

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

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)

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

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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⁽⁶⁾. 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

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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,

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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.

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- (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.

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(31) 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) in Article 2(5), point (b) is replaced by the following:
 - (b) biocidal products when used as processing aids within the meaning of Regulation (EC) No 1831/2003 and Regulation (EC) No 1333/2008.;
- (2) Article 3(1) is amended as follows:
 - (a) point (s) is replaced by the following:
 - (s) “biocidal product family” means a group of biocidal products having:
 - (i) similar uses;
 - (ii) the same active substances;
 - (iii) similar composition with specified variations; and
 - (iv) similar levels of risk and efficacy;;
 - (b) point (v) is deleted;
- (3) Article 19 is amended as follows:
 - (a) paragraph 1 is amended as follows:
 - (i) point (a) is replaced by the following:
 - (a) the active substances are included in Annex I or approved for the relevant product-type and any conditions specified for those active substances are met;;
 - (ii) 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⁽¹¹⁾, Regulation (EC) No 396/2005 of the European Parliament and of the Council⁽¹²⁾, Regulation (EC) No 470/2009 of the European Parliament and of the Council⁽¹³⁾ or Directive 2002/32/EC of the European Parliament and of the Council⁽¹⁴⁾, or specific migration limits or limits for the residual content in food contact materials 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⁽¹⁵⁾.;
 - (b) in paragraph 4, points (b) and (c) are replaced by the following:

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- (b) it meets the criteria according to Regulation (EC) No 1272/2008 for classification as:
- acute oral toxicity category 1, 2 or 3,
 - acute dermal toxicity category 1, 2 or 3,
 - acute inhalation toxicity (gases and dust/mist) category 1, 2 or 3,
 - acute inhalation toxicity (vapours) category 1 or 2,
 - specific target organ toxicity by single or repeated exposure category 1,
 - a category 1A or 1B carcinogen,
 - a category 1A or 1B mutagen, or
 - toxic for reproduction category 1A or 1B;
- (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) paragraphs 6 and 7 are replaced by the following:
6. The assessment of the biocidal product family conducted according to the common principles set out in Annex VI shall consider the maximum risks to human health, animal health and the environment and the minimum level of efficacy over the whole potential range of products within the biocidal product family.
- A biocidal product family shall be authorised only if:
- a the application explicitly identifies the maximum risks to human health, animal health and the environment, and the minimum level of efficacy, on which the assessment is based, as well as the permitted variations in composition and uses referred to in point (s) of Article 3(1) together with their respective classification, hazard and precautionary statements and any appropriate risk mitigation measures; and
 - b it can be established based on the assessment referred to in the first subparagraph of this paragraph that all the biocidal products within the family comply with the conditions set out in paragraph 1.
- 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 or limits for the residual content in food contact materials with respect to such substances in accordance with Regulation (EC) No 1935/2004.;
- (4) in Article 23(3), the introductory part is replaced by the following:
3. 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,

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performed in accordance with the technical guidance notes referred to in Article 24, demonstrates that both of the following criteria are met.;

(5) in Article 34(4), the second subparagraph is replaced by the following:

Within 365 days of validating an application, the reference Member State shall evaluate the application and draft an assessment report in accordance with Article 30 and shall send its assessment report and the summary of biocidal product characteristics to the Member States concerned and to the applicant.;

(6) Article 35(3) is replaced by the following:

3. Within the coordination group, all Member States referred to in paragraph 2 of this Article shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known. Where they reach agreement within 60 days of the referral of the points of disagreement referred to in paragraph 2 of this Article, the reference Member State shall record the agreement in the Register for Biocidal Products. 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 34(6) as appropriate.;

(7) 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.’;

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

(9) Article 52 is replaced by the following:

Article 52

Period of grace

Notwithstanding Article 89, where the competent authority or, in the case of a biocidal product authorised at Union level, the Commission, cancels or amends an authorisation or decides not to renew it, it shall grant a period of grace for the making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

The period of grace shall not exceed 180 days for the making available on the market and an additional maximum period of 180 days for the use of existing stocks of the biocidal products concerned.;

(10) in Article 53(1), the first subparagraph is replaced by the following:

1. By way of derogation from Article 17, a competent authority of a Member State (“Member State of introduction”) shall, at the request of the applicant, grant a parallel trade permit for a biocidal product that is authorised in another Member State (“Member State of origin”) to be made available on the market and used in the Member State of introduction, if it determines in accordance with paragraph 3 that the biocidal product is identical to a biocidal product already authorised in the Member State of introduction (“the reference product”).;

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- (11) Article 54 is amended as follows:
- (a) paragraph 1 is replaced by the following:
 - 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.;
 - (b) paragraph 3 is replaced by the following:
 - 3. The Agency shall inform the applicant of the fees payable under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.;
- (12) in Article 56(1), the first subparagraph is replaced by the following:
- 1. By way of derogation from Article 17, an experiment or a test for the purposes of scientific or product and process-orientated research and development involving an unauthorised biocidal product or a non-approved active substance intended exclusively for use in a biocidal product (“experiment” or “test”) may take place only under the conditions provided for in this Article.;
- (13) in Article 58(3), the introductory part is replaced by the following:
- 3. The person responsible for the placing on the market of a treated article shall ensure that the label provides the information listed in the second subparagraph, where.;
- (14) in Article 60(3), the first and second subparagraphs are replaced by the following:
- 3. 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), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 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), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 44(5).;
- (15) Article 66(4) is replaced by the following:
- 4. Any person submitting information related to an active substance or a biocidal product to the Agency or a competent authority for the purposes of this Regulation may request that the information in Article 67(3) and (4) not be made available, including a justification as to why the disclosure of the information could be harmful for that person’s commercial interests or those of any other party concerned.;
- (16) Article 67 is amended as follows:
- (a) in paragraph 1, the introductory part is replaced by the following:
 - 1. From the date on which the Commission adopts an implementing Regulation providing that an active substance is approved, as referred to in point (a) of Article 9(1), the following up-to-date information held by the

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Agency or the Commission on that active substance shall be made publicly and easily available free of charge.;

(b) in paragraph 3, the introductory part is replaced by the following:

3. From the date on which the Commission adopts an implementing Regulation providing that an active substance is approved, as referred to in point (a) of Article 9(1), 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 that active substance.;

(17) in Article 76(1), the following point is added:

(l) providing support and assistance to Member States with regard to control and enforcement activities.;

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

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

(19) in Article 78(2), the second subparagraph is replaced by the following:

Revenues of the Agency as referred to in Article 96(1) of Regulation (EC) No 1907/2006 shall not be used for carrying out tasks under this Regulation, unless for a joint purpose or a temporary transfer to ensure the proper functioning of the Agency. Revenues of the Agency as referred to in paragraph 1 of this Article shall not be used for carrying out tasks under Regulation (EC) No 1907/2006, unless for a joint purpose or a temporary transfer to ensure the proper functioning of the Agency.;

(20) Article 86 is replaced by the following:

Article 86

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

Active substances for which the Commission has adopted directives 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). Approval shall be subject to the conditions set out in those Commission directives.;

(21) Article 89 is amended as follows:

(a) paragraph 2 is replaced by the following:

2. By way of derogation from Articles 17(1), 19(1) and 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 available on the market or using a given biocidal product for up to three years after the date of approval of the last of the active substances to be approved

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in that biocidal product. The Member State concerned may, in accordance with its national rules, authorise the making available on the market or use in its territory only of a biocidal product containing only:

- a existing active substances which:
 - (i) have been evaluated under Commission Regulation (EC) No 1451/2007⁽¹⁶⁾, but which have not yet been approved for that product-type; or
 - (ii) are being evaluated, under Regulation (EC) No 1451/2007, but which have not yet been approved for that product-type;

or

- b a combination of active substances referred to in point (a) and active substances approved in accordance with this Regulation.

By way of derogation from the first subparagraph, in the case of a decision not to approve an active substance, a Member State may continue to apply its current system or practice of making biocidal products available on the market for up to 12 months after the date of the decision not to approve an active substance in accordance with the third subparagraph of paragraph 1, and may continue to apply its current system or practice of using biocidal products for up to 18 months after that decision.;

(b) paragraph 3 is replaced by the following:

3. 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.

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 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 shall be submitted no later than the date of approval of the last active substance for that product-type.

Where no application for authorisation or mutual recognition in parallel has been submitted in accordance with the second subparagraph:

- (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
- (b) use of existing stocks of the biocidal product may continue for up to 365 days after the date of approval of the active substance(s).;

(c) paragraph 4 is replaced by the following:

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4. Where a Member State's competent authority, or where relevant, the Commission, decides to reject an application submitted in accordance with paragraph 3 for authorisation of a biocidal product already made available on the market, or decides not to grant an authorisation or to impose conditions for the authorisation making it necessary to change such a product, the following shall apply:

- a a 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; and
- b use of existing stocks of the biocidal product may continue for up to 365 days after the date of the decision of the authority.;

(22) in Article 92(2), the following sentence is added:

Biocidal products authorised in accordance with Article 3 or 4 of Directive 98/8/EC shall be considered as authorised in accordance with Article 17 of this Regulation.;

(23) Article 93 is replaced by the following:

Article 93

Transitional measures concerning biocidal products not covered by the scope of Directive 98/8/EC

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 and using a biocidal product not covered by the scope of Directive 98/8/EC, but falling within the scope of this Regulation, and consisting of, containing or generating only active substances that were available on the market, or used in biocidal products, on 1 September 2013. The derogation shall apply until one of the following dates:

- (a) where applications for approval of all those active substances, which the biocidal product consists of, contains or generates, are submitted for the relevant product-type by 1 September 2016, the deadlines provided for in the second subparagraph of Article 89(2), in Article 89(3) and in Article 89(4); or
- (b) where an application is not submitted in accordance with point (a) for one of the active substances, until 1 September 2017.;

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

Article 94

Transitional measures concerning treated articles

1 By way of derogation from Article 58(2), a treated article treated with or intentionally incorporating one or more biocidal products containing only active substances that are under examination for the relevant product-type in the work programme referred to in Article 89(1) on 1 September 2016 or for which an application for approval for the relevant product-type is submitted by that date, or containing only a combination of such substances and active substances included in

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the list drawn up in accordance with Article 9(2) for the relevant product-type and use or included in Annex I, may be placed on the market until one of the following dates:

- a in the case of a decision adopted after 1 September 2016 to reject the application for approval of, or not to approve, one of the active substances for the relevant use, the date falling 180 days after such a decision;
- b in other cases, the date of approval for the relevant product-type and use of the last active substance to be approved and contained in the biocidal product.

- 2 By way of further derogation from Article 58(2), a treated article treated with or intentionally incorporating one or more biocidal products containing any active substances other than those referred to in paragraph 1 of this Article or those included in the list drawn up in accordance with Article 9(2) for the relevant product-type and use or included in Annex I, 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 shall 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 IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive (“the 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 (“the 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, and the product-type(s) for which they have made a submission, 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 (“the substance supplier”) or who manufactures or makes available on the market a biocidal product consisting of, containing or generating that relevant substance (“the product supplier”), may at any time submit to the Agency either a complete substance dossier for that relevant substance, 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. Following the renewal of the approval of an active substance, any substance supplier or product supplier may submit to the Agency a letter of access to all the data which was considered by the evaluating competent authority as relevant for the purpose of the renewal, and for which the protection period has not yet expired (“the relevant data”).

The Agency shall inform the submitting supplier of the fees payable under Article 80(1). It shall reject the application if the submitting supplier fails to pay those fees within 30 days and shall inform the submitting supplier 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 shall inform the submitting supplier 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 unless either the substance supplier or the product

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supplier is included in the list referred to in paragraph 1 for the product-type(s) to which the product belongs.

3 For the purposes of making a submission in accordance with the second subparagraph of paragraph 1 of this article, 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 active 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 was not taken before 1 September 2013, shall end on 31 December 2025.

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

7 The Agency shall regularly update the list referred to in paragraph 1 of this Article. Following the renewal of the approval of an active substance, the Agency shall remove from the list any substance supplier or product supplier who has not, within 12 months of the renewal, submitted all the relevant data or a letter of access to all the relevant data, either in accordance with the second subparagraph of paragraph 1 of this Article or in an application in accordance with Article 13.;

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

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

(26) in Annex I, the title of category 6 is replaced by the following:

Category 6 — Substances for which a Member State has validated an active substance dossier in accordance with Article 7(3) of this Regulation or accepted such a dossier in accordance with Article 11(1) of Directive 98/8/EC;

(27) 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*.

Point 24 of Article 1 shall apply from 1 September 2013.

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

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Done at Strasbourg, 11 March 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

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- (1) [OJ C 347, 18.12.2010, p. 62.](#)
- (2) Position of the European Parliament of 25 February 2014 (not yet published in the Official Journal) and Decision of the Council of 10 March 2014.
- (3) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([OJ L 167, 27.6.2012, p. 1.](#)
- (4) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([OJ L 268, 18.10.2003, p. 29.](#)
- (5) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ([OJ L 354, 31.12.2008, p. 16.](#)
- (6) 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 and repealing Directives 80/590/EEC and 89/109/EEC ([OJ L 338, 13.11.2004, p. 4.](#)
- (7) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ([OJ L 353, 31.12.2008, p. 1.](#)
- (8) 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 ([OJ L 396, 30.12.2006, p. 1.](#)
- (9) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives ([OJ L 312, 22.11.2008, p. 3.](#)
- (10) 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 ([OJ L 123, 24.4.1998, p. 1.](#)
- (11) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ([OJ L 37, 13.2.1993, p. 1.](#)
- (12) 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 and amending Council Directive 91/414/EEC ([OJ L 70, 16.3.2005, p. 1.](#)
- (13) 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, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council ([OJ L 152, 16.6.2009, p. 11.](#)
- (14) Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed ([OJ L 140, 30.5.2002, p. 10.](#)
- (15) 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 and repealing Directives 80/590/EEC and 89/109/EEC ([OJ L 338, 13.11.2004, p. 4.](#));
- (16) 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 of the European Parliament and of the Council concerning the placing of biocidal products on the market ([OJ L 325, 11.12.2007, p. 3.](#));

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