

**COMMISSION DELEGATED REGULATION (EU) No 1062/2014****of 4 August 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)**

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it has not been the subject of any non-approval decision or the latest non-approval decision concerning it has been repealed;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

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- (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 ⁽¹⁾ 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.

⁽¹⁾ 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, 19.6.2013, p. 17).



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 3 January 2015.
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 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).

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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⁽¹⁾ and include this as part of its conclusions.

⁽¹⁾ 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).

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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.

▼ M3*Article 6a*

Applications for which the competent authority of the United Kingdom was the evaluating competent authority before 30 March 2019

1. This Article is applicable to applications for which the competent authority of the United Kingdom was the evaluating competent authority before 30 March 2019 for the entries 79, 85, 113, 171, 187, 188, 321, 345, 346, 458, 531, 554, 571, 599, 609, 1045, 1046 and 1047 of Annex II.

2. The evaluating competent authority of a Member State having replaced the competent authority of the United Kingdom in relation to an application that has been submitted before 30 March 2019, shall inform the participant of the fees payable under Article 80(2) of Regulation (EU) No 528/2012 at the latest by 30 April 2019, and shall reject the application if the participant fails to pay the fees within a period of time fixed by the evaluating competent authority. It shall inform the participant and the Agency accordingly.

3. By derogation from the time limits laid down in Article 6(3), the assessment report and the conclusions shall be sent by the evaluating competent authority within either of the following time limits, whichever is the later:

- (a) 31 December 2020;
- (b) the time limit for submitting the assessment report pursuant to Article 6(3)(b) set out in Annex III.

▼ B*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.

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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.

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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.

▼B*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.

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▼B*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;

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- (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 30 October 2015 in cases referred to in point (b) of Article 15;
- (c) to the Commission at the latest 30 October 2015 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.

▼B*Article 17***Notification procedure****▼M1**

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

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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:

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

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(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.

▼B*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;

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

(c) where a notification has been submitted within the time limits provided for by Article 14(2) 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.

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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.

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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 subparagraph 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.

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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.

*ANNEX I***Information requirements for notifications pursuant to Article 17**

A notification pursuant to Article 17 shall contain the following information:

- (1) evidence that the substance is an existing active substance within the meaning of Article 3(1)(d) of Regulation (EU) No 528/2012;
- (2) an indication of the product-type(s) concerned by the notification;
- (3) information on any studies that have been commissioned for the purpose of application for approval or inclusion in Annex I to Regulation (EU) No 528/2012, as well as the expected date of completion;
- (4) the information referred to in Sections
 - (a) 1, 2 and 7.1 to 7.5 of the table in Title 1 of Annex II to Regulation (EU) No 528/2012 for chemical substances;
 - (b) 1, 2 and 6.1 to 6.4 of the table in Title 2 of Annex II to Regulation (EU) No 528/2012 for micro-organisms;
- (5) where the notification has been made in a case referred to in point (a) of Article 15, evidence that the substance was on the market as an active substance of a biocidal product falling under the relevant product-type on the date of notification or publication of the decision or guidance referred to in that point.

ANNEX II

SUBSTANCE/PRODUCT-TYPE COMBINATIONS INCLUDED IN THE REVIEW PROGRAMME ON 17 MARCH 2022

Active substance/product-type combinations supported on 17 March 2022, excluding any other nanomaterial than that explicitly mentioned in entry 1017 and excluding any generation in situ of the active substance except when explicitly mentioned with the reference to the supported precursor(s)

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
1	Formaldehyde	DE	200-001-8	50-00-0																		x
9	Bronopol	ES	200-143-0	52-51-7		x				x					x	x						x
36	Ethanol	EL	200-578-6	64-17-5	x	x		x														
37	Formic acid	BE	200-579-1	64-18-6		x	x	x	x	x												
1025	Performic acid generated from formic acid and hydrogen peroxide	BE				x		x							x	x						
43	Salicylic acid	NL	200-712-3	69-72-7		x	x	x														
52	Ethylene oxide	NO	200-849-9	75-21-8		x																
69	Glycolic acid	NL	201-180-5	79-14-1		x	x	x														
1026	Peracetic acid generated from tetraacetythylenediamine (TAED) and hydrogen peroxide	AT				x																
1027	Peracetic acid generated from 1,3- diacetyloxypropan-2-yl acetate and hydrogen peroxide	AT				x																
71	L-(+)-lactic acid	DE	201-196-2	79-33-4						x												

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Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
79	(2R,6aS,12aS)-1,2,6,6a,12,12a-Hexahydro-2-isopropenyl-8,9-dimethoxychromeno[3,4-b]furo[2,3-h]chromen-6-one (Rotenone)	PL	201-501-9	83-79-4														x				
85	Symclosene	DE	201-782-8	87-90-1		x	x	x	x						x							
92	Biphenyl-2-ol	ES	201-993-5	90-43-7							x		x	x								
113	3-Phenyl-propen-2-al (Cinnamaldehyde)	PL	203-213-9	104-55-2		x																
117	Geraniol	FR	203-377-1	106-24-1															x	x		
122	Glyoxal	FR	203-474-9	107-22-2		x	x	x														
133	Hexa-2,4-dienoic acid (Sorbic acid)	DE	203-768-7	110-44-1						x												
171	2-Phenoxyethanol	IT	204-589-7	122-99-6	x	x		x		x								x				
180	Sodium dimethylarsinate (Sodium Cacodylate)	PT	204-708-2	124-65-2															x			
185	Tosylchloramide sodium (Chloramin T)	ES	204-854-7	127-65-1		x	x	x	x													
187	Potassium dimethyldithiocarbamate	SE	204-875-1	128-03-0									x		x	x						
188	Sodium dimethyldithiocarbamate	SE	204-876-7	128-04-1									x		x	x						
227	2-Thiazol-4-yl-1H-benzimidazole (Thiabendazole)	ES	205-725-8	148-79-8							x		x	x								

▼M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
235	Diuron	DK	206-354-4	330-54-1							x			x								
239	Cyanamide	DE	206-992-3	420-04-2			x												x			
283	Terbutryn	SK	212-950-5	886-50-0							x		x	x								
292	(1,3,4,5,6,7-Hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl (1R-trans)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (d-Tetramethrin)	DE	214-619-0	1166-46-7															x			
321	Monolinuron	HU	217-129-5	1746-81-2		x																
330	N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine (Diamine)	PT	219-145-8	2372-82-9		x	x	x		x		x			x	x	x					
336	2,2'-Dithiobis[N-methylbenzamide] (DTBMA)	PL	219-768-5	2527-58-4						x												
339	1,2-Benzisothiazol-3(2H)-one (BIT)	ES	220-120-9	2634-33-5		x				x			x		x	x	x					
341	2-Methyl-2H-isothiazol-3-one (MIT)	SI	220-239-6	2682-20-4						x												
346	Sodium dichloroisocyanurate dihydrate	DE	220-767-7	51580-86-0		x	x	x	x						x							
345	Troclosene sodium	DE	220-767-7	2893-78-9		x	x	x	x						x							
348	Mecetronium ethylsulfate (MES)	PL	221-106-5	3006-10-8	x																	

▼M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
359	Formaldehyde released from (Ethylenedioxy)dimethanol (Reaction products of ethylene glycol with paraformaldehyde (EGForm))	PL	222-720-6	3586-55-8						x					x	x	x					
365	Pyridine-2-thiol 1-oxide, sodium salt (Sodium pyri-thione)	SE	223-296-5	3811-73-2		x				x	x		x	x			x					
368	Methenamine 3-chloroallyloch-loride (CTAC)	PL	223-805-0	4080-31-3						x						x	x					
377	2,2',2''-(Hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol (HHT)	PL	225-208-0	4719-04-4						x					x	x	x					
382	Tetrahydro-1,3,4,6-tetrakis(hydroxy-methyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione (TMAD)	ES	226-408-0	5395-50-6						x					x	x	x					
392	Methylene dithiocyanate	FR	228-652-3	6317-18-6												x						
393	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (DMDMH)	PL	229-222-8	6440-58-0						x							x					
397	Didecyldimethylammonium chloride (DDAC)	IT	230-525-2	7173-51-5	x	x				x				x	x	x						
401	Silver	SE	231-131-3	7440-22-4		x		x	x						x							

▼M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
405	Sulfur dioxide generated from sulfur by combustion	DE						x														
424	Active bromine generated from sodium bromide and sodium hypochlorite	NL				x									x	x						
1030	Active bromine generated from sodium bromide and calcium hypochlorite	NL				x									x	x						
1031	Active bromine generated from sodium bromide and chlorine	NL				x									x	x						
1032	Active bromine generated from sodium bromide by electrolysis	NL				x									x	x						
1033	Active bromine generated from hypobromous acid and urea and bromourea	NL													x	x						
1034	Active bromine generated from sodium hypobromite and N-bromosulfamate and sulfamic acid	NL													x							
434	Tetramethrin	DE	231-711-6	7696-12-0																		x
439	Hydrogen peroxide	FI	231-765-0	7722-84-1											x	x						

▼M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
1036	Hydrogen peroxide released from sodium percarbonate	FI				x	x															
444	7a-Ethylidihydro-1H,3H,5H-oxazolo[3,4-c]oxazole (EDHO)	PL	231-810-4	7747-35-5						x						x						
450	Silver nitrate	SE	231-853-9	7761-88-8	x																	
453	Disodium peroxodisulfate	PT	231-892-1	7775-27-1				x														
432	Active chlorine released from sodium hypochlorite	IT													x	x						
455	Active chlorine released from calcium hypochlorite	IT													x							
457	Active chlorine released from chlorine	IT													x							
458	Monochloramine generated from ammonium sulfate and a chlorine source	FR													x	x						
1016	Silver chloride	SE	232-033-3	7783-90-6	x	x				x	x		x									
1076	Silver-polyethylenimine-chloride	SE			x	x							x									
491	Chlorine dioxide	DE	233-162-8	10049-04-4		x	x	x	x						x	x						

▼M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
1037	Chlorine dioxide generated from sodium chlorite by electrolysis	PT				x	x	x	x						x	x						
1038	Chlorine dioxide generated from sodium chlorite by acidification	PT				x	x	x	x						x	x						
1039	Chlorine dioxide generated from sodium chlorite by oxidation	PT				x	x	x	x						x	x						
1040	Chlorine dioxide generated from sodium chlorate and hydrogen peroxide in the presence of a strong acid	PT				x			x						x	x						
494	2,2-Dibromo-2-cyanoacetamide (DBNPA)	DK	233-539-7	10222-01-2		x		x		x					x	x						
1022	Dialuminium chloride pentahydroxide	NL	234-933-1	12042-91-0		x																
1075	Reaction products of aluminium trihydroxide and hydrochloric acid and aluminium and water	NL				x																
515	Bromide activated chloramine (BAC) generated from precursors ammonium bromide and sodium hypochlorite	SE													x	x						

▼M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
522	Pyrithione zinc	SE	236-671-3	13463-41-7		x				x	x		x	x							x	
524	Dodecylguanidine monohydrochloride	ES	237-030-0	13590-97-1						x					x							
529	Active bromine generated from bromine chloride	NL													x							
531	(Benzyloxy)methanol	AT	238-588-8	14548-60-8						x							x					
550	D-Gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) (CHDG)	PT	242-354-0	18472-51-0	x	x	x															
554	p-[(Diiodomethyl)sulphonyl]toluene	CH	243-468-3	20018-09-1						x	x		x	x								
559	(Benzothiazol-2-ylthio)methyl thiocyanate (TCMTB)	NO	244-445-0	21564-17-0									x			x						
562	2-Methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin)	EL	245-387-9	23031-36-9															x			
566	Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT)	AT				x				x					x		x					

▼M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
571	2-Octyl-2H-isothiazol-3-one (OIT)	FR	247-761-7	26530-20-1						x	x		x	x	x		x					
577	Dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride	ES	248-595-8	27668-52-6		x					x		x									
588	Bromochloro-5,5-dimethylimidazolidine-2,4-dione (BCDMH)	NL	251-171-5	32718-18-6		x									x	x						
590	3-(4-Isopropylphenyl)-1,1-dimethylurea (Isoproturon)	DE	251-835-4	34123-59-6							x			x								
599	S-[(6-Chloro-2-oxooxazolo[4,5-b]pyridin-3(2H)-yl)methyl] O,O-dimethyl thiophosphate (Azamethiphos)	IT	252-626-0	35575-96-3															x			
608	Dimethyltetradecyl[3-(trimethoxysilyl)propyl]ammonium chloride	PL	255-451-8	41591-87-1									x									
1045	<i>Eucalyptus citriodora</i> oil, hydrated, cyclized	CZ		1245629-80-4																	x	
1046	<i>Cymbopogon winterianus</i> oil, fractionated, hydrated, cyclized	CZ	Not available	Not available																	x	

▼M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
619	3-Iodo-2-propynylbutylcarbamate (IPBC)	DK	259-627-5	55406-53-6							x		x	x								
620	Tetrakis(hydroxymethyl)phosphonium sulphate(2:1) (THPS)	MT	259-709-0	55566-30-8						x					x	x						
648	4,5-Dichloro-2-octylisothiazol-3(2H)-one (4,5-Dichloro-2-octyl-2H- isothiazol-3-one (DCOIT))	NO	264-843-8	64359-81-5							x		x	x	x							
656	Reaction products of paraformaldehyde and 2- hydroxypropylamine (ratio 3:2) (MBO)	AT				x				x					x	x	x					
667	Alkyl (C ₁₂₋₁₈) dimethylbenzyl ammonium chloride (ADBAC (C ₁₂₋₁₈))	IT	269-919-4	68391-01-5	x	x	x	x							x	x	x					x
671	Alkyl (C ₁₂₋₁₆) dimethylbenzyl ammonium chloride (ADBAC/ BKC (C ₁₂ -C ₁₆))	IT	270-325-2	68424-85-1	x	x									x	x	x					x
673	Didecyltrimethylammonium chloride (DDAC (C ₈₋₁₀))	IT	270-331-5	68424-95-3	x	x	x	x		x					x	x	x					
690	Quaternary ammonium compounds, benzyl-C ₁₂₋₁₈ -alkyldimethyl, salts with 1,2-benzisothiazol-3(2H)-one 1,1-dioxide (1:1) (ADBAS)	MT	273-545-7	68989-01-5		x		x														

▼M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
691	Sodium N-(hydroxymethyl) glycinate	AT	274-357-8	70161-44-3						x												
693	Pentapotassium bis(peroxy-monosulfate)bis(sulfate) (KPMS)	SI	274-778-7	70693-62-8		x	x	x	x													
939	Active chlorine generated from sodium chloride by electrolysis	SK													x							
1049	Active chlorine generated from sodium chloride and pentapotassium bis(peroxymonosulfate)bis(sulfate)	SI				x	x	x	x													
1050	Active chlorine generated from seawater (sodium chloride) by electrolysis	FR													x							
1051	Active chlorine generated from magnesium chloride hexahydrate and potassium chloride by electrolysis	FR				x																
1054	Active chlorine generated from sodium N- chlorosulfamate	SI						x							x	x						
701	Dihydrogen bis[monoperoxy-phthalato(2-)-O1,OO1] magnesate(2-) (MMPP)	PL	279-013-0	84665-66-7		x																
1024	Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide	DE																	x			

▼M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
724	Alkyl (C ₁₂ -C ₁₄) dimethylbenzylammonium chloride (ADBAC (C ₁₂ -C ₁₄))	IT	287-089-1	85409-22-9	x	x	x	x						x	x	x						x
725	Alkyl (C ₁₂ -C ₁₄) dimethyl(ethylbenzyl) ammonium chloride (ADEBAC (C ₁₂ -C ₁₄))	IT	287-090-7	85409-23-0	x	x	x	x						x	x	x						x
1057	<i>Chrysanthemum cinerariaefolium</i> extract from open and mature flowers of <i>Tanacetum cinerariifolium</i> obtained with hydrocarbon solvent	ES																	x	x		
1058	<i>Chrysanthemum cinerariaefolium</i> extract from open and mature flowers of <i>Tanacetum cinerariifolium</i> obtained with supercritical carbon dioxide	ES																	x	x		
744	Lavender, <i>Lavandula hybrida</i> , ext./Lavandin oil	PT	294-470-6	91722-69-9																x		
779	Reaction products of: glutamic acid and N-(C ₁₂ -C ₁₄ -alkyl)propylenediamine (Glucoprotamin)	DE	403-950-8	164907-72-6		x		x														
785	6-(Phthalimido)peroxyhexanoic acid (PAP)	IT	410-850-8	128275-31-0	x	x																
791	2-Butyl-benzo[d]isothiazol-3-one (BBIT)	CZ	420-590-7	4299-07-4						x	x		x	x			x					

▼M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
792	Chlorine dioxide generated from tetrachlorodecaoxide complex (TCDO) by acidification	DE				x		x														
811	Silver sodium hydrogen zirconium phosphate	SE	422-570-3	265647-11-8				x					x									
797	cis-1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (cis CTAC)	PL	426-020-3	51229-78-8						x							x					
1014	Silver zeolite	SE	Not available	Not available				x					x									
152	Reaction products of 5,5-dimethylhydantoin, 5-ethyl-5-methylhydantoin with bromine and chlorine (DCDMH)	NL	Not available	Not available											x							
459	Reaction mass of titanium dioxide and silver chloride	SE	Not available	Not available	x	x				x	x		x	x	x							
777	Reaction products of 5,5-dimethylhydantoin, 5-ethyl-5-methylhydantoin with chlorine (DCEMH)	NL	Not available	Not available											x							
810	Silver phosphate glass	SE	Not available	308069-39-8		x					x		x									
1077	Silver borophosphate glass	SE				x					x		x									
1078	Silver phosphoborate glass	SE				x					x		x									

▼M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
824	Silver zinc zeolite	SE	Not available	130328-20-0		x		x			x		x									
1013	Silver copper zeolite	SE	Not available	130328-19-7				x					x									
1017	Silver adsorbed on silicon dioxide (as a nanomaterial in the form of a stable aggregate with primary particles in the nanoscale)	SE	Not available	Not available									x									
854	(RS)-3-Allyl-2-methyl-4-oxocyclopent-2-enyl-(1R,3R;1R,3S)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate (mixture of 4 isomers 1R trans, 1R: 1R trans, 1S: 1R cis, 1R: 1R cis, 1S 4:4:1:1) (d-Allethrin)	DE	Plant protection product	231937-89-6															x			
843	4-Bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethylpyrrole-3-carbonitrile (Chlorfenapyr)	PT	Plant protection product	122453-73-0															x			
859	Polymer of N-Methylmethanamine (Einecs 204-697-4 with (chloromethyl)oxirane (Einecs 203-439-8)/Polymeric quaternary ammonium chloride (PQ Polymer)	HU	Polymer	25988-97-0		x									x							

▼ M4

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
869	Poly(oxy-1,2-ethanediyl),.alpha.-[2-(didecylmethylammonio)ethyl]-.omega.-hydroxy-, propanoate (salt) (Bardap 26)	IT	Polymer	94667-33-1		x		x						x								
872	N-Didecyl-N-dipolyethoxyammonium borate/Didecylpolyoxethylammonium borate (Polymeric betaine)	EL	Polymer	214710-34-6								x										
1070	Orange, sweet, ext. <i>Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from Citrus sinensis, Rutaceae.</i>	CH	232-433-8	8028-48-6																x		
1071	Garlic, ext. <i>Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from Allium sativum, Liliaceae.</i>	AT	232-371-1	8008-99-9																x		
1072	Brandy	tbd	Not available	Not available																x		
1073	Peanut butter	BE	Not available	Not available																x		
1074	Copper, powder	FR	231-159-6	7440-50-8																	x	

▼B*ANNEX III***Time limits**

Product-types	Time limits for submitting the assessment report pursuant to Article 6(3)(b)	Time limits for starting the preparation of the opinion pursuant to Article 7(2)(b)
8, 14, 16, 18, 19 and 21	31.12.2015	31.3.2016
3, 4 and 5	31.12.2016	31.3.2017
1 and 2	31.12.2018	31.3.2019
6 and 13	31.12.2019	31.3.2020
7, 9 and 10	31.12.2020	31.3.2021
11, 12, 15, 17, 20 and 22	31.12.2022	► C1 30.9.2023 ◀