EUROPEAN PARLIAMENT 2009 - 2014

Committee on the Environment, Public Health and Food Safety

2009/0076(COD)

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COMPROMISE AND CONSOLIDATED AMENDMENTS 1 - 3

Draft report
Christa Klaß
(PE438.377v02-00)

on the proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products

Proposal for a regulation
(COM(2009)0267 – C7-0036/2009 – 2009/0076(COD))

AM_Com_LegCompr

Compromise amendment 1
Christa Klaß, Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Julie Girling, Sabine Wils

Proposal for a regulation
Article 5

Text proposed by the Commission	*Amendment*
Article 5	Article 5
Exclusion criteria	Exclusion criteria
1. ***Notwithstanding Article 4(1),*** active substances ***referred to in paragraph 2*** shall be included in Annex I ***only if at least one of the following conditions is met:***	1. ***The following*** active substances shall ***not*** be included in Annex I:
(a) the exposure of humans to that active substance in a biocidal product, under normal conditions of use, is negligible, in particular where the product is used in closed systems or strictly controlled conditions;	***(a) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meets the criteria to be classified as, carcinogen category 1A or 1B;***
(b) it is shown that the active substance is necessary to control a serious danger to public health;	***(b) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;***
(c) it is shown that not including the active substance in Annex I would cause disproportionate negative impacts when compared with the risk to human health or the environment arising from the use of the substance and that there are no suitable alternative substances or technologies.	***(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;***
Point (c) shall not apply to active substances for product types 4 and 14 to 19.	***(d) active substances which, on the basis of the assessment of Community or internationally agreed test guidelines or other peer reviewed scientific data and information, including a review of the scientific literature, reviewed by the Agency, are considered as having endocrine disrupting properties that may cause adverse effect in humans, or which are identified under Article 57(f) of***

Regulation (EC) No 1907/2006 as having endocrine disrupting properties.

Until 13 December 2013, the Commission shall, by means of delegated acts in accordance with Articles XY, adopt measures on specific scientific criteria for determining endocrine-disrupting properties. Pending the adoption of these criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine-disrupting properties. In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.

(e) active substances that are persistent, bio-accumulative and toxic;

(f) active substances that are very persistent and very bio-accumulative;

(g) persistent organic pollutants (POP) under Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants;

2. ***The following*** active substances ***shall*** be included in Annex I ***where*** at least one of the conditions ***set out in paragraph*** 1 is met:

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

(a) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meets the criteria to be classified as, carcinogen category 1A or 1B;

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

(b) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the

(b) it is shown by evidence that the active substance is necessary to prevent or control a serious danger to public or

criteria to be classified as, mutagen category 1A or 1B;	***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;***
(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;	***The use of any biocidal product containing active substance 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.***
(d) active substances identified under Article 57(f) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties.	***A Member State authorising a biocidal product containing an active substance included in Annex I pursuant to this paragraph shall draw up a substitution plan concerning the control of the serious danger by other means including non-chemical methods, which are as effective as the biocidal product concerned and shall without delay transmit that plan to the Commission. The use of the biocidal product with the active substance concerned shall be restricted to those Member States where the serious danger has to be prevented or, if it occurs, controlled.***

Or. en

Compromise amendment 2
Christa Klaß, Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Julie Girling, Sabine Wils

Proposal for a regulation
Article 83

Text proposed by the Commission	*Amendment*
Article 83	Article 83
Transitional measures concerning access to the active substance dossier	Transitional measures concerning access to the active substance dossier

As of 1 January 2014, ***the person responsible for the placing on the market of a biocidal product containing one or more*** existing active substances shall ***own*** a dossier or ***have*** a letter of access to a dossier***, or to each component of the dossier, satisfying*** the requirements ***set out in*** Annex II for each of these active substances ***unless all relevant protection periods referred to in Article 49 have expired***.	***1.*** By ***1 January 2015***, ***manufacturers of*** existing active substances which are on the market for use in biocidal products shall ***submit to the Agency*** a dossier or a letter of access to a dossier ***which complies with*** the requirements ***of*** Annex II for each of these active substances.
	For the purpose of subparagraph 1, Article 52(3) shall apply to all data included in the dossier.
	The applicant for the authorisation of a biocidal product containing an active substance for which a letter of access was submitted in accordance with subparagraph 1 shall be allowed to use this letter of access for the purposes of Article 18(1).
	2. The Agency shall make publicly available the list of manufacturers which have submitted a dossier or a letter of access to a dossier in accordance with paragraph 1.
Biocidal products for which ***the person responsible for the placing on the market does not fulfil the requirement of the first subparagraph*** shall ***no longer*** be placed on the market.	***3.*** Biocidal products ***containing existing active substances*** for which ***a dossier or a letter of access to a dossier was not submitted in accordance with paragraph 1*** shall ***not*** be placed on the market ***after 1 January 2015***.
Disposal, storage and use of existing stocks of biocidal products which ***do not fulfil the requirement of the first subparagraph*** is allowed until ***1 January 2015***.	Disposal, storage and use of existing stocks of biocidal products ***for*** which ***a dossier or a letter of access to a dossier was not submitted in accordance with paragraph 1*** is allowed until ***1 January 2016***.
	4. For the purpose of paragraph 3, competent authorities shall carry out official controls as required by Article 54(2).

Or. en

Consolidated amendment 3
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Julie Girling

Proposal for a regulation
Article 33 – paragraph 1

Text proposed by the Commission	*Amendment*
Article 33	*Article 33*
Biocidal products for which Community authorisation may be granted	Biocidal products for which Community authorisation may be granted
1.The Community authorisation may be granted to the following categories of biocidal products:	1.The Community authorisation may be granted to the following categories of biocidal products:
(a) biocidal products containing one or more new active substances;	
(b) low-risk biocidal products.	(b) low-risk biocidal products.
	(c) biocidal products designed to be used by consumers in domestic settings, or by professional users, according to conditions and instructions of use which are similar within the European Union, and which meet the criteria listed in Article 33(3).
	2. A Community authorisation may not be granted for biocidal products that contain active substances that fall under Article 5 or 9.
	3. In accordance with article 33 paragraph 1 point c (new), a product shall be considered a biocidal product with similar use conditions if all of the following criteria are met. The biocidal product:
	(i) has similar conditions of use across the European Union, according to use instructions;
	(ii) is already placed on the market in at least [X] Member States or is intended to be placed on the market in at least [X]

Member States within two years after the authorisation has been granted[1];

(iii) does not require personal protective equipment in conditions of use according to Annex VI, and when used under their normal and reasonably foreseeable conditions of use, meets the requirements in Article 16(1).

In order to adapt the number of Member States mentioned in paragraph (ii), the Commission may adopt a delegated act in accordance with article 71 (new).

The number of Member States agreed under paragraph 3 (ii) shall not be reduced by more than two every two years.

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[1]The exact number shall be defined during the legislative process.

Or. en