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Committee on the Environment, Public Health and Food Safety

2009/0076(COD)

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COMPROMISE AND CONSOLIDATED AMENDMENTS 1 - 7

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

The placing on the market and use of biocidal products

Council position at first reading
(05032/2/2011 – C7-0251/2011 – 2009/0076(COD))

AM_Com_LegCompr

Compromise Amendment 1
EPP; S&D; ALDE; GREENS/EFA; ECR; GUE/NGL, EFD
Compromise amendment replacing Amendments 118-120

Council position
Article 3 – paragraph 1 – point a

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

Or. en

Consolidated Amendment 2
EPP; S&D; ALDE; GREENS/EFA; GUE/NGL, EFD
Consolidated amendment 2 replacing Amendments 129, 130, 131, 132, 133, 134, 135/136, 137, 138/139/140, 141, 142

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 effect in humans, or which are*** identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties***.***
(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 ***to*** the environment to the active substance in ***question in*** a biocidal product, under ***normal*** conditions of use, is negligible, ***meaning that*** the product is used in closed systems or ***under other*** conditions ***excluding contact with humans***;
(b) 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.	***deleted***
When deciding whether an active substance may be approved in accordance with the first subparagraph, the availability of suitable and sufficient alternative substances or technologies shall also be taken into account.	***deleted***
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	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.	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.

Or. en

Consolidated Amendment 3
EPP; S&D; ALDE; GREENS/EFA; GUE/NGL, EFD
Consolidated amendment 3 replacing Amendments 213, 214, 215, 219, 220, 221, 222, 223, 224/225, 226/227, 228/229, 230

Council position
Article 36

Council position	*Amendment*
By way of derogation from Article 31(2), any of the Member States concerned may ***propose to*** refuse to grant an authorisation or ***to*** adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of:	By way of derogation from Article 31(2), any of the Member States concerned may refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of:
(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, 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.	(e) the target organisms not being present in harmful quantities.
Any of the Member States concerned may,	Any of the Member States concerned may,

in particular, ***propose*** in accordance with the first subparagraph ***to*** refuse to grant an authorisation or ***to*** adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or 10(1) applies.	in particular, in accordance with the first subparagraph***,*** refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or 10(1) applies.
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.	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:***	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***.
(a) may ask the Agency for an opinion on scientific or technical questions raised by the applicant or the Member State concerned;	***deleted***
(b) shall adopt a decision on the derogation in accordance with the examination procedure referred to in Article 81(3).	***deleted***
The Commission's decision shall be addressed to the Member State concerned and the Commission shall inform the applicant thereof.	***deleted***
The Member State concerned shall take necessary measures to comply with the Commission's decision within 30 days of its notification.	***deleted***

Or. en

Compromise Amendment 4
EPP; S&D; ALDE; GREENS/EFA; ECR; GUE/NGL, EFD
Compromise amendment replacing Amendments 46, 233, 234, 235, 236, 237, 238 and 239

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(a) for a definition of "similar conditions of use across the Union".***

Or. en

Consolidated Amendment 5
EPP; S&D; ALDE; GREENS/EFA; GUE/NGL, EFD
<<<Consolidated amendment 5 replacing Amendments 244 and 245

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

Council position	*Amendment*
	3 a. 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, 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.
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).

Or. en

Consolidated Amendment 6
EPP; S&D; ALDE; GREENS/EFA; GUE/NGL
Consolidated amendment replacing Amendments 62; 257; 259; 260; 261; 262; 263

Council position
Article 57 – paragraph 1-5

Council position	*Amendment*
1. This Article shall apply exclusively to treated articles within the meaning of Article 3(1)(l) that are not biocidal products within the meaning of Article 3(1)(a). It shall not apply to treated articles where the sole treatment undertaken was the fumigation or disinfection of premises or containers used for storage or transport and where no residues are expected to remain from such treatment.	1. This Article shall apply exclusively to treated articles within the meaning of Article 3(1)(l) that are not biocidal products within the meaning of Article 3(1)(a). It shall not apply to treated articles where the sole treatment undertaken was the fumigation or disinfection of premises or containers used for storage or transport and where no residues are expected to remain from such treatment.
2. A treated article shall not be placed on the market unless all active substances	2. A treated article shall not be placed on the market unless all active substances

contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2), for the relevant product-type and use, or in Annex I, and any conditions or restrictions specified therein are met.	contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2), for the relevant product-type and use, or in Annex I, and any conditions or restrictions specified therein are met.
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 being 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	***4. Deletion***

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.***

Or. en

Consolidated Amendment 7
EPP; S&D; ALDE; GREENS/EFA; GUE/NGL, EFD
Consolidated amendment replacing Amendments 71 and 312
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.

Council position
Article 89 – paragraph 2 – subparagraph 1

Council position	*Amendment*
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 1451/2007.	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.
	To ensure a smooth transition, no later than ... *, the Commission shall 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

Or. en

Council position
Article 89 a (new)

Council position	
	Article 89a
	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, no later than ... *, the Commission shall 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

Or. en