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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	4 August 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2014) 5391 final
Subject:	COMMISSION DELEGATED REGULATION (EU) No …/.. of 4.8.2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council

Delegations will find attached document C(2014) 5391 final.

Encl.: C(2014) 5391 final

EUROPEAN
COMMISSION

Brussels, 4.8.2014
C(2014) 5391 final

COMMISSION DELEGATED REGULATION (EU) No …/..

of 4.8.2014

on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

The delegated act lays down the rules for the work programme for systematic examination of all existing biocidal active substances, which was commenced in accordance with Article 16(2) of Directive 98/8/EC. Such rules are currently provided for by Regulation (EC) No 1451/2007. As Regulation (EU) No 528/2012 has repealed Directive 98/8/EC and replaced the provisions therein with different provisions, it is appropriate to replace Regulation (EC) No 1451/2007 by a new Regulation containing rules adapted to Regulation (EU) No 528/2012.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The draft delegated act has been discussed on two occasions with national experts and industry stake holders in the expert meeting of Competent Authorities for biocidal products. The draft has been made publically available in advance of those meetings.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act defines the rights and obligations of competent authorities and of participants in the work programme.

COMMISSION DELEGATED REGULATION (EU) No …/..

of 4.8.2014

on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[1], and in particular the first subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Regulation (EC) No 1451/2007[2] lays down the detailed rules for the programme of review of existing biocidal active substances (the 'review programme') commenced in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council[3]. Since that Directive has been repealed and replaced by Regulation (EU) No 528/2012, the detailed rules for the continuation of the review programme should be adapted to the provisions of that Regulation.

(2) It is important to identify the active substance/product-type combinations that may be made available on the market and used, subject to national rules, by virtue of the transitional provisions laid down in Article 89 of Regulation (EU) No 528/2012. Such should be the case for active substance/product-type combinations that are under evaluation in the review programme.

(3) Where a product has benefitted from the derogation for food and feed provided for by Article 6 of Regulation (EC) No 1451/2007, but is not covered by the exemption for food and feed laid down in Article 2(5)(a) of Regulation (EU) No 528/2012, the active substances it contains should be evaluated in the review programme for the relevant product-type. Subject to national rules, it should be allowed to be made available on the market and used until the end of that evaluation. A system of prior declaration should define which products benefit from this provision. The same should apply

[1] OJ L 167, 27.6.2012, p. 1.

[2] 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).

[3] 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).

where the failure to notify an active substance/product-type combination is due to the new definition of product-types in Regulation (EU) No 528/2012 compared with that in Directive 98/8/EC, or is well justified based on a Commission decision taken in accordance with Article 3(3) of Regulation (EU) No 528/2012, on the case law, such as case C-420/10[4], or on authoritative guidance from the Commission or Member States' competent authorities, which is subsequently reviewed.

(4) Where a biocidal product contains, consists of or generates an active substance which is no longer included in the review programme but the use of that biocidal product is essential in a Member State, that use and the making available on the market for that use should be allowed in that Member State, under the responsibility of the Member State, subject to certain conditions and for a limited period of time.

(5) With a view to ensure consistency and simplification, the procedure for evaluation of active substances in the review programme should, in all relevant parts, be identical with that for applications submitted pursuant to Article 7 of Regulation (EU) No 528/2012 or pursuant to Commission Implementing Regulation (EU) No 88/2014[5].

(6) For substances meeting the exclusion or substitution criteria, the evaluating Competent Authority should submit to the Agency a proposal for harmonised classification and labelling pursuant to Article 37(1) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council[6] for the endpoints of concern, while preserving the right of the Member State to submit a proposal on other or all endpoints. The evaluating Competent Authority should also consult the Agency on substances which would meet the criteria for being persistent, bioaccumulative or toxic, or on substances that would be considered as having endocrine disrupting properties.

(7) In order to ensure that the review programme is finalised by the target date indicated in Article 89(1) of Regulation (EU) No 528/2012, the evaluations should be limited to active substance/product-type combinations for which the relevant data has been submitted within the deadlines laid down in Regulation (EC) No 1451/2007 or this Regulation. Furthermore, appropriate time limits should be established for finalising the evaluations, taking into account the possibility that applications could be validated less than a year before those deadlines.

(8) No data requirements have yet been established for inclusion in category 7 of Annex I to Regulation (EU) No 528/2012. It is therefore appropriate at this time to limit applications for inclusion in that Annex to category 1, 2, 3, 4, 5 or 6.

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4 Case C-420/10: Judgment of the Court (Third Chamber) of 1 March 2012 (reference for a preliminary ruling from the Landgericht Hamburg — Germany) — Söll GmbH v Tetra GmbH (Placing on the market of biocidal products — Directive 98/8/EC — Article 2(1)(a) — Concept of 'biocidal products' — Product causing flocculation of harmful organisms without destroying or deterring them or rendering them harmless).

5 Commission Implementing Regulation (EU) No 88/2014 of 31 January 2014 specifying a procedure for the amendment of Annex I to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 32, 1.2.2014, p.3).

6 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).

(9) Notwithstanding Article 90(2) of Regulation (EU) No 528/2012, it follows from Article 91 of that Regulation that the criteria listed in Article 10 of that Regulation should be relevant for the subsequent authorisation of biocidal products in all cases. It is therefore appropriate to identify substances fulfilling those criteria in all active substance evaluations.

(10) A prospective participant in the review programme should be allowed to join or replace an existing participant by mutual agreement, provided that the evaluation is not thereby delayed by limited data access, as the prospective applicant would otherwise have to generate data again.

(11) Since participation in the review programme is voluntary, a participant should be allowed to withdraw from that programme. Where that occurs, prospective participants should be allowed to take over the support, unless that opportunity has already been granted once, thereby already causing delay to the review programme, and unless the Agency has already begun working on its opinion.

(12) Where the evaluation of an active substance demonstrates that the identity formally included in the review programme does not exactly match that of the substance actually being evaluated, and the evaluation does not allow conclusions to be drawn regarding the formally included substance identity, it should be possible to redefine the substance in the course of the evaluation and allow other persons to take over the support of the formally included substance.

(13) Certain substances included in the review programme are not supported by any participant at the time of adoption of this Regulation. The same applies to certain nanomaterials, although, pursuant to Article 4(4) of Regulation (EU) No 528/2012, such materials cannot be approved unless explicitly mentioned. Persons should be allowed to take over the participation for those substances and those nanomaterials, failing which those substances and nanomaterials should be excluded from the review programme.

(14) In order to ensure that no substance is unduly maintained or included in the review programme without subsequently being evaluated, maintenance or inclusion of a substance not yet under evaluation should be subject to a notification of essential data regarding the substance,

HAS ADOPTED THIS REGULATION:

Chapter 1
Subject matter and definitions

Article 1
Subject matter

This Regulation lays down rules for the carrying out of the work programme for the systematic examination of all existing active substances referred to in Article 89 of Regulation (EU) No 528/2012.

Article 2
Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) 'non-approval decision' means a decision not to approve a substance/product-type combination pursuant to Article 9(1)(b) of Regulation (EU) No 528/2012 or to the third subparagraph of Article 89(1) of that Regulation, or not to include it in Annex I or IA to Directive 98/8/EC;

(b) 'substance/product-type combination included in the review programme' means a substance/product-type combination listed in Annex II which complies with the following conditions:

(i) it has not been the subject of either of the following:

- a Directive on inclusion in Annex I or IA to Directive 98/8/EC;

- a Regulation providing that it is approved pursuant to the third subparagraph of Article 89(1) of Regulation (EU) No 528/2012;

(ii) it has not been the subject of any non-approval decision or the latest non-approval decision concerning it has been repealed;

(c) ‘participant’ means a person who has submitted an application for a substance/product-type combination included in the review programme, or has submitted a notification found compliant pursuant to Article 17(5) of this Regulation, or on whose behalf such application or notification has been submitted.

(d) 'evaluating competent authority' means the competent authority designated pursuant to Article 81 of Regulation (EU) No 528/2012 of the Member State indicated in Annex II to this Regulation.

Chapter 2
Process for evaluation of dossiers

Article 3
Application for approval or inclusion in Annex I to Regulation (EU) No 528/2012

1. An application for approval or inclusion in Annex I to Regulation (EU) No 528/2012 may be submitted only by a participant whose notification has been found compliant by the Agency pursuant to Article 17(5) of this Regulation.

Where the application concerns inclusion in Annex I to Regulation (EU) No 528/2012, it may only concern category 1, 2, 3, 4, 5 or 6 of that Annex.

2. Applications referred to in paragraph 1 shall be submitted to the Agency within two years of the declaration of compliance pursuant to Article 17(5).

Article 4
Acceptance of applications

1. The Agency shall inform the participant of the fees payable under Commission Implementing Regulation (EU) No 564/2013[7] and shall reject the application if the participant fails to pay the fees within 30 days. It shall inform the participant and the evaluating competent authority accordingly.

2. Upon receipt of the fees payable under Implementing Regulation (EU) No 564/2013, the Agency shall accept the application and inform the participant and the evaluating competent authority accordingly, indicating the date of the acceptance of the application and its unique identification code.

3. An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012 against decisions of the Agency taken pursuant to paragraph 1 of this Article.

4. The evaluating competent authority shall inform the participant of the fees payable under Article 80(2) of Regulation (EU) No 528/2012 within 30 days after the Agency has accepted the application, and shall reject the application if the participant fails to pay the fees within 30 days. It shall inform the participant and the Agency accordingly.

Article 5
Validation of applications for approval or inclusion in category 6 of Annex I to Regulation (EU) No 528/2012

1. Where an application for approval or inclusion in category 6 of Annex I to Regulation (EU) No 528/2012 containing the data required in accordance with Article 6(1) and (2) thereof has been accepted by the Agency pursuant to Article 4(2) and the fee has been paid pursuant to Article 4(4) the evaluating competent authority shall validate the application within 30 days of the payment of the fees.

2. Where the evaluating competent authority has received from the participant the dossier pursuant to Regulation (EC) No 1451/2007 but not yet accepted the dossier as complete pursuant to Article 13 thereof, the evaluating competent authority shall validate the application at the latest [60 days after the date of entry into force of this Regulation].

3. In the cases referred to in paragraphs 1 and 2, the evaluating competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

4. Where the evaluating competent authority considers that the application is incomplete, it shall inform the participant as to what additional information is required for the validation of the application and shall set a reasonable time limit for

[7] Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 19/06/2013, p. 17).

the submission of that information. That time limit shall not normally exceed 90 days.

The evaluating competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirement laid down in paragraph 2.

The evaluating competent authority shall reject the application if the participant fails to submit the requested information within the deadline and shall inform the participant and the Agency accordingly. In such cases, part of the fees paid in accordance with Article 80(1) and (2) of Regulation (EU) No 528/2012 shall be reimbursed.

On validating an application, the evaluating competent authority shall without delay inform the participant, the Agency and other competent authorities accordingly, indicating the date of the validation.

Article 6
Evaluation of applications

1. This Article shall apply where any of the following conditions applies:

   (a) where an application has been validated pursuant to Article 5;

   (b) where the evaluating competent authority has accepted the dossier as complete pursuant to Article 13 of Regulation (EC) No 1451/2007 but not yet submitted the competent authority report to the Commission pursuant to Article 14(4) of that Regulation;

   (c) where an application for inclusion in category 1, 2, 3, 4 or 5 of Annex I to Regulation (EU) No 528/2012 has been accepted by the Agency pursuant to Article 4(2) and the fee has been paid pursuant to Article 4(4).

2. The evaluating competent authority shall evaluate the application in accordance with Articles 4 and 5 of Regulation (EU) No 528/2012, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3) of that Regulation, and send an assessment report and the conclusions of its evaluation to the Agency.

3. Where several participants support the same substance/product-type combination, the evaluating competent authority shall draft only one assessment report. The assessment report and the conclusions shall be sent within either of the following time-limits, whichever is the later:

   (a) 365 days of the last validation referred to in paragraph 1(a), acceptance of completeness referred to in paragraph 1(b) or payment of the fee referred to in paragraph 1(c), for the substance/product-type combination in question;

   (b) the time limits provided for by Annex III.

4. Prior to submitting its conclusions to the Agency, the evaluating competent authority shall give the participant the opportunity to provide written comments on the assessment report and on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

5. Where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the participant to submit such information within a specified time limit, and shall inform the Agency accordingly.

The 365-day period referred to in paragraph 3 shall be suspended from the date of issue of the request until the date the information is received. Unless it is justified by the nature of the data requested or by exceptional circumstances, the suspension shall not exceed the following time-limits:

(a) 365 days in cases where the additional information relates to concerns which were not addressed under Directive 98/8/EC or under the practice established for application of that Directive;

(b) 180 days in other cases.

6. Where the evaluating competent authority considers that there are concerns for human health, animal health or the environment as a result of the cumulative effects from the use of biocidal products containing the same or different active substances, it shall document its concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[8] and include this as part of its conclusions.

7. Upon finalisation of its hazard evaluation, the evaluating competent authority shall without undue delay and no later than at the time of submission of the assessment report pursuant to paragraph 3, as appropriate:

(a) submit a proposal to the Agency pursuant to Article 37(1) of Regulation (EC) No 1272/2008, where it considers that one of the criteria referred to in Article 36(1) thereof is fulfilled and not properly addressed in part 3 of Annex VI to that Regulation;

(b) consult the Agency where it considers that one of the criteria of Article 5(1)(d) or (e) of Regulation (EU) No 528/2012, or the condition of Article 10(1)(d) of that Regulation, is fulfilled and not properly addressed in Annex XIV to Regulation (EC) No 1907/2006 or in the candidate list referred to in Article 59(1) of that Regulation.

[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).

Article 7
Opinion of the Agency

1. This Article shall apply where either of the following conditions applies:

   (a) where the evaluating competent authority has submitted an assessment report pursuant to Article 6(2) and, where relevant, a proposal or a consultation pursuant to Article 6(7);

   (b) where a competent authority report has been submitted to the Commission pursuant to Article 14(4) of Regulation (EC) No 1451/2007, but the assessment report has not yet been reviewed within the Standing Committee on Biocidal Products pursuant to Article 15(4) of that Regulation.

2. Upon acceptance of the report, the Agency shall prepare and submit to the Commission an opinion on the approval of the substance/product-type combination or its inclusion in category 1, 2, 3, 4, 5 or 6 of Annex I to Regulation (EU) No 528/2012, or both, having regard to the conclusions of the evaluating competent authority.

   The Agency shall start the preparation of the opinion within either of the following deadlines, whichever is the later:

   (a) three months of the acceptance of the report;

   (b) the time limits provided for by Annex III.

   The Agency shall submit the opinion to the Commission within 270 days of the start of the preparation.

Article 8
Active substances which are candidates for substitution

1. When preparing its opinion pursuant to Article 7(2), the Agency shall examine whether the active substance fulfils any of the criteria listed in Article 10(1) of Regulation (EU) No 528/2012 and address the matter in its opinion.

2. Prior to submitting its opinion to the Commission, the Agency shall make publicly available, without prejudice to Articles 66 and 67 of Regulation (EU) No 528/2012, information on potential candidates for substitution during a period of no more than 60 days, during which time interested third parties may submit relevant information, including information on available substitutes. The Agency shall take due account of the information received when finalising its opinion.

3. Where the active substance is approved and fulfils one of the criteria laid down in Article 10(1) of Regulation (EU) No 528/2012, it shall be identified as a candidate for substitution in the Regulation adopted pursuant to the first subparagraph of Article 89(1) of that Regulation.

Article 9
Commission decision

Upon receipt of the opinion of the Agency pursuant to Article 7(2), the Commission shall without undue delay prepare a draft decision for adoption pursuant to Article 89(1) or, as appropriate, Article 28(1) of Regulation (EU) No 528/2012.

Chapter 3
Changes of elements of the review programme

Article 10
Joining or replacing participants by mutual agreement

1. The role of participant may be taken over or shared by mutual agreement between an existing participant and a prospective participant, provided that the prospective participant has the right to refer to all the data submitted or referred to by the existing participant.

2. A notification for the purpose of this Article shall be submitted jointly to the Agency by the prospective and the existing participant through the Register for Biocidal Products referred to in Article 71 of Regulation (EU) No 528/2012 (hereinafter 'the Register'), and shall include all relevant letters of access.

3. Upon receipt of a notification complying with paragraph 2, the Agency shall update the information in the Register with respect to the identity of the participant.

4. A person established in the Union having taken over or joined the role of participant pursuant to this Article shall be considered as having submitted a dossier or a letter of access to a dossier for the purpose of Article 95 of Regulation (EU) No 528/2012.

Article 11
Participants' withdrawal

1. A participant shall be considered to have withdrawn its support for a substance/product-type combination in the review programme in the following cases:

   (a) where it has informed the Agency or the evaluating competent authority through the Register of its intention to withdraw;

   (b) where it has failed to submit an application within the time limits specified in Article 3(2);

   (c) where its application has been rejected pursuant to Article 4(1), Article 4(4) or Article 5(4);

   (d) where it has failed to provide the additional information within the time limits provided for by Article 6(5);

(e) where it has otherwise failed to pay the fees payable to the evaluating competent authority or the Agency.

2. A withdrawal shall be considered as timely unless it occurs after the date when the evaluating competent authority submits its competent authority report to the applicant pursuant to Article 6(4) of this Regulation.

Article 12
Consequences of a timely withdrawal

1. Where a timely withdrawal is known to the evaluating competent authority but not to the Agency, the evaluating competent authority shall without undue delay inform the Agency thereof through the Register.

2. Where a timely withdrawal is known to the Agency, it shall update the information in the Register with respect to the identity of the participant.

3. Where all participants supporting the same substance/product-type combination have made a timely withdrawal from the review programme, and where the role of participant for that combination has previously been taken over, the Agency shall inform the Commission thereof through the Register.

Article 13
Redefinition of active substances

1. Where the evaluation of an existing active substance does not allow for conclusions to be drawn relating to the substance as identified in Annex II, the evaluating competent authority shall, after consultation with the participant concerned, establish a new substance identity. The evaluating competent authority shall inform the Agency thereof.

2. The Agency shall update the information in the Register with respect to the identity of the substance.

Article 14
Taking over the role of participant

1. The Agency shall publish an open invitation to take over the role of participant for a substance/product-type combination where one of the following cases applies:

(a) where all participants supporting the same substance/product-type combination have made a timely withdrawal pursuant to Article 11, and the role of participant for that combination has not previously been taken over;

(b) following a redefinition pursuant to Article 13, in which case, the invitation shall only concern any substance covered by the existing identity in Annex II, but not by the new substance identity.

2. Within 12 months from the date of the publication referred to in paragraph 1, any person may submit a notification for the combination pursuant to Article 17.

3. Within 12 months from the date of entry into force of this Regulation, any person may notify a substance/product-type combination included in part 2 of Annex II pursuant to Article 17.

Article 15
Substance/product-type combinations eligible for inclusion in the review programme

Where a biocidal product covered by the scope of Regulation (EU) No 528/2012 and being placed on the market consists of, contains or generates an existing active substance which is neither approved, nor included in the review programme, for the product-type, and is not included in Annex I to that Regulation, that substance shall be eligible for inclusion in the review programme for the relevant product-type on any of the following grounds:

(a) the person placing the product on the market has relied on guidance published by, or written advice received from, the Commission or a competent authority designated in accordance with Article 26 of Directive 98/8/EC or Article 81 of Regulation (EU) No 528/2012, where that guidance or advice gave objectively justified reasons to believe that the product was excluded from the scope of Directive 98/8/EC or of Regulation (EU) No 528/2012, or that the relevant product-type was one for which the active substance had been notified and where that guidance or advice is subsequently reviewed in a decision adopted pursuant to Article 3(3) of Regulation (EU) No 528/2012 or in new, authoritative guidance published by the Commission;

(b) the substance has benefitted from the derogation for food and feed provided for by Article 6 of Regulation (EC) No 1451/2007;

(c) the biocidal product belongs under Regulation (EU) No 528/2012 to a different product-type than the one it belonged to under Directive 98/8/EC, as a result of a modification of scope of those product-types, and contains a substance included in the review programme for the original product-type but not for the new one.

Article 16
Declaration of interest to notify

1. A declaration of interest to notify a substance which is eligible for inclusion in the review programme pursuant to Article 15 shall be submitted through the Register by any person with an interest to notify a substance/product-type combination to one of the following recipients:

   (a) to the Commission at the latest 12 months after the publication of the decision or guidance referred to in point (a) of Article 15;

   (b) to the Agency at the latest [12 months after the entry into force of this Regulation] in cases referred to in point (b) of Article 15;

   (c) to the Commission at the latest [12 months after the entry into force of this Regulation] in cases referred to in point (c) of Article 15.

2. A declaration shall indicate the relevant substance/product-type combination. In cases referred to in point (a) of Article 15, the declaration shall provide a substantiated justification showing that all the conditions listed therein are fulfilled.

3. Where a declaration has been made in a case referred to in point (a) or (c) of Article 15, and the Commission finds, in consultation with the Member States, that paragraph 6 is not applicable, and, where relevant, that the conditions for notification listed in point (a) of Article 15 are fulfilled, it shall inform the Agency thereof.

4. Where a declaration has been made in the case referred to in point (b) of Article 15, or where the Commission has informed the Agency pursuant to paragraph 3, the Agency shall make that information publicly available by electronic means, mentioning the relevant substance/product-type combination. For the purposes of this Regulation, a publication made pursuant to the third subparagraph of Article 3a(3) of Regulation (EC) No 1451/2007 shall be considered as a publication made pursuant to this paragraph.

5. Within 6 months from the date of a publication referred to in paragraph 4, any person with an interest to notify the substance/product-type combination may do so pursuant to Article 17.

6. In cases referred to in points (a) and (c) of Article 15, a substance/product-type combination shall be considered as notified by a participant, and shall not be eligible for additional notification where the following conditions apply:

   (a) the relevant active substance is already included in the review programme;

   (b) one of the dossiers submitted to the evaluating Member State for the relevant active substance already contains all the data required for the evaluation of the product-type;

   (c) the participant which has submitted that dossier indicates an interest to support the substance/product-type combination.

Article 17
Notification procedure

1. Notifications pursuant to Article 14(2) and (3) or Article 16(5) shall be made to the Agency through the Register.

2. The notification shall be submitted in IUCLID format. It shall contain the information referred to in Annex I.

3. Where no evaluating competent authority is indicated in Annex II for the active substance in question, the notifier shall inform the Agency of the name of its choice of competent authority designated in accordance with Article 81 of Regulation (EU) No 528/2012, and provide written confirmation that that competent authority agrees to evaluate the dossier.

4. Upon receipt of a notification, the Agency shall inform the Commission thereof, and inform the notifier of the fees payable under Regulation (EU) No 564/2013. If the notifier fails to pay the fee within 30 days from the receipt of that information, the Agency shall reject the notification and inform the notifier and the Commission thereof.

5. Upon receipt of payment of the fees, the Agency shall verify within 30 days whether the notification complies with the requirements of paragraph 2. If the notification does not comply with those requirements, the Agency shall grant the notifier a period of 30 days in which to complete or correct the notification. After the expiry of that 30-day period, the Agency shall, within 30 days, either declare that the notification complies with the requirements of paragraph 2 or reject the notification, and inform the notifier and the Commission thereof.

6. An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012 against decisions of the Agency taken pursuant to paragraph 4 or paragraph 5.

7. Where a notification has been found compliant pursuant to paragraph 5, the Agency shall without delay:

   (a) where the notification has been submitted pursuant to Article 14(2) or (3), update the information in the Register with respect to the identity of the participant and, where relevant, of the substance;

   (b) where the notification has been submitted pursuant to Article 16(5), inform the Commission of the compliance.

Article 18
Inclusion in the review programme

Where a substance/product-type combination is considered notified in accordance with Article 16(6), or where the Agency informs the Commission of compliance in accordance with Article 17(7)(b), the Commission shall include the substance/ product-type combination in the review programme.

Article 19
Information on substances no longer supported under the review programme

Where no notification has been received within the time limit referred to in Article 16(5), or where a notification referred to in that Article has been received and subsequently rejected by the Agency pursuant to Article 17(4) or (5), the Agency shall inform the Member States thereof through the Register and publish that information electronically.

Article 20
Commission decisions on substances no longer supported under the review programme

The Commission shall prepare a draft non-approval decision pursuant to the third subparagraph of Article 89(1) of Regulation (EU) No 528/2012 in the following cases:

(a) where the Agency informs the Commission of all participants' timely withdrawal pursuant to Article 12(3) of this Regulation;

(b) where no person has submitted a notification within the time limits provided for by Article 14(2) or 14(3) of this Regulation, or where such a notification has been submitted and rejected pursuant to Article 17(4) or 17(5) thereof;

(c) where a notification has been submitted within the time limits provided for by Article 14(2) or 14(3) of this Regulation and has been found compliant pursuant to Article 17(5) thereof, but the substance identity in the notification only covers part of the existing identity in Annex II to this Regulation.

In case referred to in point (c) of first paragraph, the draft non-approval decision shall cover any substance covered by the existing identity in Annex II to this Regulation, but not by the notification or any approval decision.

Chapter 4
Transitional measures

Article 21

Transitional measures for substances referred to in Article 15

1. A Member State may continue to apply its current system or practice of making available on the market and using a biocidal product consisting of, containing or generating an existing active substance referred to in points (b) and (c) of Article 15. In such cases:

   (a) the biocidal product shall no longer be made available on the market with effect from 24 months after the date of entry into force of this Regulation;

   (b) the use of existing stocks of the biocidal product may continue until 30 months after the date of entry into force of this Regulation.

2. A Member State may continue to apply its current system or practice of making available on the market and using a biocidal product consisting of, containing or generating an existing active substance referred to in point (a) of Article 15. In such cases:

   (a) The biocidal product shall no longer be made available on the market with effect from 24 months after of either of the following, whichever is the later:

      (i) the date of entry into force of this Regulation;

      (ii) the notification or publication of the decision or guidance referred to in point (a) of Article 15.

   (b) Use of existing stocks of the biocidal product may continue until 30 months after either of the following, whichever is the later:

      (i) the date of entry into force of this Regulation;

(ii) the notification or publication of the decision or guidance referred to in point (a) of Article 15.

3. A Member State may continue to apply its current system or practice of making available on the market or using a biocidal product consisting of, containing or generating an existing active substance for which the Agency has made a publication pursuant to Article 16(4) for the relevant product-type. In such cases:

(a) The biocidal product shall no longer be made available on the market with effect from 12 months after the date when the Agency has made the electronic publication referred to in Article 19; and

(b) Use of existing stocks of the biocidal product may continue until 18 months after the date of that publication.

Article 22
Essential use

1. Without prejudice to Article 55(1) of Regulation (EU) No 528/2012, within 18 months of the date of a decision not to approve an existing active substance, where a Member State considers this existing active substance essential for one of the reasons referred to in points (b) or (c) of the first subparagraph of Article 5(2) of Regulation (EU) No 528/2012, that Member State may submit a reasoned application to the Commission for a derogation from the second sub-paragraph of Article 89(2) of that Regulation.

2. The requesting Member State shall submit the reasoned application to the Agency through the Register. Where the application contains confidential information, the requesting Member State shall at the same time submit a non-confidential version.

3. The Agency shall make the application or, where relevant, the non-confidential version, publicly available by electronic means. Member States or any other person may submit comments within 60 days of the publication.

4. Taking account of the comments received, the Commission may grant a derogation from the second sub-paragraph of Article 89(2) of Regulation (EU) No 528/2012 allowing biocidal products consisting of, containing or generating the substance to be made available on the market of the requesting Member State and used in that Member State in accordance with national rules and subject to the conditions in paragraph 5 and any further conditions imposed by the Commission.

5. The Member State to which the derogation is granted shall:

(a) ensure that continued use is limited to such cases where and such time during which the conditions of paragraph 1 are fulfilled;

(b) impose appropriate risk mitigation measures to ensure that exposure of humans, animals and the environment is minimised;

(c) ensure that alternatives are being sought, or that an application for approval of the active substance is being prepared for submission in accordance with

Article 7 of Regulation (EU) No 528/2012 in due time before the expiry of the derogation.

Chapter 5
Final provisions

Article 23

Repeal

Regulation (EC) No 1451/2007 is repealed.

References to that Regulation shall be construed as references to this Regulation.

Article 24

Entry into force

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, 4.8.2014

For the Commission
The President
José Manuel BARROSO