# Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 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)

REGULATION (EU) No 334/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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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)

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[(2)],

Whereas:

(1) Article 2 of Regulation (EU) No 528/2012 of the European Parliament and of the Council[(3)] sets out the scope of that Regulation, and, among other things, excludes from its application biocidal products when used as processing aids. Article 2(5) should be amended to clarify beyond doubt that ‘processing aids’ means those defined in Regulations (EC) No 1831/2003[(4)] and (EC) No 1333/2008[(5)] of the European Parliament and of the Council.

(2) Point (s) of Article 3(1) and Article 19(6) of Regulation (EU) No 528/2012 should be amended to allow similar biocidal products to be part of a biocidal product family if they can be satisfactorily assessed based on identifiable maximum risks and minimum level of efficacy.

(3) In point (e) of Article 19(1) and in 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[(6)] are specific migration limits or limits for the residual content in food contact materials.

(4) To ensure consistency between Regulation (EU) No 528/2012 and Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(7)], point (b) of Article 19(4) of Regulation (EU) No 528/2012 should be amended to include specific target

organ toxicity by single or repeated exposure category 1 as a classification criterion, in order to preclude authorisation for the making available on the market for use by the general public of a biocidal product meeting the criteria for this classification. Point (c) of Article 19(4) of Regulation (EU) No 528/2012 prohibits authorisation for making available on the market 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[8]. However, whereas biocidal products are often mixtures and sometimes articles, those criteria apply only to substances. Point (c) of Article 19(4) of Regulation (EU) No 528/2012 should therefore refer to biocidal products consisting of, containing or generating, substances meeting those criteria.

(5) As comparative assessment is not referred to in Annex VI to Regulation (EU) No 528/2012, the reference to that Annex in Article 23(3) of that Regulation should be deleted.

(6) Article 34(4) of Regulation (EU) No 528/2012 should be amended to correct the cross reference to Article 30.

(7) Pursuant 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 biocidal product is to be authorised in accordance with Article 33(4) or 34(6) thereof. However, the provisions referring to decisions by all Member States concerned to grant authorisations by mutual recognition are laid down in Articles 33(3) and 34(6) of that Regulation. Article 35(3) should therefore be amended accordingly.

(8) 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) of that Regulation. However, fees can only be paid subsequent to the information about their level provided by the European Chemicals Agency ('the Agency') in accordance with the second subparagraph of Article 45(3) of that Regulation. Therefore, and to ensure consistency with Articles 7(1), 13(1) and 43(1) of that Regulation, the second subparagraph of Article 45(1) should be deleted.

(9) The use of the word 'disposal' in Articles 52, 89 and 95 of Regulation (EU) No 528/2012 could be misleading and could result in problems of interpretation, having regard to the obligations imposed by Directive 2008/98/EC of the European Parliament and of the Council[9]. It should therefore be deleted.

(10) Some technical corrections should be made to Article 54 of Regulation (EU) No 528/2012 in order to avoid duplication between Article 54(1) and (3) as regards the payment of the applicable fees under Article 80(1).

(11) 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), 34(6) or 44(4) thereof. However, the provisions referring to decisions to grant authorisations are laid down in Articles 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) and 44(5) of that Regulation. Furthermore, the second subparagraph of Article 60(3) of that Regulation

does not indicate any period for protection of data referred to in point (b) of Article 20(1) submitted in an application pursuant to Article 26(1) thereof. Article 60(3) should therefore also refer to Articles 26(3), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) and 44(5) of that Regulation.

(12) Article 66(4) of Regulation (EU) No 528/2012 should be amended to correct the cross reference to Article 67.

(13) In order to facilitate good cooperation, coordination and exchange of information between the Member States, the Agency and the Commission regarding enforcement, the Agency should also be given the task of providing support and assistance to Member States with regard to control and enforcement activities by making use of existing structures, where appropriate.

(14) In order to allow the preparation of applications for biocidal product authorisations 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 thereof, should be available from the day when the Commission adopts the Regulation providing that the active substance is approved.

(15) 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) thereof. 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.

(16) 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[(10)]. It should be clarified that that Article applies to all active substances for which the Commission has adopted a directive including them in that Annex, that the conditions for such inclusion are applicable to the approval, and that the approval date is the date of inclusion.

(17) The first subparagraph of Article 89(2) of Regulation (EU) No 528/2012 allows Member States to apply their current system for up to two years after the date of approval of an active substance. The first subparagraph of Article 89(3) thereof requires Member States to ensure that biocidal 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 referred 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) of that Regulation.

(18) 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 could 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 those products are consequently eligible for authorisation in accordance with Regulation (EU) No 528/2012.

(19) Articles 89(4) and 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 a biocidal product already on the market, where an authorisation is granted but the conditions of the authorisation require the biocidal product to be changed.

(20) Article 93 of Regulation (EU) No 528/2012 should clarify that the derogation provided for therein applies only subject to Member States' national rules.

(21) Article 94(1) of Regulation (EU) No 528/2012 seeks to allow the 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) of that Regulation or based on an application submitted pursuant to Article 94(1). However, the reference in Article 94(1) to Article 58 of Regulation (EU) No 528/2012 could be interpreted as an unintended derogation from the labelling and information requirements in Article 58(3) and (4). Article 94(1) of that Regulation should therefore refer only to Article 58(2).

(22) As Article 94(1) of Regulation (EU) No 528/2012 applies only to treated articles already placed on the market, an unintended ban on most new treated articles was introduced from 1 September 2013 until the approval of the last active substance contained in those treated articles. The scope of Article 94(1) should therefore be extended to include new treated articles. That Article 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 is submitted by 1 September 2016. To avoid potentially serious adverse effects on economic operators and whilst fully respecting the principle of legal certainty, provision should be made for those modifications to apply from 1 September 2013.

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

(24) Under the third subparagraph of Article 95(1) of Regulation (EU) No 528/2012, the right to refer to data provided for in the second subparagraph of Article 63(3) thereof is extended to all studies required for the human health and environmental risk assessment, to allow prospective relevant persons to be included in the list referred to in Article 95(2) thereof. Without such a right to refer, many prospective relevant persons would not be able to comply with Article 95(1) in time to be included in that 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 are to 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. Article 95 should therefore be amended accordingly.

(25) 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 from 1 September 2013 for the purpose of compliance with the first subparagraph of Article 95(1), but which on that date could not yet be shared for the purpose of substantiating applications for product authorisations. Such is the case for data relating to active substance/product-type combinations for which a decision on inclusion in Annex I to Directive 98/8/EC was not taken before 1 September 2013. Article 95(1) of that Regulation should therefore refer to that date.

(26) 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) thereof. Article 95(2) thereby allows those participants to benefit from the cost compensation mechanism set out in that Regulation. The possibility of benefitting from a cost compensation mechanism should be open to all persons who have submitted a complete substance 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 be open to those who submitted dossiers for any substance which is not itself an active substance but which generates active substances.

(27) 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 Articles 89(2) and 93(2) of that Regulation, certain active substances will be legally present on the market in biocidal products even though no complete substance dossier has yet been submitted. The prohibition under Article 95(3) should not apply to such substances. Furthermore, where no substance manufacturer or importer is listed for a substance for which a complete substance dossier has been submitted, the possibility should be allowed for another person 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.

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

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

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