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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products with regard to certain conditions for access to the market

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

The proposal relates to the recently adopted Regulation (EU) No 528/2012 ('the Biocidal Products Regulation'), which has not yet become applicable. An analysis of the Biocidal Products Regulation has shown that certain provisions will lead to unforeseen consequences.

The main problem identified is that the transitional rules of the Biocidal Products Regulation will introduce an un-intended market freeze of up to eleven years for articles treated with biocidal substances which are legal on the EU market, but which have not yet been evaluated at EU level. Other un-intended market barriers for certain companies have also been identified. Finally, the Biocidal Products Regulation fails to define a protection period for data relating to those products with the most favourable risk profile.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

Stakeholders and experts have been consulted in several meetings of the expert group named Competent authorities for biocidal products. The proposal has received broad support in those meetings.

3. LEGAL ELEMENTS OF THE PROPOSAL

The proposal contains provisions that will remove market barriers for suppliers of new articles treated with biocidal products and for a large number of suppliers of biocidal active substances. It also defines the protection periods for the data relating to those biocidal products with the best profile.

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Article 19(4)(c) of Regulation (EU) No 528/2012[2] prohibits authorisation for making available for use by the general public of biocidal products meeting the criteria for being persistent, bioaccumulative and toxic ('PBT'), or very persistent and very bioaccumulative ('vPvB') in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[3]. However, whereas biocidal products are often mixtures and sometimes articles, those criteria apply only to substances. Article 19(4)(c) of Regulation (EU) No 528/2012 should therefore refer to biocidal products consisting of, containing or generating substances meeting those criteria.

(2) In Article 19(1)(e) and Article 19(7) of Regulation (EU) No 528/2012, it should be clarified that the limits required to be established in accordance with 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[4] are specific migration limits.

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1 OJ C 347, 18.12.2010, p. 62.
2 OJ L 167, 27.6.2012, p. 1.
3 OJ L 396, 30.12.2006, p.1.
4 OJ L 338, 13.11.2004, p. 4.

(3) Since comparative assessments are not regulated by Annex VI to Regulation (EU) No 528/2012, the reference to that Annex in Article 23(3) of that Regulation should be deleted.

(4) According to Article 35(3) of Regulation (EU) No 528/2012, where all Member States concerned have reached an agreement with the reference Member State on mutual recognition, a product is to be authorised in accordance with Article 33(4) or Article 34(6). However, the provisions referring to decisions by all Member States concerned to grant authorisations by mutual recognition are laid down in Article 33(3) and Article 34(6). Article 35(3) should therefore be amended accordingly.

(5) The second subparagraph of Article 45(1) of Regulation (EU) No 528/2012 requires an application for renewal of Union authorisation to be accompanied by the fees payable under Article 80(1). However, fees can only be paid subsequent to the information about their level provided by the European Chemicals Agency (hereinafter 'Agency') in accordance with the second subparagraph of Article 45(3). Therefore, and to ensure consistency with Article 7(1), Article 13(1), and Article 43(1), the second subparagraph of Article 45(1) should be deleted.

(6) The first and second subparagraphs of Article 60(3) of Regulation (EU) No 528/2012 refer to authorisations granted in accordance with Article 30(4), Article 34(6) or Article 44(4). However, the provisions referring to decisions to grant authorisations are laid down in Article 30(1), Article 33(3), Article 33(4), Article 34(6), Article 34(7), Article 36(4), Article 37(2), Article 37(3), and Article 44(5). Furthermore, the second subparagraph of Article 60(3) does not indicate any period for protection of data referred to in Article 20(1)(b) submitted in an application pursuant to Article 26(1). Article 60(3) should therefore also refer to Article 26(3), Article 30(1), Article 33(3), Article 33(4), Article 34(6), Article 34(7), Article 36(4), Article 37(2), Article 37(3), and Article 44(5).

(7) In order to allow the preparation of applications for product authorisation by the date of approval of an active substance as provided for by the second subparagraph of Article 89(3) of Regulation (EU) No 528/2012, the electronic public access to information on active substances provided for by Article 67 of that Regulation should be granted as of the day when the Commission adopts the Regulation providing that the active substance is approved.

(8) The first subparagraph of Article 77(1) of Regulation (EU) No 528/2012 provides for appeals against decisions of the Agency taken pursuant to Article 26(2). However, since Article 26(2) does not empower the Agency to take any decision, the reference to that Article in Article 77(1) should be deleted.

(9) Article 86 of Regulation (EU) No 528/2012 refers to active substances included in Annex I to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[5] It should be clarified that the provision applies to all active substances for which the Commission has adopted a Directive including them in that Annex, that the conditions for an inclusion is applicable to an approval, and that the approval date is considered to be the date of inclusion.

(10) The first subparagraph of Article 89(2) of Regulation (EU) No 528/2012 allows Member States to apply their current system until two years after the date of approval of an active substance. The first subparagraph of Article 89(3) requires Member States

[5] OJ L 150, 8.6.2002, p. 71.

to ensure that product authorisations are granted, modified or cancelled within two years of approval of an active substance. However, taking into account the time required for the various steps of the authorisation process, in particular where a disagreement on mutual recognition persists between Member States and therefore has to be submitted to the Commission for a decision, it is appropriate to extend those deadlines to three years, and to reflect that extension in the second subparagraph of Article 37(3).

(11) The first subparagraph of Article 89(2) of Regulation (EU) No 528/2012 allows Member States to apply their current system to existing active substances. A biocidal product may contain a combination of new active substances which have been approved and existing active substances which have not yet been approved. For the purpose of rewarding innovation by granting such products access to the market, Member States should be allowed to apply their current systems to such products until the existing active substance has been approved, and the products are hence eligible for authorisation in accordance with Regulation (EU) No 528/2012.

(12) Article 89(4) and Article 93(2) of Regulation (EU) No 528/2012 provide phase-out periods for biocidal products for which no authorisation is granted. The same periods should apply for phasing out the existing form of a product already on the market, where an authorisation is granted but the conditions of the authorisation require the product to be changed.

(13) The first and second subparagraphs of Article 93(2) should clarify that the derogation provided for therein applies only subject to Member States' national rules.

(14) Article 94(1) of Regulation (EU) No 528/2012 seeks to allow placing on the market of articles treated with biocidal products containing active substances which, albeit not yet approved, are being evaluated, either in the context of the work programme referred to in Article 89(1) or based on an application submitted pursuant to Article 94(1). However, the reference to the entire Article 58 could be interpreted as an unintended derogation from the labelling and information requirements in Article 58(3) and (4). Article 94(1) should therefore refer to Article 58(2).

(15) Article 94(1) of Regulation (EU) No 528/2012 only applies to treated articles already placed on the market, and will hence introduce an unintended ban on most new treated articles, lasting from 1 September 2013 until the approval of the last active substance contained in the articles. Its scope should therefore be extended to include new treated articles. Article 94(1) should also provide for a phasing-out period for treated articles for which no application for the approval of the active substance for the relevant product-type will be submitted by 1 September 2016. In the interest of simplification, Article 94(2) should be merged with Article 94(1).

(16) The first subparagraph of Article 95(1) of Regulation (EU) No 528/2012 prescribes the submission of a complete substance dossier. It should be clarified that such a complete dossier may include data referred to in Annex IIIA or IVA to Directive 98/8/EC.

(17) The third subparagraph of Article 95(1) of Regulation (EU) No 528/2012 intends to extend the right to refer to data provided in the second subparagraph of Article 63(3) to all studies required for the human health and environmental risk assessment, in order to allow prospective relevant persons to be included in the list referred to in Article 95(2). Without such a right to refer, many prospective relevant persons will not have time to comply with Article 95(1) by such time as required in order to be included in the list by the date referred to in Article 95(3). However, the third

subparagraph of Article 95(1) fails to include studies on environmental fate and behaviour. Moreover, since prospective relevant persons will pay for the right to refer in accordance with Article 63(3), they should be entitled to fully benefit from that right by passing it onto applicants for product authorisation. This Article should therefore be amended accordingly.

(18) The fifth subparagraph of Article 95(1) of Regulation (EU) No 528/2012 intends to limit the protection period for data which can be shared already as of 1 September 2013 for the purpose of compliance with the first subparagraph of Article 95(1) before it will be shared for the purpose of substantiating applications for product authorisations. Such will be the case for data relating to substance/product-type combinations for which a decision on inclusion in Annex I to Directive 98/8/EC has not been taken on 1 September 2013. Article 95 of that Regulation should therefore refer to that date.

(19) Pursuant to Article 95(2) of Regulation (EU) No 528/2012, the list published by the Agency is to contain the names of the participants in the work programme referred to in Article 89(1). The provision aims to allow those participants to benefit from the cost compensation mechanism set forth by Article 95. That possibility should cover all persons who have submitted a complete dossier in accordance with Regulation (EU) No 528/2012 or with Directive 98/8/EC, or a letter of access to such a dossier. It should also cover dossiers submitted for any substance which is not itself an active substance, but which generates such active substances.

(20) The first subparagraph of Article 95(3) of Regulation (EU) No 528/2012 prohibits the placing on the market of biocidal products containing active substances for which the manufacturer or importer (the 'relevant person') is not included in the list referred to in that Article. By virtue of Article 89(2) and Article 93(2), certain active substances will be legally on the market in biocidal products although no complete dossier has yet been submitted. The prohibition should not apply to such substances. Furthermore, where no substance manufacturer or importer is listed for a substance for which a complete dossier has been submitted, another person should be allowed to place biocidal products containing that substance on the market, subject to the submission of a dossier or a letter of access to a dossier by that person or the manufacturer or importer of the biocidal product.

(21) The phase-out period for use of biocidal products provided for by the second subparagraph of Article 95(3) of Regulation (EU) No 528/2012 should depend on the time when the substance is included in the list.

(22) Article 95(4) of Regulation (EU) No 528/2012 stipulates that Article 95 applies to active substances listed under category 6 in Annex I. Those substances have been included in Annex I based on submissions of complete dossiers, the owners of which should be entitled to benefit from the cost compensation mechanism installed by that Article. In the future, other substances may be included in Annex I based on such submissions. Category 6 in Annex I to that Regulation should therefore be regulating all such substances.

(23) The description in Annex V to Regulation (EU) No 528/2012 of products used in food contact materials should be consistent with the terminology used in Regulation (EC) No 1935/2004.

(24) It should be clarified in the first subparagraph of Article 96 of Regulation (EU) No 528/2012 that Directive 98/8/EC is repealed without prejudice to all provisions of Regulation (EU) No 528/2012 referring to Directive 98/8/EC.

(25) Regulation (EU) No 528/2012 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 528/2012 is amended as follows:

(1) Article 19 is amended as follows:

(a) in paragraph 1, point (e) is replaced by the following:

"(e) where appropriate, maximum residue limits for food and feed have been established with respect to active substances contained in a biocidal product in accordance with Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food*, Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin**, Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin*** or Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed****, or specific migration limits have been established with respect to such active substances in accordance with 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*****.

* OJ L 37, 13.2.1993, p. 1.

** OJ L 70, 16.3.2005, p. 1.

*** OJ L 152, 16.6.2009, p. 11.

**** OJ L 140, 30.5.2002, p. 10.

***** OJ L 338, 13.11.2004, p. 4. ";

(b) in paragraph 4, point (c) is replaced by the following:

"(c) it consists of, contains or generates a substance that meets the criteria for being PBT or vPvB in accordance with Annex XIII to Regulation (EC) No 1907/2006;";

(c) paragraph 7 is replaced by the following:

"7. Where appropriate, the prospective authorisation holder or its representative shall apply for the establishment of maximum residue limits with respect to active substances contained in a biocidal product in accordance with Regulation (EEC) No 315/93, Regulation (EC) No 396/2005, Regulation (EC) No 470/2009 or Directive 2002/32/EC, or for the establishment of specific migration limits with respect to such substances in accordance with Regulation (EC) No 1935/2004.";

(2) in Article 23(3), the introductory sentence is replaced by the following:

"The receiving competent authority or, in the case of a decision on an application for a Union authorisation, the Commission shall prohibit or restrict the making available

on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where a comparative assessment performed in accordance with the technical guidance notes referred to in Article 24 demonstrates that both of the following criteria are met:";

(3) in Article 35(3), the fourth sentence is replaced by the following:

"The procedure shall then be considered to be closed and the reference Member State and each of the Member States concerned shall authorise the biocidal product in accordance with Article 33(3) or Article 34(6) as appropriate.";

(4) in Article 37(3), the second subparagraph is replaced by the following:

"While the procedure under this Article is ongoing, the Member States' obligation to authorise a biocidal product within three years of the date of approval, referred to in the first subparagraph of Article 89(3), shall be temporarily suspended.";

(5) in Article 45(1), the second subparagraph is deleted;

(6) in Article 60(3) , the first and second subparagraphs are replaced by the following:

"The protection period for data submitted with a view to the authorisation of a biocidal product containing only existing active substances shall end 10 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 26(3), Article 30(1), Article 33(3), Article 33(4), Article 34(6), Article 34(7), Article 36(4), Article 37(2), Article 37(3), or Article 44(5).

The protection period for data submitted with a view to the authorisation of a biocidal product containing a new active substance shall end 15 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 26(3), Article 30(1), Article 33(3), Article 33(4), Article 34(6), Article 34(7), Article 36(4), Article 37(2), Article 37(3), or Article 44(5).";

(7) in Article 67(1), the introductory sentence is replaced by the following:

"From the date on which the Commission adopts a Regulation in accordance with Article 9(1)(a), the following up-to-date information held by the Agency or the Commission on that active substance shall be made publicly and easily available free of charge:";

(8) in Article 67(3), the introductory sentence is replaced by the following:

"From the date on which the Commission adopts a Regulation in accordance with Article 9(1)(a), the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to-date information on active substances:";

(9) in Article 77(1), the first subparagraph is replaced by the following:

"Appeals against decisions of the Agency taken pursuant to Article 7(2), Article 13(3), Article 43(2), Article 45(3), Article 54(3), Article 54(4) and Article 54(5), Article 63(3) and Article 64(1) shall lie with the Board of Appeal set up in accordance with Regulation (EC) No 1907/2006.";

(10) Article 86 is replaced by the following:

"Article 86

Active substance included in Annex I to Directive 98/8/EC

The active substances for which the Commission has adopted a Directive including them in Annex I to Directive 98/8/EC shall be deemed to have been approved, under this Regulation on the date of inclusion, and shall be included in the list referred to in Article 9(2). The approval shall be subject to the conditions set out in those Commission Directives.";

(11) Article 89 is amended as follows:

(a) in paragraph 2, the first subparagraph is replaced by the following:

"By way of derogation from Article 17(1), Article 19(1) and Article 20(1) of this Regulation, and without prejudice to paragraphs 1 and 3 of this Article, a Member State may continue to apply its current system or practice of making a given biocidal product available on the market until three years after the date of approval of the last of the active substances to be approved in that biocidal product. It may, according to its national rules, authorise the making available on the market in its territory only of a biocidal product containing only existing active substances which have been or are being evaluated under Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC*, but which have not yet been approved for that product-type, or a combination of such substances and active substances approved in accordance with this Regulation.

* OJ L 325, 11.12.2007, p. 3.";

(b) in paragraph 3, the first subparagraph is replaced by the following:

"Following a decision to approve a particular active substance for a specific product-type Member States shall ensure that authorisations for biocidal products of that product-type and containing that active substance are granted, modified or cancelled as appropriate in accordance with this Regulation within three years of the date of approval.";

(c) paragraph 4 is replaced by the following:

"4. Where a Member State's competent authority decides to reject the application for authorisation of a biocidal product submitted under paragraph 3, decides not to grant authorisation, or decides to impose conditions of the authorisation making it necessary to change a product, the following shall apply:

(a) the biocidal product which has not been authorised or, where relevant, which does not comply with the conditions of the authorisation, shall no longer be made available on the market with effect from 180 days after the date of the decision of the authority;

(b) disposal and use of existing stocks of the biocidal product may continue until 365 days after the date of the decision of the authority.";

(12) in Article 93(2), the first and second subparagraphs are replaced by the following:

"By way of derogation from Article 17(1), a Member State may continue to apply its current system or practice of making available on the market biocidal products referred to in paragraph 1 of this Article for which an application was submitted in accordance with paragraph 1 of this Article until the date of the decision granting the

authorisation. In the case of a decision refusing to grant the authorisation, or imposing conditions on the authorisation making it necessary to change a product, the biocidal product which has not been authorised or, where relevant, which does not comply with the conditions of the authorisation, shall no longer be made available on the market 180 days after such a decision.

By way of derogation from Article 17(1), a Member State may continue to apply its current system or practice of making available on the market biocidal products referred to in paragraph 1 of this Article for which an application was not submitted in accordance with paragraph 1 of this Article until 180 days after 1 September 2017."

(13) Articles 94 and 95 are replaced by the following:

"Article 94
Transitional measures concerning treated articles

By way of derogation from Article 58(2), a treated article treated with or incorporating a biocidal product containing only active substances referred to in Article 89(2) or for which an application for approval for the relevant product type is submitted at the latest by 1 September 2016, or only a combination of such substances and active substances referred to in Article 58(2), may be placed on the market until either of the following dates:

1. in the absence of a decision not to approve one of the active substances for the relevant use, until the date of approval for the relevant product type and use of the last active substance contained in the biocidal product,
2. in the case of a decision not to approve one of the active substances for the relevant use, until 180 days after such a decision.

By further way of derogation from Article 58(2), a treated article treated with or incorporating a biocidal product containing any other substance than those referred to in that Article or in paragraph 1 of this Article may be placed on the market until 1 March 2017.

Article 95
Transitional measures concerning access to the active substance dossier

1. As of 1 September 2013, the Agency shall make publicly available and regularly update a list of all active substances, and all substances generating an active substance, for which a dossier complying with Annex II to this Regulation or with Annex IVA or IIA to Directive 98/8/EC and, where relevant, IIIA thereto (hereinafter 'complete substance dossier') has been submitted and accepted or validated by a Member State in a procedure provided for by this Regulation or that Directive (hereinafter 'relevant substances'). For each relevant substance, the list shall also include all persons having made such a submission or a submission to the Agency in accordance with the second subparagraph of this paragraph, and indicate their role as specified in that subparagraph, as well as the date of inclusion of the substance in the list.

A person established within the Union who manufactures or imports a relevant substance, on its own or in biocidal products, (hereinafter 'substance supplier') may at any time submit to the Agency either a complete substance dossier, a letter of access

to a complete substance dossier, or a reference to a complete substance dossier for which all data protection periods have expired.

Where, for a relevant substance, no substance supplier is included in the list referred to in the first subparagraph, a person established within the Union who manufactures a biocidal product consisting of, containing or generating that relevant substance or places it on the market (hereinafter 'product supplier), may submit that information.

The Agency shall inform the submitting supplier of the fees payable under Article 80(1) and shall reject the application if the applicant fails to pay the fee within 30 days. It shall inform the submitter accordingly.

Upon receipt of the fees payable under Article 80(1), the Agency shall verify whether the submission complies with the second subparagraph of this paragraph and inform the submitter accordingly.

2. As of 1 September 2015, a biocidal product consisting of, containing or generating a relevant substance included in the list referred to in paragraph 1 shall not be made available on the market or used unless either the substance supplier or the product supplier is included in the list referred to in paragraph 1.

3. For the purposes of making a submission in accordance with the second subparagraph of paragraph 1, Article 63(3) of this Regulation shall apply to all toxicological, ecotoxicological and environmental fate and behaviour studies relating to substances listed in Annex II to Regulation (EC) No 1451/2007, including any such studies not involving tests on vertebrates.

4. A substance supplier or a product supplier included in the list referred to in paragraph 1 to whom a letter of access has been issued for the purpose of this Article or a right to refer to a study has been granted in accordance with paragraph 3 shall be entitled to allow applicants for the authorisation of a biocidal product to make reference to that letter of access or that study for the purposes of Article 20(1).

5. By way of derogation from Article 60, all data protection periods for substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but for which a decision on inclusion in Annex I to Directive 98/8/EC has not been taken by 1 September 2013, shall end on 31 December 2025.

6. By way of derogation from paragraph 2, disposal and use of existing stocks of biocidal products consisting of, containing or generating a relevant substance for which neither the substance supplier, nor the product supplier is included in the list referred to in paragraph 1 may continue until 1 September 2016 or until one year after the inclusion of the substance in the list, whichever is the later.

7. Paragraphs 1 to 6 shall not apply to substances listed in Annex I in categories 1 to 5 and 7 or to biocidal products containing only such substances.";

(14) in Article 96, the first paragraph is replaced by the following:

"Without prejudice to Article 86, Article 89 to Article 93 and Article 95 of this Regulation, Directive 98/8/EC is hereby repealed with effect from 1 September 2013."

(15) in Annex I, the entry named Category 6 is replaced by the following:

"Category 6 – Substances for which a complete substance dossier has been submitted";

(16) in Annex V the second paragraph under the heading "Product-type 4: Food and feed area" is replaced by the following:

"Products used to be incorporated into materials which may enter into contact with food.".

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*