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***II
RECOMMENDATION FOR SECOND READING

on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products
(05032/2/2011 – C7-0251/2011 – 2009/0076(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Christa Klaß

PR_COD_2am

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

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

Amendments to a draft act

In amendments by Parliament, amendments to draft acts are highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold.** Any deletions that Parliament wishes to make in such passages are indicated thus: **[...]**.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council position at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products
(05032/2/2011 – C7-0251/2011 – 2009/0076(COD))

(Ordinary legislative procedure: second reading)

The European Parliament,

– having regard to the Council position at first reading (05032/2/2011 – C7-0251/2011),

– having regard to the opinion of the European Economic and Social Committee of 17 February 2010[1],

– having regard to its position at first reading[2] on the Commission proposal to the European Parliament and to the Council (COM(2009)0267),

– having regard to Article 294(7) of the Treaty on the Functioning of the European Union,

– having regard to Rule 66 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A7-0336/2011),

1. Adopts its position at second reading hereinafter set out;

2. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] OJ C 347, 18.12.2010, p. 62.
[2] Texts adopted of 22.9.2010, P7_TA-PROV(2010)0333.

Amendment 1

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, or contain 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.

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 2

Council position
Recital 10

Council position	*Amendment*
(10) In order to ensure legal certainty, it is necessary to establish a Union list of active substances approved for use in biocidal products. A procedure should be laid down for assessing whether or not an active substance can be entered in that list. The information that interested parties should submit in support of an application for approval of an active substance and its inclusion in the list should be specified.	(10) In order to ensure legal certainty ***and transparency,*** it is necessary ***to maintain, within this Regulation,*** a Union list of active substances ***which are*** approved for use in biocidal products. A procedure should be laid down for assessing whether or not an active substance can be entered in that list. The information that interested parties should submit in support of an application for approval of an active substance and its inclusion in the list should be specified.

Justification

Active substances should continue to be included in an Annex to the Regulation. The new proposed approach in the Council text - by which they would be subject to separate

authorisations by way of implementing acts - lacks transparency.

Amendment 3

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.

(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 4

Council position

Recital 65

Council position	*Amendment*
(65) ***It*** is appropriate to provide for ***a deferred application of this Regulation so as to facilitate the smooth transition to the new systems*** for the approval of active substances and authorisation of biocidal products.	(65) ***To ensure a smooth transition, it*** is appropriate to provide for ***procedures so that the applications submitted*** for the approval of active substances and authorisation of biocidal products***, before the application of this Regulation are assessed against the requirements of this Regulation.***

Amendment 5

Council Position
Recital 71

Council Position	*Amendment*
The Commission should adopt immediately applicable delegated acts where, in duly justified cases relating to the restriction of an active substance in Annex I or to the removal of an active substance from that Annex, imperative grounds of urgency so require.	***deleted***

Justification

This Recital does not comply with the standard clauses on delegated acts and should therefore be deleted.

Amendment 6

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.***

(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 7

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

Council position	*Amendment*
	(ja) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption[1].
	[1] OJ L 111, 20.4.2001, p. 31.

Justification

This amendment would introduce a reference to the Drinking Water Directive 98/83/EC. DWD should remain the main legislation for biocidal products used for drinking water treatment. Under Articles 7 and 10 of that Directive, biocidal products intended for water disinfection that are put on the market or generated in situ are approved and authorised at national level. To avoid any duplication, drinking water disinfectants generated in situ already authorised by national Health Authorities should not be subject to the authorisation procedure required under this new Regulation.

Amendment 8

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

Council position	*Amendment*
	(jb) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food[1].
	[1] OJ L 338, 13.11.2004, p. 4.

Justification

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 9

Council position
Article 2 – paragraph 2 a (new)

Council position	*Amendment*
	2a. The Commission shall be empowered to adopt, at the request of a Member State, delegated acts in accordance with Article 82 specifying whether a specific product or group of products is a biocidal product or a treated article or neither.

Justification

The question of whether to extend the scope of the Regulation to cover additional specific products or a group of products is a measure of general application designed to supplement the basic act, and should therefore be subject to delegated, rather than implementing acts. In addition, a provision concerning the scope of the Regulation more appropriately belongs in Article 2 (rather than 3) of the Regulation.

Amendment 10

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***.

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 11

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 a biocidal product.***

Amendment 12

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

(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 13

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;

(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 14

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;

(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 15

Council position
Article 3 – paragraph 1 – point m

Council position	*Amendment*
(m) "national authorisation" means an administrative act by which the competent authority of a Member State authorises the making available on the market and the use of a biocidal product in its territory or in a part thereof;	(m) "national authorisation" means an administrative act by which the competent authority of a Member State authorises the making available on the market and the use of a biocidal product ***or a biocidal product family*** in its territory or in a part thereof;

Justification.
It should be made clear that a national authorisation can be granted both for an individual biocidal product and for a biocidal product family.

Amendment 16

Council position
Article 3 – paragraph 1 – point p

Council position	*Amendment*
(p) "authorisation holder" means the person responsible for the ***making available*** on the market of a biocidal product in a particular Member State or in the Union and specified in the authorisation***. If the person responsible for the placing on the market of the biocidal product is not established within the Union, the authorisation holder shall be a person established within the Union that the person responsible for placing on the market has designated by written mandate as the authorisation holder and who has accepted that designation in writing***;	(p) "authorisation holder" means the person ***established within the Union who is*** responsible for the ***placing*** on the market of a biocidal product in a particular Member State or in the Union and specified in the authorisation;

Justification

The new definition introduced by the Council is unnecessarily complicated. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 17

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, and presenting specified variations in their composition ***as compared to a reference biocidal product belonging to that group which contains the same active substances of the same specifications, provided that such permitted specified variations*** do not adversely affect the level of risk or significantly reduce the efficacy of the products;

Amendment 18

Council position
Article 3 – paragraph 1 – point v

Council position	*Amendment*
(v) "food contact materials" means any material or article as referred to in Article 1(2) of 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;	***deleted***

Justification

The definition of "food contact materials" is not necessary as food contact materials will be regarded as treated articles.

Amendment 19

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 amend this Regulation to include that definition in this Regulation.***

(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 20

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***;

Justification

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

Amendment 21

Council position
Article 3 – paragraph 1 – point ad a (new)

Council position	*Amendment*
	(ada) ‘professional user’ means any natural or legal person who/which uses biocidal products in the framework of his/its professional activity;

Justification.

Reinstatement of first reading position.

Amendment 22

Council position
Article 3 – paragraph 3

Council position	*Amendment*
The Commission may, at the request of a Member State, decide, by means of implementing acts, whether a specific product or group of products is a biocidal product or a treated article or neither. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).	***deleted***

Justification

See amendment to Article 2(2a)(new). The provision on scope should be contained in Article

2, rather than 3 of the Regulation. And in addition, measures of this kind should be subject to delegated rather than implementing acts.

Amendment 23

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.)*

(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 24

Council Position
Article 4 – paragaph 3 – point g a (new)

Council position	*Amendment*
	(ga) the date of inclusion in Annex -I;

Justification

This is important information concerning the active substance and its approval/inclusion and so should be included as a condition of approval/inclusion

Amendment 25

Council position
Article 5

Council position	*Amendment*
1. Subject to paragraph 2, the following active substances shall not be approved:	1. Subject to paragraph 2, the following active substances shall not be approved:
(a) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B;	(a) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B;
(b) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;	(b) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;
(c) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;	(c) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;
(d) active substances identified 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 effects 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**.**
(e) active substances which fulfil the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) according to Annex XIII to Regulation (EC) No 1907/2006.	(e) active substances which fulfil the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) according to Annex XIII to Regulation (EC) No 1907/2006.
2. Without prejudice to Article 4(1), active substances referred to in paragraph 1 of this Article may be approved if it is shown that at least one of the following conditions is met:	2. Without prejudice to Article 4(1), active substances referred to in paragraph 1 of this Article may be approved if it is shown that at least one of the following conditions is met:
(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 ***exposure of*** humans or the environment to the active substance in ***question in*** a biocidal product, under ***normal*** conditions of use, is negligible, ***meaning that*** the product is used in closed systems or ***under other*** conditions ***excluding contact with humans***;
(b) 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.
(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.	
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.	
3. ***The*** Commission shall ***be empowered to*** adopt delegated acts in accordance with Article 82 specifying scientific criteria for the determination of endocrine disrupting properties.	3. ***No later than 13 December 2013, the*** Commission shall adopt delegated acts in accordance with Article 82 specifying scientific criteria for the determination of endocrine disrupting properties.
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.	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.
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.	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.

Amendment 26

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***;

(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 27

Council position
Article 6 – paragraph 4

Council position	*Amendment*
4. ***In order to establish uniform conditions for the application of point (a) of paragraph 2,*** the Commission shall***, by means of implementing acts, specify in which circumstances the exposure associated with the proposed uses would justify adapting*** the data ***requirements of points (a) and (b) of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).***	4. The Commission shall ***be empowered to adopt delegated acts in accordance with Article 82 adapting the criteria for what constitutes adequate justification to adapt*** the data ***required under paragraph 1 on the grounds referred to in point (a) of paragraph 2***.

Justification

As this is a provision of general application designed to supplement the basic act, it should therefore be subject to delegated rather than implementing acts.

Amendment 28

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	Upon receipt of the fees payable under Article 79(1) ***and (2)***, the Agency shall

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.	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.

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 29

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

Council position	*Amendment*
	The evaluating competent authority shall, as soon as possible after the Agency has accepted an application, 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 30 days.

Justification

The Council text does not take account of the changes to Article 79 where fees are now split between fees for the Agency and fees for the evaluating authority. And for the sake of consistency, there does not appear to be any reason for the deadline for the payment of fees to the evaluating competent authority to be shorter or longer than the deadline for payment of fees to the Agency. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to clarify the text.

Amendment 30

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	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.	and the Agency accordingly. In such cases, part of the fees paid in accordance with ***Article 79(1) and (2)*** shall be reimbursed.

Justification

The Council text does not take account of the changes to Article 79 where fees are now split between fees for the Agency and fees for the evaluating authority. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 31

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 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.	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. ***Where such additional information includes animal testing, the applicant shall be advised by experts from the Agency or the evaluating 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.

Amendment 32

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.

(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 33

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) in 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).

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 34

Council position
Article 9 – paragraph 2

Council position	*Amendment*
2. Approved active substances shall be included in a Union list of authorised active substances. The Commission shall keep the list up to date and make it electronically available to the public.	***deleted***
	(Note: This amendment applies throughout the text. If adopted, any reference to Article 9(2) is to be deleted, and any reference to "the list drawn up in accordance with Article 9(2)" or the "list referred to in Article 9(2)" is to be replaced by a reference to "Annex -I".)

Justification

See linked amendments to Article 4(1) and Article 9(1). For reasons of legal certainty and transparency, active substances should continue to be included in an Annex to the Regulation itself and not in a separate document which is not part of the Regulation. This would also ensure that the Regulation is continually updated and amended (automatically upon the inclusion of an active substance), and would thus render a separate list unnecessary.

Amendment 35

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;

(Reinstatement of amendment 65 of first reading.)

Justification

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

Amendment 36

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;

Justification

Reinstatement of first reading.

Amendment 37

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.

(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 38

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

Council position	*Amendment*
	The evaluating competent authority shall, as soon as possible after the Agency has accepted an application, 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 30 days.

Justification

The new text takes into account the wording of Article 79 in which there is now one fee to be paid to the Agency and a separate fee for the evaluating competent authority. For consistency, there does not appear to be any reason for the deadline for the payment of fees to the evaluating competent authority to be shorter or longer than the deadline for payment of fees to the Agency. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation), and to clarify the text.

Amendment 39

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.	

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 40

Council position
Article 14 – paragraph 6

Council position	*Amendment*
6. Where the Commission decides not to renew the ***approval*** of an active substance	6. Where the Commission decides not to renew ***or to amend*** the ***inclusion*** of an

for one or more product-types ***it may grant a period of grace for the disposal, making available on the market and use of existing stocks*** of biocidal products of the product-type(s) concerned containing that active substance.	active substance ***in Annex -I*** for one or more product-types***, the Member States or, in the case of a Union authorisation, the Commission shall cancel or, where appropriate, amend the authorisations*** of biocidal products of the product-type(s) concerned containing that active substance. ***Article 51 shall apply accordingly.***
The period of grace shall not exceed 180 days for making available on the market and an additional maximum of 180 days for disposal and use of existing stocks of biocidal products of the product-type(s) concerned containing that active substance.	

Justification

According to Article 14 (4) of the Council proposal, the Commission can refuse the renewal of an approval, renew the approval or renew it in amended form under new conditions. In this third case, the original approval is amended, so it is important to refer to this possibility here. The current version of the text does not specify what happens after the Commission has taken a non-favourable decision on renewal. Therefore, it is important to describe the steps between the decision of non-renewal or restriction and the period of grace.

Amendment 41

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 about the safety of such biocidal products or treated articles.	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 ***significant*** concerns about the safety of such biocidal products or treated articles.

	The Commission may also review, and shall, in the light of new scientific and technical knowledge and monitoring data, take into account the request of a Member State to 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.

(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 42

Council position
Article 15 – paragraph 1 - subparagraph 2

Council position	*Amendment*
Where those indications are confirmed the Commission shall adopt ***an implementing Regulation*** amending the conditions of ***approval*** of an active substance or cancelling its ***approval***. ***That implementing Regulation shall be adopted in accordance with the examination procedure referred to in Article 81(3). Article 9(2) shall apply.*** The Commission shall inform the initial applicant(s) for the ***approval*** accordingly.	Where those indications are confirmed the Commission shall adopt ***delegated acts in accordance with Article 82*** amending the conditions of ***inclusion*** of an active substance ***in Annex -I*** or cancelling its ***inclusion***. The Commission shall inform the initial applicant(s) for the ***inclusion in Annex -I that it is carrying out a review and shall provide an opportunity for the applicant to submit comments. The Commission shall take due account of those comments in its review***.

Justification

The amendment of the conditions of approval/inclusion of an active substance in the Regulation is a measure of general application supplementing the basic act, and should therefore be subject to delegated rather than implementing acts.

Amendment 43

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***.

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 44

Council Position
Article 15 – paragraph 3 a (new)

Council position	*Amendment*
	3a. Where the Commission decides to cancel or amend the inclusion of an active substance in Annex -I for one or more product-types, the Member States or, in the case of a Union authorisation, the Commission shall cancel or, where appropriate, amend the authorisations of biocidal products of the product-type(s) concerned containing that active substance. Article 29 and Article 43, as appropriate, shall apply mutatis mutandis.

Justification

Amendment of the provision introduced by Council. The consequences of a review are the same as for a renewal: the Commission may cancel the approval or modify the conditions of approval.

Amendment 45

Council position
Article 16

Council position	*Amendment*
Implementing measures	***Detailed rules***
The Commission ***may*** adopt***, by means of implementing*** acts, detailed measures for the ***implementation*** of Articles 12 to 15, further specifying the procedures for the renewal and review of the ***approval*** of an active substance. ***Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).***	The Commission ***shall be empowered to*** adopt ***delegated*** acts ***in accordance with Article 82 specifying*** detailed ***rules*** for the ***application*** of Articles 12 to 15, further specifying the procedures for the renewal and review of the ***inclusion*** of an active substance ***in Annex -I***.

Justification

The drawing up of detailed rules for the application of Articles 12 to 15 is a measure of general application supplementing the basic act, and should therefore be subject to delegated rather than implementing acts.

Amendment 46

Council position
Article 17 – paragraph 1 a (new)

Council position	*Amendment*
	1a. 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.

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 47

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 notify each competent authority that has granted a national authorisation for a biocidal product family of each product within the 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.

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 48

Council position
Article 17 – paragraph 6 a (new)

Council position	*Amendment*
	6a. In order to unify authorisation practices in the Union and to reduce the administrative burden on manufacturers and competent authorities, the Commission shall adopt delegated acts in accordance with Article 82 specifying the conditions, criteria and procedures for authorising different undertakings to place on the market the same product for the same use. The criteria and the procedures for such measures shall be

based on, but not limited to, the following principles:

(a) no additional evaluation will be performed, as the biocidal product has already been authorised;
(b) authorisation decisions shall be taken within a short timeframe;
(c) authorisation fees shall be low in accordance with the limited administrative work required.

Justification.

The aim is to make it easier for biocidal products with the same formulation and intended use to be marketed under different brand names and by different manufacturers. As such authorisations relate to biocidal products whose formulations are identical, there is no need to assess their impact on human health and the environment again.

Amendment 49

Council position
Article 17 a (new)

Council position	*Amendment*
	Measures geared to the sustainable use of biocidal products
	Member States shall establish and implement mandatory measures on the basis of a Union framework directive in order to achieve the sustainable professional use of biocidal products, including the introduction of National Action Plans, integrated pest management, risk reduction measures and the promotion of alternatives.
	By ...*, the Commission shall submit a legislative proposal for the framework directive referred to in paragraph 1 to the European Parliament and the Council.
	**** Please insert date two years after adoption of this Regulation.***

Justification.

Reinstatement of Parliament's first-reading position.

Amendment 50

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

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

(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 51

Council position
Article 18 – paragraph 2 – point d

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

Justification

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

Amendment 52

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

Council position	*Amendment*
	(da) synergistic effects.

Justification

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

Amendment 53

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.

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 54

Council position
Article 18 – paragraph 7 a (new)

Council position	*Amendment*
	7a. Where, for active substances covered by Article 10(1)(a) of Regulation (EC) No 470/2009, it is not possible to establish a maximum residue limit in accordance with Article 9 of that Regulation at the time of the inclusion of the active substance in Annex -I, or where a limit established in accordance with Article 9 of that Regulation needs to be amended, the maximum residue limit shall be established or amended following the procedure referred to in Article 8 of that Regulation and on the basis of an application submitted by the prospective authorisation holder or its representative in accordance with Article 3 of that Regulation.

Justification

The Council text is not compatible with the procedures established under Regulation 470/2009. The proposed text ensures that the text of Biocides Regulation and that of Regulation 470/2009 are aligned. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation).

Amendment 55

Council position
Article 19 – paragraph 2 a (new)

Council position	*Amendment*
	2a. 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 of the official languages 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).

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 56

Council Position
Article 21 – paragraph 2 – point q a (new)

Council position	*Amendment*
	(qa) for toxicologically and ecotoxicologically relevant components of biocidal products and/or residues thereof, analytical methods including recovery rates and the limits of determination (LOD);

Justification.

Zum Inhalt von Zulassungen soll auch die Angabe der Analysemethoden und die jeweiligen Bestimmungsgrenzen zählen.

Amendment 57

Council Position
Article 21 – paragraph 2 a (new)

Council position	*Amendment*
	2a. In the case of a biocidal product family, one single authorisation number shall be provided for all biocidal products which belong to that product family.

Justification

Since there is single authorisation for biocidal product families, it should be expressly mentioned that the product family has one single authorisation number.

Amendment 58

Council position
Article 22 – paragraph 3 a (new)

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

(Partial reinstatement of amendment 124 from first reading.)

Justification

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

Amendment 59

Council position
Article 22 – paragraph 7

Council position	*Amendment*
7. Where it is decided not to authorise or to	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.	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.

(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 60

Council position
Article 23

Council position	*Amendment*
The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter and, in particular, Articles 21(2) and 22(3).	The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter and, in particular, Articles ***18(2)(d) and (da),*** 21(2) and 22(3).

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 61

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

Council position	*Amendment*
	(ba) the biocidal product does not contain

a nanomaterial;

(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 62

Council Position
Article 24 – point c a (new)

Council position	*Amendment*
	(ca) the biocidal product meets the critieria laid down in Article 18(1)(b)(ii) to (iv); and

Justification

This amendment ensures that future use of active substances/biocidal products in treated articles is already considered at the stage of approval of the active substances or authorisation of the biocidal products. Only those active substances/biocidal products fulfilling the conditions of Art. 18(1) or Art. 24 respectively shall be authorised for use in treated articles.

Amendment 63

Council position
Article 25 – paragraph 2 – subparagraph 1

Council position	*Amendment*
The Agency shall, ***after checking*** that it has been submitted in the correct format, notify the evaluating competent authority without delay ***that the application is available via the Register for Biocidal Products.***	The Agency shall ***check*** that it has been submitted in the correct format ***and*** notify the evaluating competent authority without delay.

Justification

The reference to the Register for Biocidal Products in this provision is now redundant. Article 70, as modified by the Council, now makes clear that the Biocidal Products Register is the exclusive means of exchanging information regarding applications and provides indications as to what should be uploaded into the Register and when. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve

consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 64

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 30 days. It shall inform the applicant accordingly.

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 65

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.

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 66

Council position
Article 25 – paragraph 5

Council position	*Amendment*
5. On authorising the biocidal product in accordance with paragraph 3 or 4, the evaluating competent authority shall without delay inform the applicant, the Agency and other competent authorities accordingly via the Register for Biocidal Products indicating the exact date of the authorisation.	***deleted***

Justification

The reference to the Register for Biocidal Products in this provision is now redundant. Article 70, as modified by the Council, now makes clear that the Biocidal Products Register is the exclusive means of exchanging information regarding applications and provides indications as to what should be uploaded into the Register and when. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 67

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 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.	1. A biocidal product authorised in accordance with Article 25 may be placed on the market in all Member States without the need for mutual recognition. However, the authorisation holder shall notify each Member State ***30 days*** 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.

Justification

As the objective of the simplified authorisation procedure is to ensure that certain products presenting lower risks to the environment and human health can be put quickly on the market, the deadline for the notification is sufficiently short in order not to prolong unnecessarily the related procedures. At the same time, it gives Member States enough time to act if necessary.

Amendment 68

Council position
Article 27 – paragraph 4 a (new)

Council position	*Amendment*
	4a. The Commission may adopt implementing acts further specifying the procedures to be followed with respect to an amendment of Annex I. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

Justification

The simplified procedure introduced by Council is not sufficiently specific regarding the procedures for introducing new substances into Annex I. In particular the role of ECHA in the process is unclear. These procedural arrangements could be addressed through implementing measures as foreseen in the amendment. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 69

Council position
Article 29 – paragraph 4

Council position	*Amendment*
4. Where the receiving competent authority decides to grant an authorisation it shall enter the following information in the Register for Biocidal Products:	***deleted***
(a) the summary of biocidal product characteristics referred to in Article 21(2);	
(b) the final assessment report;	

(c) any terms or conditions imposed on the making available on the market or use of the biocidal product.

Where the receiving competent authority decides not to grant an authorisation it shall enter the final assessment report in the Register for Biocidal Products.

In either case, it shall notify the applicant of its decision together with an electronic copy of the final assessment report.

Justification

The reference to the Register for Biocidal Products in this provision is now redundant. Article 70, as modified by the Council, now makes clear that the Biocidal Products Register is the exclusive means of exchanging information regarding applications and provides indications as to what should be uploaded into the Register and when. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 70

Council position
Article 30 – paragraph 3 – point a

Council position	*Amendment*
(a) ***a list*** of 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 ***been*** generated since the initial authorisation or, as appropriate, previous renewal***, or a letter of access to such data***; and

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 71

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 30 days. It shall inform the applicant accordingly.

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 72

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.

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 73

Council position
Article 30 – paragraph 8

Council position	*Amendment*
8. As soon as the receiving competent authority has taken a decision on whether to grant a renewal of a national authorisation, it shall update the information referred to in Article 29(4) in the Register for Biocidal Products. It shall	***deleted***

notify the applicant of its decision together with an electronic copy of the final assessment report.

Justification

The reference to the Register for Biocidal Products in this provision is now redundant. Article 70, as modified by the Council, now makes clear that the Biocidal Products Register is the exclusive means of exchanging information regarding applications and provides indications as to what should be uploaded into the Register and when. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 74

Council position
Article 32 – paragraph 1 – subparagraph 2

Council position	*Amendment*
The competent authorities of the Member States concerned 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***. They shall inform the applicant and the other competent authorities accordingly. Upon receipt of the fees payable under ***Article 79,*** the competent authority of the Member States concerned shall accept the application and inform the applicant indicating the date of acceptance.	The competent authorities of the Member States concerned 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***. They shall inform the applicant and the other competent authorities accordingly. Upon receipt of the fees payable under ***Article 79(2),*** the competent authority of the Member States concerned shall accept the application and inform the applicant indicating the date of acceptance.

Justification

The text should include a reference to Article 79(2), which is the correct reference for fees paid to Member States.

Amendment 75

Council position
Article 32 – paragraph 2 – subparagraph 2

Council position	*Amendment*
Within 90 days of validating the application, and subject to Articles 34, 35	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.	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.***

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 76

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 paragraph 2*** 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 together with the terms and conditions of the authorisation,*** and recorded their agreement in the Register for Biocidal Products.

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 77

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.

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 78

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

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

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 79

Council position
Article 33 – paragraph 5 a (new)

Council position	*Amendment*
	5a. 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.

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 80

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.***

Amendment 81

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.

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 82

Council position
Article 36 – paragraphs 1 and 2

Council position	*Amendment*
1. 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:	1. 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:
(a) the protection of the environment;	(a) the protection of the environment;
(b) public policy or public security;	(b) public policy or public security;
(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;
(d) the protection of national treasures possessing artistic, historic or archaeological value; or	(d) the protection of national treasures possessing artistic, historic or archaeological value; or

(e) the target organisms not being present in harmful quantities.

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.

2. 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.

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:***

(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).

The Commission's decision shall be addressed to the Member State concerned and the Commission shall inform the applicant thereof.

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

(e) the target organisms not being present in harmful quantities.

(ea) implementation of other Union legislation, and in particular Directive 98/83/EC.

Any of the Member States concerned may, 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.

2. 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.

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***.

Amendment 83

Council position
Article 41

Council position	*Amendment*
1. Applicants may apply for Union authorisation for biocidal products which have similar conditions of use across the Union ***and which fall within the following categories of biocidal products:***	1. Applicants may apply for Union authorisation for biocidal products which have similar conditions of use across the Union ***with the exception of biocidal products that contain active substances that fall under Article 5***:
(a) biocidal products of product-types 6, 7, 9, 10, 12, 13 and 22; and	***a) from 2013 the Union authorisation may be granted to biocidal products containing one or more new active substances;***
(b) with effect from 1 January 2020, all other biocidal products except for those of product-types 14, 15, 17, 20 and 21.	***b) from 2017 the Union authorisation may be granted to all categories of biocidal products.***
2. The Commission shall report to the European Parliament and the Council on the application of this Article by 31 December 2017. It shall, if appropriate, accompany its report with relevant proposals for adoption in accordance with the ordinary legislative procedure.	***No later than 31 December 2012, the Commission shall adopt delegated acts in accordance with Article 82 concerning the definition of "similar conditions of use across the Union".***

Amendment 84

Council position
Article 42 – paragraph 3 – subparagraph 2 a (new)

Council position	*Amendment*
	The evaluating competent authority shall, as soon as possible after the Agency has accepted an application, inform the applicant of the fee payable under Article 79(2) and shall reject the application if the applicant fails to pay the fee within 30 days.

Justification

The Council text does not take account of the changes to Article 79 where fees are now split

between fees for the Agency and fees for the evaluating authority. And for the sake of consistency, there does not appear to be any reason for the deadline for the payment of fees to the evaluating competent authority to be shorter or longer than the deadline for payment of fees to the Agency. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) and to clarify the text.

Amendment 85

Council position
Article 42 – 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 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 accordingly. In such cases, part of the fees paid in accordance with ***Article 79(1) and 79(2)*** shall be reimbursed.

Justification

The Council text does not take account of the changes to Article 79 where fees are now split between fees for the Agency and fees for the evaluating authority. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 86

Council position
Article 42 – paragraph 4 a (new)

Council position	*Amendment*
	4a. Where the Register for Biocidal Products shows that a competent authority is examining an application relating to the same biocidal product or has already authorised the same biocidal product, that competent authority shall be the evaluating competent authority.

Justification

By minimising duplication of work, such provision will help both national competent authorities and applicants save time and resources thereby avoiding any unnecessary administrative burdens or delays in the placing on the market of biocidal products.

Amendment 87

Council position
Article 43 – paragraph 3 a (new) and 4

Council position	*Amendment*
	3a. Within 30 days of the submission of its opinion to the Commission, the Agency shall transmit, in all the official languages of the European Union, the draft summary of the biocidal product characteristics, as referred to in Article 21(2), as applicable;
4. On receipt of the opinion of the Agency, the Commission shall adopt, by means of implementing acts, a decision on the Union authorisation of the biocidal product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3). ***As soon as the Commission has taken a decision to grant a Union authorisation, it shall enter the information referred to in Article 29(4) in the Register for Biocidal Products.***	4. 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).
The Commission may, at the request of a Member State***, decide*** to adjust certain conditions of a Union authorisation specifically for the territory of that Member State or ***decide*** that a Union authorisation shall not apply in the territory of that Member State, provided that such a ***request*** can be justified on one or more of the grounds referred to in Article 36(1).	***A*** Member State ***shall inform the Commission if it decides*** to adjust certain conditions of a Union authorisation specifically for the territory of that Member State or ***decides*** that a Union authorisation shall not apply in the territory of that Member State, provided that such a ***decision*** can be justified on one or more of the grounds referred to in Article 36(1).

Amendment 88

Council position
Article 45 – paragraph 2 – subparagraph 2 a (new)

Council position	*Amendment*
	The evaluating competent authority shall, as soon as possible after the Agency has accepted the application, inform the applicant of the fee payable under Article 79(2) and shall reject the application if the applicant fails to pay the fees within 30 days.

Justification

The Council text does not take account of the changes to Article 79 where fees are now split between fees for the Agency and fees for the evaluating authority. And for the sake of consistency, there does not appear to be any reason for the deadline for the payment of fees to the evaluating competent authority to be shorter or longer than the deadline for payment of fees to the Agency. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) and to clarify the text.

Amendment 89

Council position
Article 45 – paragraph 4 – subparagraph 1

Council position	*Amendment*
4. On receipt of the opinion of the Agency, the Commission shall adopt a decision to renew, or to refuse to renew, the Union authorisation in accordance with the examination procedure referred to in Article 81(3). ***As soon as the Commission has taken a decision, it shall update the information referred to in Article 29(4) in the Register for Biocidal Products.***	4. On receipt of the opinion of the Agency, the Commission shall adopt a decision to renew, or to refuse to renew, the Union authorisation in accordance with the examination procedure referred to in Article 81(3).

Justification

The reference to the Register for Biocidal Products in this provision is now redundant. Article 70, as modified by the Council, now makes clear that the Biocidal Products Register is the exclusive means of exchanging information regarding applications and provides indications as to what should be uploaded into the Register and when. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve

consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 90

Council position
Article 47 – paragraph 1 – point a

Council position	*Amendment*
(a) the ***conditions*** referred to in Article 18 are not satisfied;	(a) the ***requirements*** referred to in Article 18***, or, where relevant, in Article 24,*** are not satisfied;

Justification

This results from the introduction of the new Article 24 by the Council. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 91

Council position
Article 47 – paragraph 1 – point a a (new)

Council position	*Amendment*
	(aa) the authorisation fails to comply with requirements of Directive 2008/56/EC establishing a framework for community action in the field of marine environmental policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration, Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 98/83/EC on groundwater and Directive 2008/1/EC concerning integrated pollution prevention and control;

(Reinstatement of amendment 163 from first reading.)

Justification

It needs to be clarified that an authorisation shall be cancelled when it fails to comply with the requirements of relevant legislation for the protection of waters.

Amendment 92

Council position
Article 47 – paragraph 4

Council position	*Amendment*
4. As soon as the competent authority or, in the case of a Union authorisation, the Commission, has taken a decision to cancel or amend an authorisation, it shall update the information referred to in Article 29(4) relating to the biocidal product concerned in the Register for Biocidal Products.	***deleted***

Justification

Redundancy given that Article 70, as modified by the Council, now makes clear that the Biocidal Products Register is the exclusive means of exchanging information regarding applications and provides indications as to what should be uploaded into the Register and when. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 93

Council position
Article 48 – paragraph 2

Council position	*Amendment*
As soon as the competent authority or, in the case of a Union authorisation, the Commission, has taken a decision to cancel an authorisation, it shall update the information referred to in Article 29(4) relating to the biocidal product concerned in the Register for Biocidal Products.	***deleted***

Justification

The reference to the Register for Biocidal Products in this provision is now redundant. Article 70, as modified by the Council, now makes clear that the Biocidal Products Register is the exclusive means of exchanging information regarding applications and provides indications as to what should be uploaded into the Register and when. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 94

Council position
Article 49 – paragraph 2

Council position	*Amendment*
2. An authorisation holder seeking to change any of the information submitted in relation to the initial application for authorisation of the product shall apply to the competent authorities of relevant Member States having authorised the biocidal product concerned, or in the case of a Union authorisation, the Agency. Those competent authorities shall decide, or, in the case of a Union authorisation, the Agency shall examine and the Commission decide whether the conditions of Article 18 are still met and whether the terms and conditions of the authorisation need to be amended.	2. An authorisation holder seeking to change any of the information submitted in relation to the initial application for authorisation of the product shall apply to the competent authorities of relevant Member States having authorised the biocidal product concerned, or in the case of a Union authorisation, the Agency. Those competent authorities shall decide, or, in the case of a Union authorisation, the Agency shall examine and the Commission decide whether the conditions of Article 18, ***or, where relevant, Article 24,*** are still met and whether the terms and conditions of the authorisation need to be amended.
The application shall be accompanied by the fees payable under ***Article 79.***	The application shall be accompanied by the fees payable under ***Article 79(1) and 79(2).***

Justification

There should also be a cross reference to Article 24 which is a new Article introduced by the Council. The language concerning the payment of fees to the national authorities has been changed to make it consistent with the drafting of Article 79. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 95

Council Position
Article 49 – paragraph 2 a (new)

Council position	*Amendment*
	2a. An amendment to an existing authorisation shall fall under one of the following categories of changes:
	(a) administrative change;
	(b) minor change;
	(c) major change.

Justification

Reinstatement of first reading position.

Amendment 96

Council Position
Article 50 – paragraph 1

Council position	*Amendment*
In order to ensure a harmonised approach to the cancellation and amendment of authorisations, the Commission shall lay down detailed rules for the application of Articles 46 to 49 ***by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3)***.	In order to ensure a harmonised approach to the cancellation and amendment of authorisations, the Commission shall ***adopt delegated acts in accordance with Article 82 laying*** down detailed rules for the application of Articles 46 to 49***, including a dispute settlement mechanism***.

Justification

This is a measure of general application designed to supplement the basic act, and should therefore be subject to delegated, rather than implementing acts.

Amendment 97

Council position
Article 52 – paragraph 9

Council position	*Amendment*
9. Where a decision concerning the	***deleted***

application for a parallel trade permit is taken in accordance with the provisions of this Article, the competent authorities of Member States which have taken such a decision shall enter the information referred to in Article 29(4) in the Register for Biocidal Products.

Justification

The reference to the Register for Biocidal Products in this provision is now redundant. Article 70, as modified by the Council, now makes clear that the Biocidal Products Register is the exclusive means of exchanging information regarding applications and provides indications as to what should be uploaded into the Register and when. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 98

Council position
Article 53 – paragraph 1

Council position	*Amendment*
1. Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence (‘the applicant’) shall submit an application to the Agency and pay the applicable fee.	1. Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence (″the applicant″) shall submit an application to the Agency ***in the correct format*** and pay the applicable fee ***in accordance with Article 79(1)***.

Justification

In the assessment of technical equivalence, the Agency should have the possibility to ensure that applications are submitted according to the correct format. Applications not submitted according to the format or for which the required fee has not been paid, should be rejected.

Amendment 99

Council position
Article 53 – paragraph 2 a (new)

Council position	*Amendment*
	2a. In the event that the Agency decides

	that the application has not been submitted in the correct format or that the appropriate fee has not been paid, it shall reject the application and inform the applicant accordingly.

Justification

In the assessment of technical equivalence, the Agency should have the possibility to ensure that applications are submitted according to the correct format. Applications not submitted according to the format or for which the required fee has not been paid, should be rejected.

Amendment 100

Council position
Article 53 – paragraph 3 a (new)

Council position	*Amendment*
	3a. Where, in the opinion of the Agency, additional information is necessary to carry out the assessment of technical equivalence, the Agency shall ask the applicant to submit such information within a time limit specified by the Agency. The Agency shall reject the application if the applicant fails to submit the additional information within the specified time limit. The 90 day period referred to in paragraph 3 shall be suspended from the date of issue of the request until the information is received. The suspension shall not exceed 180 days except where justified by the nature of the data requested or in exceptional circumstances.

Justification

The proposed amendment acknowledges the fact that in some cases it will be necessary to get more information in order to finalise the assessment of technical equivalence and that the "clock should be stopped" while this information is generated. The 180 day delay introduced here is considered to be a reasonable period for the generation of the missing data. The same deadline is used in the Council text for obtaining additional information under other provisions (e.g. Articles 8(2), 29(2) and 43(2).

Amendment 101

Council position
Article 53 – paragraph 6

Council position	*Amendment*
6. The ***Commission*** may draw up technical guidance notes to facilitate the implementation of this Article.	6. The ***Agency*** may draw up technical guidance notes to facilitate the implementation of this Article.

Justification

Article 53 is a new Article introduced by the Council. Given that ECHA will be carrying out the assessments of technical equivalence, the Agency should take responsibility for the technical guidance notes. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 102

Council position
Article 54 – paragraph 1 – subparagraph 1

Council position	*Amendment*
By way of derogation from Articles 17 and 18, a competent authority may permit, for a period not exceeding ***270 days***, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use, if such a measure is necessary because of a danger to public health or the environment which cannot be contained by other means.	By way of derogation from Articles 17 and 18, a competent authority may permit, for a period not exceeding ***four months***, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use, if such a measure is necessary because of a danger to public health or the environment which cannot be contained by other means***, and if all of the following conditions are met:*** ***(a) the active substances concerned are approved for inclusion in Annex I or evaluated according to Article 4 of this Regulation and a full dossier is provided;*** ***(b) if the relevant active substances fall under Article 5(1) or Article 10(1), a mandatory substitution plan is established and implemented by the applicant or competent authority in order to replace***

	the relevant substances with non-hazardous chemical or non-chemical alternatives within two years of the date of approval; and
	(c) the application of the product is restricted to professional users who are certified pursuant to the requirements for an integrated pest management and the use is appropriately monitored.

(Reinstatement of amendment 175 from first reading.)

Amendment 103

Council position
Article 54 – paragraph 2

Council position	*Amendment*
2. By way of derogation from point (a) of Article 18(1) and until an active substance is approved, competent authorities and the Commission may authorise, for a period not exceeding three years, a biocidal product containing a new active substance.	***deleted***
Such a provisional authorisation may be issued only if, after dossiers have been evaluated in accordance with Article 8, the evaluating competent authority has submitted a recommendation for approval of the new active substance and the competent authorities which received the application for the provisional authorisation or, in the case of a provisional Union authorisation, the Agency, consider that the biocidal product may be expected to comply with points (b), (c) and (d) of Article 18(1) taking into account the factors set out in Article 18(2).	
The competent authorities or the Commission shall enter the information referred to in Article 29(4) in the Register for Biocidal Products.	
If the Commission decides not to approve	

the new active substance, the competent authorities which granted the provisional authorisation or the Commission shall cancel that authorisation.

Where a decision on the approval of the new active substance has not yet been adopted by the Commission when the period of three years expires, the competent authorities which granted the provisional authorisation, or the Commission, may extend the provisional authorisation for a period not exceeding one year, provided that there are good reasons to believe that the active substance will satisfy the requirements of Article 4(1) or, where applicable, Article 5(2). Competent authorities which extend the provisional authorisation shall inform the other competent authorities and the Commission of such action.

(Reinstatement of amendment 176 from first reading.)

Amendment 104

Council position
Article 55 – paragraph 2 – subparagraph 1

Council position	*Amendment*
2. Any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the relevant competent authority of the Member State where the experiment or test will occur. The notification shall include the information ***listed in the second subparagraph of paragraph 1***.	2. Any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the relevant competent authority of the Member State where the experiment or test will occur. The notification shall include the ***identity of the biocidal product or active substance, labelling data and quantities supplied. The person concerned shall also compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. They shall make this*** information ***available to the competent authorities on request.***

Justification

While it is important to maintain a record of the names and addresses of consumers, it is not feasible to supply these details in advance, particularly given that this article concerns release into the environment rather than human health.

Amendment 105

Council position
Article 57 – paragraph 3-5

Council position	*Amendment*
3. Where ***the release of the active substances contained in the biocidal products with which*** a treated article ***was treated or which it incorporates, is intended or expected under normal or reasonably foreseeable conditions of use,*** the person responsible for the placing on the market of that treated article shall ensure that the label provides the following information:	3. Where a treated article ***contains a biocidal product,*** the person responsible for the placing on the market of that treated article shall ensure that the label provides the following information:
(a) a statement that the treated article incorporates biocidal products;	(a) a statement that the treated article incorporates biocidal products;
(b) where substantiated, the biocidal property attributed to the treated article;	(b) where substantiated, the biocidal property attributed to the treated article;
(c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;	(c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;
	(ca) the name of all nanomaterials, followed by the word "nano" in brackets;
(d) any relevant instructions for use, including any precautions to be taken because of the biocidal products ***with*** which a treated article ***was treated or which it*** incorporates.	(d) any relevant instructions for use, including any precautions to be taken because of the biocidal products which a treated article incorporates.
	This paragraph shall not apply where at least equivalent labelling requirements for biocidal products in treated articles to meet information requirements concerning those active substances already exist under sector-specific

	legislation.
4. Where the release of the active substances contained in the biocidal products with which a treated article was treated or which it incorporates, is not intended or expected under normal or reasonably foreseeable conditions of use, the person responsible for the placing on the market of the treated article shall ensure that the label provides the following information:	
(a) a statement that the treated article was treated with biocidal products; and	
(b) the address of a website containing the name of all active substances used for the treatment, without prejudice to Article 24 of Regulation (EC) No 1272/2008.	
The label of such a treated article shall not lay claim to any biocidal property.	
5. The labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty.	5. The labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty ***in the national language or languages of the Member State on whose market the treated article is to be placed. In the case of treated goods which are not produced as part of a series, but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the customer with the relevant information.***

Amendment 106

Council position
Article 57 – paragraph 7

Council position	*Amendment*
7. Where there are ***serious*** indications that an active substance contained in a biocidal product with which a treated article is	7. Where there are ***significant*** indications that an active substance contained in a biocidal product with which a treated

treated or which it incorporates does not meet the conditions laid down in Article 4(1), 5(2) or 24, the Commission shall review the approval of that active substance or its inclusion in Annex I in accordance with Article 15(1) or 27(2).	article is treated or which it incorporates does not meet the conditions laid down in Article 4(1), 5(2) or 24, the Commission shall review the approval of that active substance or its inclusion in Annex I in accordance with Article 15(1) or 27(2).

(Amendment in line with part of amendment 74 of first reading in a modified form.)

Justification

New text by the Council. 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 107

Council position
Article 58 – paragraph 1 – introductory part

Council position	*Amendment*
1. Without prejudice to Articles 61 and 62, data submitted for the purposes of this Regulation shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except where:	1. Without prejudice to Articles 61 and 62, data submitted for the purposes of ***Directive 98/8/EC or of*** this Regulation shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except where:

Justification

Since Article 59 extends data protection to data submitted under Directive 98/8/EC they should benefit from the same level of protection in all respects.

Amendment 108

Council position
Article 58 – paragraph 1 – point a

Council position	*Amendment*
(a) the subsequent applicant has a letter of access; or	(a) the subsequent applicant has ***and submits*** a letter of access ; or

Justification

Point a) should include that the letter of access has to be submitted to the authorities in order to be used for the benefit of a subsequent applicant.

Amendment 109

Council position
Article 59 – paragraph 1 – subparagraph 2

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

Justification

Article 59 has been changed by the Council. The proposed amendment is a consequence of that amendment to ensure that data submitted to a Member State under national systems or practices for approval of biocidal products can benefit from the same regime of data protection as data submitted for the purposes of Directive 98/8/EC. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 110

Council position
Article 61 – paragraph 2

Council position	*Amendment*
2. Any person intending to perform tests or studies involving vertebrate animals or non-vertebrate animals ("the prospective applicant") shall ***ask the Agency whether such tests or studies have already been submitted in connection with a previous application under this Regulation or Directive 98/8/EC.***	2. Any person intending to perform tests or studies involving vertebrate animals or non-vertebrate animals, ("the prospective applicant"), shall ***submit a written request to the Agency to determine whether such tests or studies have already been submitted to the Agency, or to a competent authority in connection with a previous application under this Regulation or Directive 98/8/EC for an identical or technically equivalent product.***

	The request shall be accompanied by fees in accordance with Article 79(1). If the applicant fails to pay the fees, the Agency shall not consider the request.
The ***competent authority or the*** Agency shall verify whether such tests or studies have already been submitted.	The Agency shall verify whether such tests or studies have already been submitted.
Where such tests or studies have already been submitted in connection with a previous application, under this Regulation or Directive 98/8/EC, ***the competent authority or*** the Agency shall, without delay, communicate the name and contact details of the data ***owner*** to the prospective applicant.	Where such tests or studies have already been submitted ***to the Agency, or to a competent authority*** in connection with a previous application, under this Regulation or Directive 98/8/EC, the Agency shall, without delay, communicate the name and contact details of the data ***submitter(s)*** to the prospective applicant.
	The data submitter(s) shall where relevant, facilitate contacts between the prospective applicant and the data owner(s).
Where the data acquired under those tests or studies are still protected under Article 59, the prospective applicant:	Where the data acquired under those tests or studies are still protected under Article 59, the prospective applicant:
(a) shall, in the case of data involving tests on vertebrate animals, ***request from the data owner the right to refer to those tests or studies***; and	(a) shall, in the case of data involving tests on vertebrate animals; and
(b) may, in the case of data not involving tests on vertebrate animals, request from the ***data owner the right to refer to those*** tests or studies.	(b) may, in the case of data not involving tests on vertebrate animals,
	request from the ***data owner(s) all the scientific and technical data related to the*** tests and studies ***concerned as well as the right to refer to these data when submitting applications within the framework of this Regulation***.

Justification

On the basis of the most recent experience with REACH, some changes should made to the Council text to benefit from that experience and to ensure a consistent approach between the two regulatory frameworks. Firstly, the text should be more specific in terms of the data to be made available and the purposes for which it can be used. Secondly, in some cases the Agency will know the identity of the data submitter but not the data owner. Lastly, a request under this Article should be associated with the payment of a fee to prevent the provision

being (ab)used in order to collect market intelligence.

Amendment 111

Council Position
Article 62 – paragraphs 1-3

Council position	*Amendment*
1. Where a request has been made in accordance with Article 61(2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.	1. Where a request has been made in accordance with ***the sixth subparagraph of*** Article 61(2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.
2. Where such agreement is reached, the data owner shall make the data available to the prospective applicant ***and*** shall give the prospective applicant permission to refer to the data owner's tests or studies.	2. Where such agreement is reached, the data owner shall make ***all*** the ***scientific and technical*** data ***related to the tests and studies concerned*** available to the prospective applicant ***or*** shall give the prospective applicant permission to refer to the data owner's tests or studies ***where submitting applications under this Regulation.***
3. Where no ***such*** agreement is reached ***within 60 days of a request made according to Article 61(2)*** with respect to ***data involving*** tests ***on*** vertebrate animals, the prospective applicant shall***, without delay,*** inform the Agency***, competent authority*** and the ***data owner accordingly.*** Within 60 days of being informed ***about the failure to reach an agreement***, the Agency shall give the prospective applicant ***the right*** to refer to ***those*** tests ***or*** studies. ***Where the prospective applicant and data owner cannot agree, national courts shall decide on the*** proportionate share of the cost ***that the prospective applicant shall pay to the data owner***.	3. Where no agreement is reached with respect to tests ***and studies*** involving ***vertebrate animals,*** the prospective applicant shall inform the Agency and the ***data owner(s) thereof at the earliest one month after receipt, from the Agency, of the name and address of the data submitter(s).***
	Within 60 days of being informed, the Agency shall give the prospective applicant

permission to refer to ***the requested*** tests ***and*** studies ***involving vertebrate animals provided that the prospective applicant demonstrates that it has paid the data owner(s) for these tests and studies a share of cost incurred, and that every effort has been made to reach an agreement on the sharing of these tests and studies. The data owner(s) shall have a claim on the prospective applicant for*** a proportionate share of the cost ***incurred by it***.

Justification

On the basis of the most recent experience with REACH, some changes should made to the Council text to benefit from that experience and to ensure a consistent approach between the two regulatory frameworks. Some of the proposed changes are to ensure consistency with those proposed in relation to Article 61. In addition, the text should be aligned with the provisions applicable to data sharing under REACH. This amendment is of a technical nature and does not introduce substantive changes to the text. It aims to improve consistency (both within the text and with other pieces of legislation).

Amendment 112

Council Position
Article 62 – paragraph 4 a (new)

Council position	*Amendment*
	4a. The costs referred to in paragraph 4 may include costs from investigations, experiments or reports, including exposure and risk assessments, whose purpose is to determine the properties and behaviour of an active substance or of biocidal products, predict exposure to active substances and/or their relevant metabolites, determine safe levels of exposure and establish conditions for the safe use of biocidal products.

Amendment 113

Council position
Article 64 – paragraph 2 – subparagraph 2

Council position	*Amendment*
In order to facilitate such enforcement, manufacturers of biocidal products placed on the Union market shall maintain a suitable system of quality control of the manufacturing process ***without causing disproportionate administrative burden*** to ***economic operators*** and Member ***States***.	In order to facilitate such enforcement, manufacturers of biocidal products placed on the Union market shall maintain a suitable system of quality control of the manufacturing process***. To that end they shall establish and maintain, as a minimum, appropriate documentation in paper or electronic format with respect*** to***:***
	(a) the input of the ingredients to be added to the biocidal product to include specifications, manufacturing formulae and safety data sheets which are relevant to compliance and the safety of the biocidal product to be placed on the market;
	(b) the various manufacturing operations performed which are relevant to compliance and safety of the biocidal product to be placed on the market and allow its traceability; and
	c) data concerning the results of the quality control and batch identification.
	A Member State does not need to undertake a system of official controls where a company holds an internationally recognised quality assurance certificate (e.g. ISO9001) that includes an audit to verify, as a minimum, that all of the above elements have been maintained.
	Where necessary in order to ensure uniform application of this paragraph, the Commission may adopt implementing acts in accordance with the procedure referred to in Article 81(3)".

Justification

There are too many products on the market which are of poor quality. This amendment to the Council's text reinforces the possibility to secure an efficient control of the quality of products, as it is foreseen in other legislations. Furthermore, this provision will help to stimulate innovation with a view to have safer products on the market.

Amendment 114

Council position
Article 64 – paragraph 3 – subparagraph 1 – introductory part

Council position	*Amendment*
Every three years, from … , Member States shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The report shall include:	Every three years, from …, Member States shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The ***implementation reports shall be published on the relevant website of the Commission. The*** report shall include:

(Reinstatement of amendment 199 from first reading.)

Amendment 115

Council position
Article 64 – paragraph 3 – subparagraph 1 – point b

Council position	*Amendment*
(b) information on any poisonings and, where available, occupational diseases involving biocidal products.	(b) information on any poisonings and, where available, occupational diseases involving biocidal products***, especially regarding vulnerable groups, and the actions undertaken to lower the risk of future cases***.

(Reinstatement of amendment 200 from first reading.)

Amendment 116

Council position
Article 64 – paragraph 3 – subparagraph 1 – point b a (new)

Council position	*Amendment*
	(ba) information on the impact on the environment.

(Reinstatement of amendment 201 from first reading.)

Amendment 117

Council position
Article 64 – paragraph 4

Council position	*Amendment*
4. The Commission shall draw up a report on the implementation of this Regulation, in particular Article 57, by 1 January 2020. The Commission shall submit the report to the European Parliament and to the Council.	4. The Commission shall draw up a report on the implementation of this Regulation, in particular Article 57, by 1 January 2020 ***and every three years thereafter***. The Commission shall submit the report to the European Parliament and to the Council.

(Partial reinstatement of amendment 350 from first reading.)

Amendment 118

Council position
Article 64 – paragraph 4 a (new)

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

(Reinstatement of amendment 204 from first reading.)

Amendment 119

Council position
Article 64 – paragraph 4 b (new)

Council position	*Amendment*
	4b. At the latest two years after the entry into force of this Regulation, the

	Commission shall submit to the European Parliament and Council a report on the assessment of the risks to human health and the environment presented by the use of nanomaterials in biocidal products and on specific measures to be taken with regard to them.

(Reinstatement of amendment 203 from first reading.)

Justification

Nanomaterials fall within the scope of the Regulation. However, a proper assessment may well lack the necessary methods. There should be full transparency about how this Regulation deals with nanomaterials. As such, there should be a dedicated Commission report on the matter.

Amendment 120
Council position
Article 65 – paragraph 4 – subparagraph 1 a (new)

Council position	*Amendment*
	Information accepted as confidential by a competent authority or the Agency shall be treated as confidential by other competent authorities, the Agency and the Commission.

Amendment 121

Council position
Article 66 – paragraph 1 – subparagraph 1 – introductory part

Council position	*Amendment*
The following information held by the Agency or the Commission on active substances shall be made publicly ***and easily*** available ***free*** of ***charge***:	The following information held by the Agency or***, as appropriate,*** the Commission on active substances shall be made***, free of charge,*** publicly available ***in a single database, in a structured format on at least the relevant website*** of ***the Commission***:

Amendment 122

Council position
Article 66 – paragraph 1 – subparagraph 1 – point d

Council position	*Amendment*
(d) physicochemical ***data*** and data on pathways and environmental fate and behaviour;	(d) physicochemical ***endpoints*** and data on pathways and environmental fate and behaviour;

Justification

The word "data" is too generic and means studies doesn't refers directly to endpoints. It is necessary to clarify between the specific results of studies (endpoints) from the generic word data. The aim of the amendment is to underline the difference between "end results" and "studies".

Amendment 123

Council position
Article 66 – paragraph 2 a (new)

Council position	*Amendment*
	2a. Public access shall be granted free of charge to an inventory containing details of biocidal products authorised pursuant to Article 25 and of the corresponding manufacturers.

(Reinstatement of amendment 211 from first reading.)

Justification

It is essential to establish a product list to inform consumers about biocidal products authorised according to the new simplified authorization (which replaces the low risk procedure).

Amendment 124

Council position
Article 66 – paragraph 2 b (new)

Council position	*Amendment*
	2b. The Commission shall make available on the internet a list of all active substances available within the internal

market.

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

(Partial reinstatement of amendment 219 from first reading.)

Amendment 125

Council position
Article 68 – paragraph 2 – subparagraph 1 – point a a (new)

Council position	*Amendment*
	(aa) whether the product contains nanomaterials and any specific related risks, and, following each reference to nanomaterials, the word "nano" in brackets;

(Reinstatement of amendment 213 from first reading.)

Justification

The impact of nanomaterials on health and the environment is largely unknown at present, yet they may pose specific problems. Any user of a biocidal product should therefore be informed via adequate labelling.

Amendment 126

Council position
Article 70 – paragraphs 3 and 4

Council position	*Amendment*
3. Applicants shall use the Register for Biocidal Products to generate and submit ***the application form*** for all procedures ***relating to the approval of active substances and the authorisation of biocidal products, mutual recognition, the***	3. Applicants shall use the Register for Biocidal Products to generate ***application forms*** and ***to*** submit ***applications and data*** for all procedures ***covered by this Regulation.***

granting of parallel trade permits and the renewal, the cancellation and amendment of authorisations. Once the relevant competent authority has validated an application in accordance with Article 7, 28 or 42, or accepted an application in accordance with Article 13, 19 or 44, it shall be made available via the Register for Biocidal Products to all other competent authorities and to the Agency.

4. Competent authorities shall update the information in the Register for Biocidal Products relating to biocidal products which have been authorised within their territory or for which a national authorisation has been refused, amended, renewed or cancelled. The Commission shall update the information relating to biocidal products which have been authorised in the Union or for which a Union authorisation has been refused, amended, renewed or cancelled.

4***. The competent authorities and the Commission shall use the Register for Biocidal Products to record and communicate the decisions they have taken in relation to the authorisations of biocidal products and shall update the information in the Register at the time such decisions are taken. The*** competent authorities shall ***in particular*** update the information in the Register for Biocidal Products relating to biocidal products which have been authorised within their territory; for which a national authorisation has been refused, amended, renewed or cancelled***, or for which a parallel trade permit has been granted, refused or cancelled.*** The Commission shall***, in particular,*** update the information relating to biocidal products which have been authorised in the Union or for which a Union authorisation has been refused, amended, renewed or cancelled. ***The information to be introduced into the Registry shall include, as appropriate:***

(a) the terms and conditions of the authorisations;

(b) the summary of the biocidal product characteristics referred to in Article 21 (2);

(c) the assessment report of the biocidal product;

(d) the methods of analysis referred to in Article 18(1)(c).

The information referred to in this paragraph shall also be made available to

the applicant through the Register for Biocidal Products.

Justification

Article 70 has been changed by the Council making the Register for Biocidal Products the tool to be used for exchanging information in relation to the Regulation. The amendments proposed aim to clarify the way that the Register is to be used. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 127

Council position
Article 75 – paragraph 1 – point j a (new)

Council position	*Amendment*
	(ja) providing guidance and tools for the use phase, particularly:
	- measures for integrated pest management, for specified vermin,
	- monitoring biocidal product use,
	- best practice of biocidal product use to limit use of such products to the minimum necessary dose,
	- pest management in sensitive areas like schools, workplaces, kindergartens, public spaces, lakes, canals, riversides and geriatric care centres,
	- technical equipment for biocidal product application and its inspection.

Amendment 128

Council position
Article 75 – paragraph 1 – point j b (new)

Council position	*Amendment*
	(jb) providing assistance to and coordinating between Member States in order to avoid the parallel assessment of applications relating to the same or

similar biocidal products referred to in Articles 28(4) and 42(5).

Amendment 129

Council position
Article 79

Council position	*Amendment*
1. The Commission shall adopt, on the basis of the principles set out in paragraph 3, ***an implementing Regulation*** specifying: (a) the fees payable to the Agency, including an annual fee; (b) the rules defining conditions for reduced fees, fee waivers and the reimbursement of the member of the Biocidal Products Committee who acts as a rapporteur; and (c) conditions of payments.	1. The Commission shall adopt, on the basis of the principles set out in paragraph 3, ***delegated acts pursuant to Article 82*** specifying: (a) the fees payable to the Agency, including an annual ***and a submission*** fee; (b) the rules defining conditions for reduced fees, fee waivers and the reimbursement of the member of the Biocidal Products Committee who acts as a rapporteur; and (c) conditions of payments.
That implementing Regulation shall be adopted in accordance with the examination procedure referred to in Article 81(3). It shall apply only with respect to fees paid to the Agency.	***These delegated acts*** shall apply only with respect to fees paid to the Agency.
The Agency may collect charges for other services it provides. The fees payable ***to the Agency*** shall be set at such a level as to ensure that the revenue derived from the fees, when combined with other sources of the Agency's revenue pursuant to this Regulation, is sufficient to cover the cost of the services delivered.	The Agency may collect charges for other services it provides. The fees payable shall be set at such a level as to ensure that the revenue derived from the fees, when combined with other sources of the Agency's ***and competent authorities'*** revenue pursuant to this Regulation, is sufficient to cover the cost of the services delivered. ***The fees payable shall be published by the Agency.***
2. Member States shall directly charge applicants fees for services that they provide with respect to the procedures under this Regulation, including the services undertaken by Member States' competent authorities when acting as evaluating competent authority.	2. Member States shall directly charge applicants fees for services that they provide with respect to the procedures under this Regulation, including the services undertaken by Member States' competent authorities when acting as evaluating competent authority.
Based on the principles set out in	Based on the principles set out in

paragraph 3, the Commission ***may*** issue guidance concerning a harmonised structure of fees.	paragraph 3, the Commission ***shall*** issue guidance concerning a harmonised structure of fees.
Member States may levy annual fees with respect to biocidal products made available on their markets.	
Member States may collect charges for other services they provide.	
Member States shall set and publish the amount of fees payable to their competent authorities.	Member States shall set and publish the amount of fees payable to their competent authorities.
3. Both the ***implementing Regulation*** referred to in paragraph 1 and Member States' own rules concerning fees shall respect the following principles:	3. Both the ***delegated acts*** referred to in paragraph 1 and Member States' own rules concerning fees shall respect the following principles:
(a) fees shall be set at such a level as to ensure that the revenue derived from the fees is, in principle, sufficient to cover the cost of the services delivered and shall not exceed what is necessary to cover those costs;	(a) fees shall be set at such a level as to ensure that the revenue derived from the fees is, in principle, sufficient to cover the cost of the services delivered and shall not exceed what is necessary to cover those costs***, The level should also reflect the fact that (the funding of) the evaluation and authorisation procedure shall not be entirely financed by these fees;***
(b) partial reimbursement of the fee if the applicant fails to submit the information requested within the specified time limit;	(b) partial reimbursement of the fee if the applicant fails to submit the information requested within the specified time limit;
(c) the specific needs of ***SMEs*** shall be taken into account, as appropriate;	(c) the specific needs of ***small and medium sized enterprises*** shall be taken into account, ***with respect to a fee payment system,*** as appropriate; ***this shall have no bearing on the responsibility of the relevant competent authority to carry out a careful assessment in accordance with the provisions of this Regulation;***
(d) the structure and amount of fees shall take into account whether information has been submitted jointly or separately;	(d) the structure and amount of fees shall take into account whether information has been submitted jointly or separately;
(e) in duly justified circumstances, and where it is accepted by the Agency or the competent authority, the whole fee or a part of it may be waived; and	(e) in duly justified circumstances, and where it is accepted by the Agency or the competent authority, the whole fee or a part of it may be waived; and
(f) ***as regards Member States' rules only,*** the deadlines for the payment of fees ***to competent authorities*** shall be fixed taking	(f) the deadlines for the payment of fees shall be fixed taking due account of the deadlines of the procedures provided for in

due account of the deadlines of the procedures provided for in this Regulation.	this Regulation.

Amendment 130

Council Position
Article 88 – paragraph 1 – subparagraph 3

Council position	*Amendment*
In order to facilitate a smooth transition from Directive 98/8/EC to this Regulation, during the work programme the Commission shall adopt ***either implementing regulations providing that an active substance is approved, and under which conditions, or,*** in cases where the requirements of Article 4(1) or, where applicable, 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, ***implementing decisions stating 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). Regulations approving an active substance shall specify the date of approval. Article 9(2) shall apply.***	The Commission shall adopt***, by means of delegated acts in accordance with Article 82, decisions on the inclusion of an 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.*** In cases where the requirements of Article 4(1) or, where applicable, 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, ***the active substance shall not be included in Annex -I***.

Justification

Active substances should continue to be included in an Annex to the Regulation. The new proposed approach in the Council text - by which they would be subject to separate authorisations by way of implementing acts - lacks transparency. In addition, it is inconsistent with the corresponding provisions in Article 27 for the inclusion of active substances under the simplified procedure, which would continue to be regulated by way of delegated acts.

Amendment 131

Council position
Article 88 – paragraph 3 – subparagraph 2

Council position	*Amendment*
To that effect, those wishing to apply for	To that effect, those wishing to apply for

the authorisation or mutual recognition in parallel of biocidal products of that product-type containing no active substances other than existing active substances shall submit applications for authorisation or mutual recognition in parallel to Member States' competent authorities no later than the date of approval of the active substance(s). In the case of biocidal products containing more than one active substance, applications for authorisation shall be submitted no later than the date of approval of the last active substance for that product-type.	the authorisation or mutual recognition in parallel of biocidal products of that product-type containing no active substances other than ***approved*** existing active substances shall submit applications for authorisation or mutual recognition in parallel to Member States' competent authorities no later than the date of approval of the active substance(s). In the case of biocidal products containing more than one active substance, applications for authorisation shall be submitted no later than the date of approval of the last active substance for that product-type.

Amendment 132

Council position
Article 88 – paragraph 3 – subparagraph 3 – point a

Council position	*Amendment*
(a) the biocidal product shall no longer be made available on the market with effect from ***180 days after*** the date of approval of the active substance(s); and	(a) the biocidal product shall no longer be made available on the market with effect from the date of approval of the active substance(s); and

Justification

In the absence of application for authorisation or mutual recognition in parallel, there should be no transitional period for biocidal products with the exception of existing stocks.

Amendment 133

Council position
Article 89 – paragraph 2 – subparagraph 1

Council position	*Amendment*
1. Dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by …* shall ***continue to*** be evaluated by the competent authorities in accordance with the provisions of ***Directive 98/8/EC*** and, where relevant, Regulation (EC) No	1. Dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by …* shall be evaluated by the competent authorities in accordance with the provisions of ***this Regulation*** and, where relevant, Regulation (EC) No 1451/2007.

1451/2007.

To ensure a smooth transition, the Commission shall, no later than ... *, adopt a delegated act in accordance with Article 82 regarding the evaluation of dossiers submitted in accordance with Directive 98/8/EC.

This delegated act shall be based on the following principles:

(1) the evaluation shall be carried out on the basis of the information provided in the dossier as submitted under Directive 98/8/EC;

(2) where the evaluation identifies concerns arising from the application of provisions of the present Regulation, which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information;

(3) every effort shall be made to avoid additional testing on vertebrate animals;

(4) every effort shall be made to avoid causing delays to the review programme laid down in Regulation (EC) No 1451/2007 as a result of these transitional arrangements.

* OJ: Insert the date - the day of application of this Regulation

* OJ: Insert the date - the day of application of this Regulation

Amendment 134

Council position
Article 89 a (new)

Council position	*Amendment*
	Transitional measures concerning applications for biocidal product authorisations submitted under Directive 98/8/EC
	Dossiers submitted for the purposes of

	Directive 98/8/EC for which the evaluation has not been completed by …* shall be evaluated by the competent authorities in accordance with this Regulation. ***To ensure a smooth transition, the Commission shall, no later than ... *, adopt a delegated act in accordance with Article 82 regarding the evaluation of dossiers submitted in accordance with Directive 98/8/EC. This delegated act shall be based on the following principles:*** ***(1) the evaluation shall be carried out on the basis of the information provided in the dossier as submitted under Directive 98/8/EC;*** ***(2) where the evaluation identifies concerns arising from the application of provisions of the present Regulation, which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information;*** ***(3) every effort shall be made to avoid additional testing on vertebrate animals.*** **** OJ: Insert the date - the day of application of this Regulation***

Amendment 135

Council position
Article 91 – paragraph 2

Council position	*Amendment*
2. This Regulation shall apply to biocidal products referred to in paragraph 1 from the date of the expiry of the authorisation or its cancellation.	2. This Regulation, ***with the exception of Chapter IV thereof,*** shall apply to biocidal products referred to in paragraph 1 from ***1 January 2013***. ***Chapter IV of this Regulation shall apply to biocidal products referred to in paragraph 1 from the date of expiry or cancellation of the authorisation.***

Justification

Article 91 is new text introduced by the Council. Under the current wording, the Regulation does not apply to products authorised under the Directive, at least not before the expiry or the cancellation of the authorisation granted in accordance with the provisions of the Directive. This would mean that certain important provisions, such as those concerning changes to authorised products, would not apply. This is not however a desired objective of the new Regulation and the text should therefore be amended.

Amendment 136

Council position
Article 92 – paragraph 1 a (new)

Council position	*Amendment*
	1a. Paragraph 1 shall not apply to active substances produced in situ for the purpose of disinfecting drinking water.

Justification

In some circumstances drinking water treatment involves the direct production of disinfection products on site used solely for that site or process. These are not placed on the market and therefore should be excluded from the scope of the regulation. Articles 7 and 10 of DWD provide for proper and appropriate use of disinfectants whether from the market or generated on site.

Amendment 137

Council position
Article 94

Council position	*Amendment*
1. Applications for the authorisation of biocidal products which are food contact materials and which were available on the market on …* shall be submitted at the latest by 1 January 2017.	***deleted***
By way of derogation from Article 17(1), biocidal products which are food contact materials and which were available on the market on …* for which an application was submitted in accordance with the first subparagraph of this paragraph may continue to be made available on the	

market until the date of the decision granting the authorisation. In case of a refusal to grant an authorisation, such biocidal products shall no longer be made available on the market within 180 days after such decision.

By way of derogation from Article 17(1), biocidal products which are food contact materials and which were available on the market on …* for which an application was not submitted in accordance with the first subparagraph of this paragraph may continue to be made available on the market until 180 days after the date referred to in the first subparagraph of this paragraph.

2. Disposal and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission may continue until 365 days after the date of the decision referred to in the second subparagraph of paragraph 1 or twelve months after the date referred to in the third subparagraph of paragraph 1, whichever is the later.

Justification

These transitional measures concerning food contact materials are not necessary as food contact materials will be regarded as treated articles. The transitional measures for treated articles laid down in Article 93 will apply to food contact materials. This amendment is of a technical nature and does not introduce substantive changes to the text. It is intended to improve consistency (both within the text and with other pieces of legislation) to avoid repetition, or to clarify or simplify the text.

Amendment 138

Council Position
Article 95 – paragraph 1 - subparagraph 3

Council position	*Amendment*
For the purposes of this paragraph and for existing active substances listed in Annex II to Regulation (EC) No 1451/2007, the provisions on ***mandatory***	For the purposes of this paragraph and for existing active substances listed in Annex II to Regulation (EC) No. 1451/2007, the provisions on data sharing,

data sharing, as laid down in Articles 61 ***and*** 62 of this Regulation, shall apply to all ***toxicological and ecotoxicological*** studies included in the dossier. The relevant person shall be required to apply for data sharing only for those data that it does not already possess.	as laid down in Articles 61***,*** 62 ***and 63*** of this Regulation, shall apply to all studies included in the dossier. The relevant person shall be required to apply for data sharing only for those data that it does not already possess.

Justification

Since the Regulation does not contain rules concerning mandatory data sharing, this word should be deleted. Furthermore, as Article 63 concerning the use of data for subsequent applications also provides for a kind of data sharing, it should be referred to in this paragraph. These provisions should also apply to studies in a general manner.

Amendment 139

Council position
Article 95 – paragraph 3 - subparagraph 1

Council position	*Amendment*
3. As of …*, biocidal products containing an active substance, for which no relevant person is included in the list referred to in paragraph 2, shall not be ***made available*** on the market.	3. As of …*, ***a biocidal*** product shall not be ***placed*** on the market ***if the manufacturer or importer of the active substance(s) contained in the product, or where relevant, the importer of the biocidal product is not included in the list referred to in paragraph 2***.

Justification

This Article has been changed substantially by Council. The present reference to a "relevant person" is not clear and the proposed amendment provides the necessary clarification.

Amendment 140

Council Position
Annex -I (new)

Council position	*Amendment*
	Annex -I
	List of active substances with requirements for inclusion in biocidal products

(The full text of Annex I of Parliament's Position at first reading (EP-PW-TC1-COD(2009)0076) shall be re-inserted as Annex -I (new).)

Justification

Active substances should continue to be included in an Annex to the Regulation. The new proposed approach in the Council text - by which they would be subject to separate authorisations by way of implementing acts - lacks transparency. In addition, it is inconsistent with the corresponding provisions in Article 27 for the inclusion of active substances under the simplified procedure, which would continue to be regulated by way of delegated acts.

Amendment 141

Council Position
Annex I – Category 3 – 200-580-7 Acetic acid

Council position

200-580-7	***Acetic acid***	***Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008.***

Amendment

deleted

Justification

This active substance does not comply with the exclusion criteria listed in Art. 27/2 (e.g. skin corrosivity).

Amendment 142

Council Position
Annex I – Category 3 – 201-176-3 Propionic acid

Council position

201-176-3	***Propionic acid***	***Concentration to be limited so that each biocidal product does not require classification according to either Directive***

1999/45/EC or Regulation (EC) No 1272/2008.

Amendment

deleted

Justification

This active substance does not comply with the exclusion criteria listed in Art. 27/2 (e.g. skin corrosivity).

Amendment 143

Council Position
Annex I – Category 7 – 203-376-6 Citronellal

Council position		*Amendment*
203-376-6	***Citronellal***	***deleted***

Justification

This active substance does not comply with the exclusion criteria listed in Art. 27/2 (e.g. skin corrosivity).

Amendment 144

Council position
Annex II – point 5

Council position	*Amendment*
5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[66] . However, if a method is inappropriate or not described, other methods shall be used which are***, whenever possible, internationally recognised*** and must be	5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[66] . ***Methods listed in Annex I do not cover nanomaterials, except where specifically mentioned.*** However, if a method is inappropriate or not described, other

justified in the application.	methods shall be used which are ***scientifically satisfactory*** and ***the validity of which*** must be justified in the application.

(Reinstatement of amendment 346 from first reading)

Justification

The relevant scientific committee of the Commission concluded that the knowledge on the methodology for both exposure estimates and hazard identification of nanomaterials needs to be further developed and validated. As such, existing methods for bulk chemicals cannot be assumed to provide relevant data. Until the validity of standard test methods has been assessed for nanomaterials, a special justification has to be given for the use of these tests for the assessment of nanomaterials.

Amendment 145

Council position
Annex II – Title 1 – 7.5. – Column 1

Council position	*Amendment*
7.5. Likely tonnage to be placed on the market per year	7.5. Likely tonnage to be placed on the market per year ***and where relevant, for the envisaged major use categories.***

Justification

Additional information is important at both active substance level (Annex II) and for the Biocidal Product (Annex III) in order to allow for a proper cumulative risk assessment for biocidal products where relevant.

Amendment 146

Council position
Annex II – Title 1 – 8.7. Acute toxicity – Column 1

Council position	*Amendment*
8.7. Acute toxicity	8.7. Acute toxicity
In addition to the oral route of administration (8.7.1), for substances other than gases, the information mentioned under 8.7.2 to 8.7.3 shall be provided for at least one other route of administration**.**	In addition to the oral route of administration (8.7.1), for substances other than gases, the information mentioned under 8.7.2 to 8.7.3 shall be provided for at least one other route of administration.

– The choice for the second route will depend on the nature of the substance and the likely route of human exposure.	– The choice for the second route will depend on the nature of the substance and the likely route of human exposure.
– Gases and volatile liquids should be administered by the inhalation route	– Gases and volatile liquids should be administered by the inhalation route
– If the only route of exposure is the oral route, then information for only that route need be provided. If either the dermal or inhalation route is the only route of exposure to humans then an oral test may be considered.	– If the only route of exposure is the oral route, then information for only that route need be provided. If either the dermal or inhalation route is the only route of exposure to humans then an oral test may be considered. ***Before a new dermal acute toxicity study is carried out, an in vitro dermal penetration study (OECD 428) should be conducted to assess the likely magnitude and rate of dermal bioavailability.***
– There may be ***specific*** circumstances where all routes of administration are deemed necessary.	– There may be ***exceptional*** circumstances where all routes of administration are deemed necessary.

Justification

Acute toxicity studies can sometimes lead to morbidity or mortality in animal specimens. Requiring such studies by more than one exposure route (i.e. oral + skin + inhalation) should be the exception rather than the rule. This is especially true for dermal (skin) testing, which has been shown in several independent analyses to add nothing of value for classification purposes in more than 98% biocides and other substances examined.

Amendment 147

Council Position
Annex II – Title 1 – 8.7. Acute toxicity – Column 3

Council position	*Amendment*
The study/ies do(es) not generally need to be conducted if:	The study/ies do(es) not generally need to be conducted if:
– the substance is classified as corrosive to the skin.	– the substance is classified as corrosive ***or severely irritating*** to the skin.
	If studies are nevertheless carried out concentrations that are corrosive or severely irritating to the skin shall not be used.

Amendment 148

Council Position
Annex II – Title 1 – 8.7.3. Acute toxicity - by dermal route – Column 1

Council position	*Amendment*
8.7.3. By dermal route	8.7.3. By dermal route
Testing by the dermal route is ***appropriate*** if:	Testing by the dermal route is ***necessary only*** if:
– inhalation of the substance is unlikely; ***or***	– inhalation of the substance is unlikely;
– skin contact in production and/or use is likely; ***or***	– skin contact in production and/or use is likely;
– the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.	– the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin; ***and***
	– the results of an in vitro dermal penetration study (OECD 428) demonstrate high dermal absorption and bioavailability.

Amendment 149

Council Position
Annex II – Title 1 – 8.9. Repeated dose toxicity – Column 1 - point (i)

Council position	*Amendment*
Repeated dose toxicity	Repeated dose toxicity
(i) toxicity is observed in ***the*** acute dermal toxicity test at lower doses than in the oral toxicity test ;	(i) toxicity is observed in ***an*** acute dermal toxicity test at lower doses than in the oral toxicity test;

Amendment 150

Council Position
Annex II – Title 1 – 8.9. Repeated dose toxicity – Column 3 - subparagraph 1a (new)

Council position	*Amendment*
	In order to reduce testing carried out on vertebrate animals and in particular the need for free-standing, single-end point studies the design of the repeated dose toxicity studies shall take account of the possibility to explore several end-points within the framework of one study.

Amendment 151

Council Position
Annex II – Title 1 – 8.10.1 – Column 1

Council position	*Amendment*
8.10.1. Pre-natal developmental toxicity study, preferred species is rabbit; oral route of administration is the preferred route.	8.10.1. Pre-natal developmental toxicity study, preferred species is rabbit; oral route of administration is the preferred route.
The study shall be initially performed on one species. ***A decision on the need to perform additional studies on a second species (rat) or mechanistic studies should be based on the outcome of the first test and all other relevant available data.***	The study shall be initially performed on one species.

Amendment 152

Council position
Annex II – Title 1 – 8.10.2 – Column 1

Council position	*Amendment*
8.10.2. Two-generation reproductive toxicity study, rat, oral route of administration is the preferred route.	8.10.2. Two-generation reproductive toxicity study, rat, oral route of administration is the preferred route.
If another reproductive toxicity test is used justification shall be provided.	If another reproductive toxicity test is used justification shall be provided. ***Now that an extended one-generation reproductive***

	toxicity study has been adopted at OECD level it should be considered as an alternative approach to the multi-generation study.

Amendment 153

Council Position
Annex II – Title 1 – 8.10.3 – Column 1

Council position	*Amendment*
8.10.3. Further pre-natal developmental toxicity study**,** preferred species is rat, oral route of administration.	8.10.3. Further pre-natal developmental toxicity study. ***A decision on the need to perform additional studies on a second species or mechanistic studies should be based on the outcome of the first test (8.10.1) and all other relevant available data (in particular rodent reprotox studies).*** Preferred species is rat, oral route of administration.

Amendment 154

Council Position
Annex II – Title 1 – 8.13.2. Neurotoxicity including developmental neurotoxicity – Column 1 - title

Council position	*Amendment*
8.13.2. Neurotoxicity, ***including developmental neurotoxicity***	8.13.2. Neurotoxicity

Justification.

Die Prüfung der Entwicklungsneurotoxizität wird unter den klar im Text definierten Umständen weiterhin notwendig.

Amendment 155

Council Position
Annex II – Title 1 – 8.13.4. Immunotoxicity including developmental immunotoxicity – Column 1 - title

Council position	*Amendment*
8.13.4. Immunotoxicity ***including developmental immunotoxicity***	8.13.4. Immunotoxicity

Justification.

Die Prüfung der Entwicklungsneurotoxizität wird unter den klar im Text definierten Umständen weiterhin notwendig.

Amendment 156

Council position
Annex II – Title 1 – 8.13. – Column 1 – paragraph 1a (new)

Council position	*Amendment*
	Other available data: Available data from emerging methods and models, including toxicity pathway-based risk assessment, in vitro and 'omic (genomic, proteomic, metabolomic, etc.) studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening shall be submitted in parallel.

Justification

The explosive growth of computing power and computational biology has made available a wide range of new tools for studying the effects of chemicals on cells, tissues and organisms in a rapid and cost-efficient manner. As companies begin to incorporate these tools and tests into their in-house product stewardship programmes, these data should be submitted in parallel to maximise the availability of mechanistic data to support regulation, and to build confidence in the use of new methods to replace or reduce animal use.

Amendment 157

Council position

Annex II – Title 1 – 9.1.11. – Columns 1 and 2

Council position	*Amendment*
9.1.11. Amphibian metamorphosis assay - ADS	***deleted***

Amendment 158

Council position
Annex II – Title 1 – 9.9. – Column 3 (new)

Council position	*Amendment*
	Data are derived from the mammalian toxicological assessment. The most sensitive relevant mammalian long-term toxicological endpoint (NOAEL) expressed as mg test compound/kg bw/day shall be reported.

Justification

Because it is standard to use rodent and other mammalian data developed for human health assessments in environmental toxicology assessments aimed at protecting wild mammals, this should be stated explicitly to avoid unnecessary additional animal testing. The language of the proposed amendment is derived from proposed new EU data requirements for plant protection products.

Amendment 159

Council position
Annex II – Title 2 – 7. Effects on human and animal health – Column 3 (new)

Council position	*Amendment*
	Information requirements in this section may be adapted as appropriate in accordance with the specifications of Title 1 of this Annex.

Justification

Adaptation of certain standard information requirements for microbial biocides through the addition of qualifying sentence to the introductory text.

Amendment 160

Council position
Annex II – Title 2 – 7.2.2.2. Acute inhalatory toxicity– Column 2 (new)

Council position	*Amendment*
	ADS

Justification

Acute toxicity studies can sometimes lead to morbidity or mortality in animal specimens. Requiring such studies by more than one exposure route (i.e. oral + inhalatory + intraperitoneal/subcutaneous) should be the exception rather than the rule. Accordingly, acute pulmonary toxicity should at most be a second-tier data requirement.

Amendment 161

Council position
Annex II – Title 2– 7.2.2.3. Intraperitoneal/subcutaneous single dose – Column 2 (new)

Council position	*Amendment*
	ADS

Justification

Acute toxicity studies involve literally poisoning animals to death, making them among the most severe and ethically objectionable type of toxicity test. Requiring such studies by more than one exposure route (i.e. oral + pulmonary + intraperitoneal/subcutaneous) should be the exception rather than the rule. Accordingly, acute pulmonary toxicity should at most be a second-tier data requirement. Accordingly, an acute injection study should at most be a second-tier data requirement.

Amendment 162

Council position
Annex II – Title 2 – 8. Effects on non-target organisms – Column 3 (new)

Council position	*Amendment*
	Information requirements in this section may be adapted as appropriate in accordance with the specifications of Title 1 of this Annex.

Justification

The Commission has expressed support in principle for the adaptation of certain standard information requirements for microbial biocides through the addition of qualifying sentence to the introductory text.

Amendment 163

Council position
Annex III – point 5

Council position	*Amendment*
5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. However, if a method is inappropriate or not described, other methods shall be used which are***, whenever possible, internationally recognised and*** scientifically ***appropriate*** and must be justified in the application**.**	5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. ***Methods listed in Annex I do not cover nanomaterials, except where specifically mentioned.*** However, if a method is inappropriate or not described, other methods shall be used which are scientifically ***satisfactory*** and ***the validity of which*** must be justified in the application

(Reinstatement of amendment 293 from first reading.)

Justification

The relevant scientific committee of the Commission concluded that the knowledge on the methodology for both exposure estimates and hazard identification of nanomaterials needs to be further developed and validated. As such, existing methods for bulk chemicals cannot be assumed to provide relevant data. Until the validity of standard test methods has been assessed for nanomaterials, a special justification has to be given for the use of these tests for the assessment of nanomaterials.

Amendment 164

Council position
Annex III – Title 1 – 7.5. – Column 1

Council position	*Amendment*
7.5 Likely tonnage to be placed on the market per year	7.5 Likely tonnage to be placed on the market per year ***and where relevant, for different use categories.***

Justification

Additional information is important at both active substance level (Annex II) and for the Biocidal Product (Annex III) in order to allow for a proper cumulative risk assessment for biocidal products where relevant.

Amendment 165

Council Position
Annex III – Title 1 – 8.5.4. – Column 1

Council position	*Amendment*
8.5.4. For biocidal products that are intended to be authorised for use with other biocidal products, ***consideration should be given totesting combinations of the products for acute dermal toxicity and skin and eye irritation.***	8.5.4. For biocidal products that are intended to be authorised for use with other biocidal products, ***the risks to human health and the environment arising from the use of these product combinations shall be assessed. In some cases, for example where there is no valid data available of the kind set out in column 3, this may require a limited number of acute toxicity studies to be carried out using combinations of the products.***

Amendment 166

Council Position
Annex III – Title 1 – 8.7 – Column 1

Council position	*Amendment*
8.7. Available toxicological data relating to: – co-formulants (i.e. substance(s) of concern), or – a mixture that a substance(s) of concern is a component of **–** If ***no*** data ***is*** available, ***then the appropriate*** test(s) described in Annex II, shall be carried out for the ***co-formulants (i.e***. substance(s) of concern***)*** or a mixture that a substance(s) of concern is a component of.	8.7. Available toxicological data relating to: – co-formulants (i.e. substance(s) of concern), or – a mixture that a substance(s) of concern is a component of. If ***insufficient*** data ***are*** available ***for a co-formulant(s) and cannot be inferred through read-across or other accepted non-testing approaches, targeted acute*** test(s) described in Annex II, shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern

	is a component of.

Amendment 167

Council Position
Annex III – Title 1 – 9.3. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk – Column 3

Council position	*Amendment*
	Data for the assessment of hazards to wild mammals are derived from the mammalian toxicological assessment.

Amendment 168

Council position
Annex III – Title 2 – 8.7. – Column 1

Council position	*Amendment*
8.7. Available toxicological data relating to:	8.7. Available toxicological data relating to:
- co-formulants (i.e. substance(s) of concern), or	– co-formulants (i.e. substance(s) of concern), or
- a mixture that a substance(s) of concern is a component of	– a mixture that a substance(s) of concern is a component of**.**
If ***no*** data ***is*** available, ***then the appropriate*** test(s) described in Annex II, shall be carried out for the ***co-formulants (i.e.*** substance(s) of concern***)*** or a mixture that a substance(s) of concern is a component of	If ***insufficient*** data ***are*** available ***for a coformulant(s) and cannot be inferred through read-across or other accepted non-testing approaches***, ***targeted acute*** test(s) described in Annex II, shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of**.**

Justification

Annex III sets out the requirements for biocidal products, including chemical products (Title 1) and micro-organisms (Title 2). The data requirement 8.7 appears in both titles. If the data requirement 8.7 in Title 1 is amended (Amendment 96), the same amendment needs to be made to the corresponding data requirement 8.7 in Title 2 to ensure consistency.

Amendment 169

Council Position
Annex III – Title 2 – 8.8. – Column 1

Council position	*Amendment*
Supplementary studies for combinations of biocidal products	Supplementary studies for combinations of biocidal products
For biocidal products that are intended to be authorised for use with other biocidal products, ***the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate.***	For biocidal products that are intended to be authorised for use with other biocidal products, ***the risks to humans and the environment arising from the use of these product combinations shall be assessed. In some cases, for example where there is no valid data available of the kind set out in column 3, this may require a limited number of acute toxicity studies to be carried using combinations of the products.***

Amendment 170

Council Position
Annex III – Title 2 – 9.3. Effects on any other specific non-target organisms (flora and fauna) believed to be at risk – Column 3

Council position	*Amendment*
	Data for the assessment of hazards to wild mammals are derived from the mammalian toxicological assessment.

Amendment 171

Council position
Annex V – Main Group 1: Disinfectants – Product-type 2 – paragraph 5 a (new)

Council position	*Amendment*
	These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Justification.

Clarification, to ensure that washing and cleaning products which contain for example acids (to remove lime), alkalis (to remove greasy dirt), oxidising agents (to bleach stains) or alcohol (as a solvent) do not require authorisation as biocidal products. These substances may have a biocidal side-effect.

Amendment 172

Council position
Annex V – Main group 1: Disinfectants – product-type 6 – paragraph 2

Council position	*Amendment*
Products used as preservatives for the storage or use of rodenticide or ***insecticide*** baits.	Products used as preservatives for the storage or use of rodenticide***, insecticide*** or ***other*** baits.

Amendment 173

Council Position
Annex V– Main Group 2: Preservatives – Product-type 9 – paragraph 1 a (new)

Council position	*Amendment*
	This product-type includes agents which antagonise the settlement of micro organisms (e.g. pathogenic germs and those developing odour) on the surface of materials and therefore hamper or avoid the development of odour and /or offer other kinds of benefits.

Justification.

If textiles are treated with biocidal products, the prime concern is generally not to protect the fibres but rather to control the settlement of micro-organisms on the surface of the textile.

Amendment 174

Council position
Annex VI– Introduction – point 3

Council position	*Amendment*
3. In order to ensure a high and harmonised level of protection of human and animal health and of the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of any risks that are identified. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product taking into account any cumulative and synergistic effects.	3. In order to ensure a high and harmonised level of protection of human and animal health and of the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of any risks that are identified. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product taking into account any cumulative and synergistic effects. ***Scientific definitions and methodologies for the assessment of cumulative or synergistic effects will be based on the technical guidance notes provided by the Commission as foreseen in Article 23.***

Justification

At present, there is no single agreed scientific definition for the concepts of cumulative and synergistic effects, neither is there a common, agreed method of analysis. The Commission should adopt these definitions and methodologies by way of technical guidance notes, before the regulation's entry into force.

Amendment 175

Council position
Annex VI – Assessment – point 15

Council position	*Amendment*
15. In carrying out the assessment, the possibility of cumulative or synergistic effects shall also be taken into account.	15. In carrying out the assessment, the possibility of cumulative or synergistic effects shall also be taken into account. ***Scientific definitions and methodologies for the assessment of cumulative or synergistic effects will be based on the technical guidance notes provided by the Commission as foreseen in Article 23.***

Justification

At present, there is no single agreed scientific definition for the concepts of cumulative and synergistic effects, neither is there a common, agreed method of analysis. The Commission should adopt these definitions and methodologies by way of technical guidance notes, before the regulation's entry into force.

Amendment 176

Council position
Annex VI – Assessment – point 47 a (new)

Council position	*Amendment*
	47 a. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) if it contains any substance of concern or of relevant metabolites or breakdown or reaction products fulfilling the criteria for being PBT or vPvB in accordance with Annex XIII of Regulation (EC) No 1907/2006, or have endocrine-disrupting properties unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Justification

In order to ensure proper consideration of potentially PBT and vPvB substances. The exclusion criteria in Article 5 give some security that the active substances do not have such properties; however this also applies for coformulants in biocidal products especially because the concentration of these substances normally exist in much higher concentrations compared to the active substances.

Amendment 177

Council position
Annex VI – Assessment – point 52

Council position	*Amendment*
52. In each of the areas where risk assessments have been carried out, the evaluating body shall combine the results for the active substance together with the	52. In each of the areas where risk assessments have been carried out, the evaluating body shall combine the results for the active substance together with the

results for any substance of concern to produce an overall assessment for the biocidal product itself. This shall also take account of any cumulative or synergistic effects.	results for any substance of concern to produce an overall assessment for the biocidal product itself. This shall also take account of any cumulative or synergistic effects. ***Scientific definitions and methodologies for the assessment of cumulative or synergistic effects will be based on the technical guidance notes provided by the Commission as foreseen in Article 23.***

Justification

At present, there is no single agreed scientific definition for the concepts of cumulative and synergistic effects, neither is there a common, agreed method of analysis. The Commission should adopt these definitions and methodologies by way of technical guidance notes, before the regulation's entry into force.

Amendment 178

Council position
Annex VI – Conclusion – point 68 – introductory part

Council position	*Amendment*
68. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) if the foreseeable concentration of the active substance or a substance of concern or of relevant metabolites, breakdown or reaction products to be expected in surface water or its sediments after use of the biocidal product under the proposed conditions of use:	68. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) if the foreseeable concentration of the active substance or a substance of concern or of relevant metabolites, breakdown or reaction products to be expected in ***groundwater or*** surface water or its sediments after use of the biocidal product under the proposed conditions of use:

(Reinstatement of amendment 328 from first reading)

Amendment 179

Council position
Annex VI – Conclusion – point 68 – indent 1 a (new)

Council position	*Amendment*
	– risks non-achievement of the objectives or standards fixed by:
	– Directive 98/83/EC, or
	– Directive 2000/60/EC, or
	– Directive 2006/118/EC, or
	– Directives 2008/56/EC, or
	– Directive 2008/105/EC, or
	– international agreements containing important obligations on the protection of marine waters from pollution, or

(*Reinstatement of amendment 329 from first reading.*)

EXPLANATORY STATEMENT

The rapporteur welcomes the fact that, in its common position on the proposal for a regulation concerning the making available on the market and use of biocidal products, the Council has incorporated just under half of Parliament's amendments. She nonetheless considers the proposal to be in considerable need of improvement in order to achieve the stated purposes, such as eliminating the shortcomings in the existing authorisation directive, 98/8/EC, improving the authorisation procedure and streamlining decision-making while further developing the high level of protection. This applies, for example, to the simplified authorisation of product families and brands.

The rapporteur regrets that the common position contains many inconsistencies and contradictions, which the European Parliament must now correct, and she is critical of the arbitrary restructuring of the articles.
Many of the amendments are therefore of a technical nature and do not contain any substantive modifications of the text. Instead, their aim is to improve consistency (within the text and between this regulation and other EU legislation), eliminate duplications of legal obligations and simplify the text.

For reasons associated with competition and the internal market, clear and transparent rules on fees are called for, both for the Agency and for Member States.

The rapporteur welcomes the fact that active substances for biocidal products which are subject to a simplified authorisation procedure are now listed in the annex to the regulation. However, the annex should not confine itself to this specific product group: the authorisation of all active substances should be regulated by means of delegated acts.

As part of the requirements relating to information on active substances and biocidal products, important newly developed methods of avoiding animal testing should be exploited.

Treated products require clear rules, although care should be taken to avoid including in the labelling biocidal products which are no longer present in the end-product. Duplication of regulation with other legal acts relating to labelling must be avoided.

The introduction of a Community authorisation system represents a significant step towards a harmonised European market for biocidal products. It is the best and most efficient system for improving the availability of these products, providing incentives for innovation and creating added value for human health and nature conservation. A central authorisation system will also have an unequivocally positive effect on the internal market as it will facilitate consistent assessments and uniform enforcement of the requirements in all EU Member States. This will, in particular, also improve consumer protection. In order to make allowances for the current workload of ECHA and the regrettably sluggish rate at which active substances are being reviewed, the rapporteur proposes introducing Union authorisation in stages.

Among the requirements for the safe use of biocidal products, it is necessary that, by analogy with the Framework Directive on the sustainable use of pesticides, a Framework Directive on

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

PROCEDURE

Title	The placing on the market and use of biocidal products
References	05032/2/2011 – C7-0251/2011 – 2009/0076(COD)
Date of Parliament's first reading – P number	22.9.2010 T7-0333/2010
Commission proposal	COM(2009)0267 - C7-0036/2009
Receipt of Council position at first reading announced in plenary	29.9.2011
Committee responsible Date announced in plenary	ENVI 29.9.2011
Rapporteur(s) Date appointed	Christa Klaß 15.9.2009
Discussed in committee	8.9.2011
Date adopted	4.10.2011
Result of final vote	+: 57 –: 1 0: 2
Members present for the final vote	János Áder, Elena Oana Antonescu, Kriton Arsenis, Sophie Auconie, Pilar Ayuso, Paolo Bartolozzi, Sandrine Bélier, Sergio Berlato, Milan Cabrnoch, Nessa Childers, Chris Davies, Bairbre de Brún, Esther de Lange, Anne Delvaux, Bas Eickhout, Edite Estrela, Jill Evans, Karl-Heinz Florenz, Elisabetta Gardini, Gerben-Jan Gerbrandy, Françoise Grossetête, Satu Hassi, Jolanta Emilia Hibner, Dan Jørgensen, Karin Kadenbach, Christa Klaß, Holger Krahmer, Jo Leinen, Corinne Lepage, Peter Liese, Kartika Tamara Liotard, Radvilė Morkūnaitė-Mikulėnienė, Miroslav Ouzký, Vladko Todorov Panayotov, Gilles Pargneaux, Antonyia Parvanova, Mario Pirillo, Pavel Poc, Vittorio Prodi, Frédérique Ries, Anna Rosbach, Oreste Rossi, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Theodoros Skylakakis, Bogusław Sonik, Claudiu Ciprian Tănăsescu, Salvatore Tatarella, Anja Weisgerber, Åsa Westlund, Glenis Willmott, Sabine Wils
Substitute(s) present for the final vote	Matthias Groote, Alojz Peterle, Marianne Thyssen, Marita Ulvskog, Kathleen Van Brempt
Substitute(s) under Rule 187(2) present for the final vote	Arlene McCarthy, Konrad Szymański
Date tabled	10.10.2011