment 224
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 36 – paragraph 2 – subparagraph 2 – point a

Council position	*Amendment*
(a) may ask the Agency for an opinion on scientific or technical questions raised by the applicant or the Member State concerned;	***deleted***

Or. en

(Reinstatement of amendment 342 from first reading.)

Justification

A Member State should be free to derogate from mutual recognition as long as it provides a proper justification on the basis of the grounds listed in the first paragraph of this Article. As such, there is no need for the Commission to ask the Agency for an opinion.

Amendment 225
Dan Jørgensen

Council position
Article 36 – paragraph 2 – subparagraph 2 – point a

Council position	*Amendment*
(a) may ask the Agency for an opinion on scientific or technical questions raised by the applicant or the Member State concerned;	***deleted***

Or. en

Amendment 226
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 36 – paragraph 2 – subparagraph 2 – point b

Council position	*Amendment*
(b) shall adopt a decision on the derogation in accordance with the examination procedure referred to in Article 81(3).	***deleted***

Or. en

(Reinstatement of amendment 342 from first reading)

Justification

A Member State should be free to derogate from mutual recognition as long as it provides a proper justification on the basis of the grounds listed in the first paragraph of this Article. As such, there is no need for a Commission on this matter.

Amendment 227
Dan Jørgensen

Council position
Article 36 – paragraph 2 – subparagraph 2 – point b

Council position	*Amendment*
(b) shall adopt a decision on the derogation in accordance with the examination procedure referred to in Article 81(3).	***deleted***

Or. en

Amendment 228
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 36 – paragraph 2 – subparagraph 3

Council position	*Amendment*
The Commission's decision shall be addressed to the Member State concerned and the Commission shall inform the	***deleted***

applicant thereof.

Or. en

(Reinstatement of amendment 342 from first reading)

Justification

A Member State should be free to derogate from mutual recognition as long as it provides a proper justification on the basis of the grounds listed in the first paragraph of this Article. In that case, there is no need for this clause.

Amendment 229
Dan Jørgensen

Council position
Article 36 – paragraph 2 – subparagraph 3

Council position	*Amendment*
The Commission's decision shall be addressed to the Member State concerned and the Commission shall inform the applicant thereof.	***deleted***

Or. en

Amendment 230
Dan Jørgensen

Council position
Article 36 – paragraph 2 – subparagraph 4

Council position	*Amendment*
The Member State concerned shall take necessary measures to comply with the Commission's decision within 30 days of its notification.	***deleted***

Or. en

Justification

Member States should have the possibility to refuse to grant an authorisation/ adjust the contain conditions without a say from the Commission. Such a decision shall be justified according to the grounds referred to paragraph 1