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2014/703/EU

(1) Text with EEA relevance



Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

2014/704/EU:

II

(Non-legislative acts)

REGULATIONS

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)

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 Since that Directive has been repealed and replaced by Regulation (EU) No 528/2012, the detailed rules for the continuation of the review programme should be adapted to the provisions of that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 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

⁽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).

Regulation (EU) No 528/2012, on the case law, such as case C-420/10 (¹), 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 (2).
- (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 (3) 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.
- (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.

(2) 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).

biocidal products (OJ L 32, 1.2.2014, p. 3).

(*) 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).

⁽¹) 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).

- (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 (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.

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.

⁽¹) Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and chargespayable 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).

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 (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).

- 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.

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.

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.

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.

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.

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 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.

- 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 August 2014.

For the Commission
The President
José Manuel BARROSO

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.

SUBSTANCE/PRODUCT-TYPE COMBINATIONS INCLUDED IN THE REVIEW PROGRAMME ON 4 AUGUST 2014

ANNEX II

PART 1

Active substance/product-type combinations supported on 4 August 2014, excluding any other nanomaterial than those explicitly mentioned in entries 1017 and 1019

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	х															Х
6	2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (Piperonyl butoxide/PBO)	EL	200-076-7	51-03-6															X			
9	Bronopol	ES	200-143-0	52-51-7		x				x			X		X	x						Х
29	Chlorocresol	FR	200-431-6	59-50-7	X	X	X			X			X				x					
36	Ethanol	EL	200-578-6	64-17-5	х	X		x														
37	Formic acid	BE	200-579-1	64-18-6		X	х	х	х	х					х	x						
40	Propan-2-ol	DE	200-661-7	67-63-0	х	X		x														
43	Salicylic acid	NL	200-712-3	69-72-7		х	х	х														
45	Propan-1-ol	DE	200-746-9	71-23-8	х	X		x														
52	Ethylene oxide	N	200-849-9	75-21-8		х																
60	Citric acid	BE	201-069-1	77-92-9	х																	
69	Glycolic acid	LT	201-180-5	79-14-1		Х	Х	Х														
70	Peracetic acid	FI	201-186-8	79-21-0	х	Х	Х	х	х	х					X	Х						
71	L-(+)-lactic acid	DE	201-196-2	79-33-4		х	х	х		х												

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-hexa-hydro-2-isopropenyl-8,9-dimethoxychromeno[3,4-b]furo[2,3-h]chromen-6-one (Rotenone)	UK	201-501-9	83-79-4														х				
85	Symclosene	UK	201-782-8	87-90-1		Х	х	х	х						Х	х						
92	Biphenyl-2-ol	ES	201-993-5	90-43-7	X	X	х	x		X	х		X	X			х					
113	Cinnamaldehyde/3-phenyl-propen-2-al (Cinnamic aldehyde)	UK	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		х	х	х														
133	Hexa-2,4-dienoic acid (Sorbic acid)	DE	203-768-7	110-44-1						х												
136	Glutaral (Glutaraldehyde)	FI	203-856-5	111-30-8		X	х	х		х					X	х						
154	Clorophene (Chlorophene)	N	204-385-8	120-32-1		х	х															
171	2-Phenoxyethanol	UK	204-589-7	122-99-6	х	X		х		х							х					
172	Cetylpyridinium chloride	UK	204-593-9	123-03-5		х																
179	Carbon dioxide	FR	204-696-9	124-38-9																х		
180	Sodium dimethylarsinate (Sodium Cacodylate)	PT	204-708-2	124-65-2															Х			
185	Tosylchloramide sodium (Tosylchloramide sodium — Chloramin T)	ES	204-854-7	127-65-1		х	х	х	х													_ _
187	Potassium dimethyldithiocarbamate	UK	204-875-1	128-03-0									x		X	X						
188	Sodium dimethyldithiocarbamate	UK	204-876-7	128-04-1		_							х	_	х	х						_ _

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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
195	Sodium 2-biphenylate	ES	205-055-6	132-27-4	х	х	х	X		х	х		X	х			х					
198	N-(trichloromethylthio)phthalimide (Folpet)	IT	205-088-6	133-07-3							х		X									
206	Thiram	BE	205-286-2	137-26-8									X									
210	Metam-sodium	BE	205-293-0	137-42-8									Х		Х							
227	2-thiazol-4-yl-1H-benzoimidazole (Thiabendazole)	ES	205-725-8	148-79-8							х		Х	Х								
235	Diuron	DK	206-354-4	330-54-1							х			Х								
239	Cyanamide	DE	206-992-3	420-04-2			Х												Х			
253	Tetrahydro-3,5-dimethyl-1,3,5-thiadia- zine-2-thione (Dazomet)	BE	208-576-7	533-74-4						х						х						
279	Dichloro-N-[(dimethylamino)sulphonyl] fluoro-N-(ptolyl)methanesulphenamide (Tolylfluanid)	FI	211-986-9	731-27-1							х										X	
283	Terbutryn	SK	212-950-5	886-50-0							Х		X	X								
288	N-(Dichlorofluoromethylthio)-N',N'-dimethyl-N-phenylsulfamide (Dichlofluanid)	UK	214-118-7	1085-98-9							х										X	
289	Copper thiocyanate	FR	214-183-1	1111-67-7																	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)cyclo-propanecarboxylate (d-Tetramethrin)	DE	214-619-0	1166-46-7															х			

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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
958	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime	UK	215-137-3	1305-62-0		х	х															
959	Calcium oxide/lime/burnt lime/quicklime	UK	215-138-9	1305-78-8		Х	х															
306	Dicopper oxide	FR	215-270-7	1317-39-1																	Х	
315	2-Butanone, peroxide	HU	215-661-2	1338-23-4	х	х																
321	Monolinuron	UK	217-129-5	1746-81-2		х																
330	N-(3-aminopropyl)-N-dodecylpropane- 1,3-diamine (Diamine)	PT	219-145-8	2372-82-9		х	х	х		х		х			х	Х	х					
336	2,2'-dithiobis[N-methylbenzamide] (DTBMA)	PL	219-768-5	2527-58-4						Х												
339	1,2-benzisothiazol-3(2H)-one (BIT)	ES	220-120-9	2634-33-5		х				х			х		х	х	X					
341	2-methyl-2H-isothiazol-3-one (MIT)	SI	220-239-6	2682-20-4						х					Х	х	х					
346	Sodium dichloroisocyanurate dihydrate	UK	220-767-7	51580-86-0		х	х	Х	х						Х	х						
345	Troclosene sodium	UK	220-767-7	2893-78-9		х	х	Х	Х						X	X						
348	Mecetronium ethyl sulphate (MES)	PL	221-106-5	3006-10-8	Х																	
354	Triclosan	DK	222-182-2	3380-34-5	х																	
359	(ethylenedioxy)dimethanol (Reaction products of ethylene glycol with parafor- maldehyde (EGForm))	PL	222-720-6	3586-55-8		Х				х					X	X	х					
365	Pyridine-2-thiol 1-oxide, sodium salt (Sodium pyrithione)	SE	223-296-5	3811-73-2		x	х			х	х		х	х			х					

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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
368	Methenamine 3-chloroallylochloride (CTAC)	PL	223-805-0	4080-31-3						х						х	X					
377	2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol (HHT)	PL	225-208-0	4719-04-4						х					X	X	х					
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	X					
387	N,N'-methylenebismorpholine (MBM)	AT	227-062-3	5625-90-1						x							x					ı
392	Methylene dithiocyanate	FR	228-652-3	6317-18-6												х						
393	1,3-bis(hydroxymethyl)-5,5-dimethylimi- dazolidine-2,4-dione (DMDMH)	PL	229-222-8	6440-58-0						х							х					
397	Didecyldimethylammonium chloride (DDAC)	IT	230-525-2	7173-51-5	X	x	X	X		х		X		X	X	x						
401	Silver	SE	231-131-3	7440-22-4		X		X	х						x							
403	Copper	FR	231-159-6	7440-50-8																	X	
405	Sulphur dioxide	DE	231-195-2	7446-09-5				X														
424	Sodium bromide	NL	231-599-9	7647-15-6		х									х	х						
432	Sodium hypochlorite	IT	231-668-3	7681-52-9	X	X	х	X	х						х	х						
434	Tetramethrin	DE	231-711-6	7696-12-0															X			
439	Hydrogen peroxide	FI	231-765-0	7722-84-1	X	X	X	X	х	х					х	х						
444	7a-ethyldihydro-1H,3H,5H-oxazolo[3,4-c] oxazole (EDHO)	PL	231-810-4	7747-35-5						х							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
450	Silver nitrate	SE	231-853-9	7761-88-8	х																	
453	Disodium persulphate peroxodisulphate/Sodium	PT	231-892-1	7775-27-1				х														
455	Calcium hypochlorite	IT	231-908-7	7778-54-3		X	X	х	X						х							
457	Chlorine	IT	231-959-5	7782-50-5		X			х						х							
458	Ammonium sulphate	UK	231-984-1	7783-20-2											х	х						
473	Pyrethrins and Pyrethroids	ES	232-319-8	8003-34-7															х	х		
491	Chlorine dioxide	PT	233-162-8	10049-04-4		X	х	х	х						х	Х						
494	2,2-dibromo-2-cyanoacetamide (DBNPA)	DK	233-539-7	10222-01-2		X		х		х					х	Х	х					
501	Carbendazim	DE	234-232-0	10605-21-7							х		x	x								
515	Ammonium bromide	SE	235-183-8	12124-97-9											х	х						
522	Pyrithione zinc (Zinc pyrithione)	SE	236-671-3	13463-41-7		Х				х	х		х	х							Х	
524	Dodecylguanidine monohydrochloride	ES	237-030-0	13590-97-1						Х					х							
526	Potassium 2-biphenylate	ES	237-243-9	13707-65-8						х			х	х			х					
529	Bromine chloride	NL	237-601-4	13863-41-7											х							
531	(benzyloxy)methanol	UK	238-588-8	14548-60-8						х							Х					
534	Bis(1-hydroxy-1H-pyridine-2-thionato- O,S)copper (Copper pyrithione)	SE	238-984-0	14915-37-8																	х	
541	Sodium p-chloro-m-cresolate	FR	239-825-8	15733-22-9	х	X	Х			Х			Х				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
550	D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) (CHDG)	РТ	242-354-0	18472-51-0	X	Х	X															
554	p-[(diiodomethyl)sulphonyl]toluene	UK	243-468-3	20018-09-1						х	х		X	X								
559	(benzothiazol-2-ylthio)methyl thiocyanate (TCMTB)	N	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			
563	Potassium (E,E)-hexa-2,4-dienoate (Potassium Sorbate)	DE	246-376-1	24634-61-5						х		X										
566	.alpha.,.alpha.',.alpha.''-trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol (HPT)	AT	246-764-0	25254-50-6		X				х					х		X					
571	2-octyl-2H-isothiazol-3-one (OIT)	UK	247-761-7	26530-20-1						х	х		X	X	X		X					
577	Dimethyloctadecyl[3-(trimethoxysilyl) propyl]ammonium chloride	ES	248-595-8	27668-52-6		х					х		х									
578	N'-tert-butyl-N-cyclopropyl-6- (methylthio)-1,3,5-triazine-2,4-diamine (Cybutryne)	NL	248-872-3	28159-98-0																	X	
588	Bromochloro-5,5-dimethylimidazolidine- 2,4-dione (BCDMH/Bromochlorodi- methylhydantoin)	NL	251-171-5	32718-18-6		Х									х	Х						
590	3-(4-isopropylphenyl)-1,1-dimethylurea/ Isoproturon	DE	251-835-4	34123-59-6							х			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
597	1-[2-(allyloxy)-2-(2,4-dichlorophenyl) ethyl]-1H-imidazole (Imazalil)	DE	252-615-0	35554-44-0			X															
599	S-[(6-chloro-2-oxooxazolo[4,5-b]pyridin-3(2H)-yl)methyl] O,O-dimethyl thiophosphate (Azamethiphos)	UK	252-626-0	35575-96-3															X			
600	2-bromo-2-(bromomethyl)pentanedinitrile (DBDCB)	CZ	252-681-0	35691-65-7						х												
961	Calcium magnesium oxide/dolomitic lime	UK	253-425-0	37247-91-9		X	X															
962	Calcium magnesium tetrahydroxide/ calcium magnesium hydroxide/hydrated dolomitic lime	UK	254-454-1	39445-23-3		X	X															
606	.alphacyano-3-phenoxybenzyl 2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropanecarboxylate (Cyphenothrin)	EL	254-484-5	39515-40-7															х			
608	Dimethyltetradecyl[3-(trimethoxysilyl) propyl]ammonium chloride	PL	255-451-8	41591-87-1									X									
609	Mixture of cis- and trans-p-menthane-3,8 diol (Citriodiol)	UK	255-953-7	42822-86-6																x		
614	(RS)-α-cyano-3phenoxybenzyl-(1RS)- cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethyl- cyclopropanecarboxylate (Cypermethrin)	BE	257-842-9	52315-07-8															Х			
615	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Permethrin)	ΙE	258-067-9	52645-53-1								X							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
618	1-ethynyl-2-methylpent-2-enyl 2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropanecarboxylate (Empenthrin)	BE	259-154-4	54406-48-3															X			
619	3-iodo-2-propynylbutylcarbamate (IPBC)	DK	259-627-5	55406-53-6							X		X	X			X					
620	Tetrakis(hydroxymethyl)phosphonium sulphate(2:1) (THPS)	MT	259-709-0	55566-30-8		X				X					X	X						
628	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (Propiconazole)	FI	262-104-4	60207-90-1							х											
635	Coco alkyltrimethylammonium chloride (ATMAC/TMAC)	ΙΤ	263-038-9	61789-18-2								x										
648	4,5-Dichloro-2-octylisothiazol-3(2H)-one (4,5-Dichloro- 2-octyl-2H- isothiazol-3-one (DCOIT))	N	264-843-8	64359-81-5							х		X	X	X							
649	2-chloro-N-[[[4-(trifluoromethoxy) phenyl]amino]carbonyl]benzamide (Triflumuron)	IT	264-980-3	64628-44-0															X			
656	3,3'-methylenebis[5-methyloxazolidine] (Oxazolidin/MBO)	AT	266-235-8	66204-44-2		X				Х					Х	Х	X					
657	N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine)	EL	266-257-8	66215-27-8															X			
666	.alphacyano-4-fluoro-3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclo- propanecarboxylate (Cyfluthrin)	DE	269-855-7	68359-37-5															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
667	Alkyl (C_{12-18}) dimethylbenzyl ammonium chloride (ADBAC (C_{12-18}))	IT	269-919-4	68391-01-5	х	х	х	х						x	х	х						Х
671	Alkyl (C ₁₂₋₁₆) dimethylbenzyl ammonium chloride (ADBAC/BKC (C ₁₂ -C ₁₆))	IT	270-325-2	68424-85-1	х	х	х	х						X	х	х						X
673	$\begin{array}{ccc} \mbox{Didecyldimethylammonium} & \mbox{chloride} \\ \mbox{(DDAC } (\mbox{C}_{8\text{-}10})) & \end{array}$	IT	270-331-5	68424-95-3	х	х	х	х		х				X	х	х						
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														
691	Sodium N-(hydroxymethyl)glycinate	AT	274-357-8	70161-44-3						х												
692	Amines, C ₁₀₋₁₆ -alkyldimethyl, N-oxides	PT	274-687-2	70592-80-2				х														
693	Pentapotassium bis(peroxymonosulphate) bis(sulphate)	SI	274-778-7	70693-62-8		X	х	х	х													
701	Magnesium monoperoxyphthalate hexahydrate (MMPP)	PL	279-013-0	84665-66-7		Х																
1015	Margosa extract	DE	283-644-7	84696-25-3																Х		
724	Alkyl (C_{12} - C_{14}) dimethylbenzylammonium chloride (ADBAC (C_{12} - C_{14}))	IT	287-089-1	85409-22-9	х	Х	х	х						Х	Х	х						Х
725	Alkyl $(C_{12}$ - $C_{14})$ ethylbenzylammonium chloride (ADEBAC $(C_{12}$ - $C_{14})$)	IT	287-090-7	85409-23-0	х	х	х	х						X	х	х						Х
731	Chrysanthemum cinerariaefolium, ext.	ES	289-699-3	89997-63-7															X			
744	Lavender, Lavandula hybrida, ext./Lavandin oil	PT	294-470-6	91722-69-9																х		

Official Journal of the European Union

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
776	1-(3,5-dichloro-4-(1,1,2,2-tetrafluor-oethoxy)phenyl)-3-(2,6-difluorobenzoyl) urea (Hexaflumuron)	PT	401-400-1	86479-06-3															Х			
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	х	х	х	Х														
791	2-butyl-benzo[d]isothiazol-3-one (BBIT)	CZ	420-590-7	4299-07-4						х	X		X	X			X					
792	Tetrachlorodecaoxide complex (TCDO)	DE	420-970-2	92047-76-2	X	X		X														
811	Silver sodium hydrogen zirconium phosphate	SE	422-570-3	265647-11-8	x	x		x			х		x									
794	sec-butyl 2-(2-hydroxyethyl)piperidine-1-carboxylate/Icaridine (Icaridine)	DK	423-210-8	119515-38-7																X		
797	cis-1-(3-chloroallyl)-3,5,7-triaza-1- azoniaadamantane chloride (cis CTAC)	PL	426-020-3	51229-78-8						X							x					
800	[2,4-Dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1R)-cis-chrysanthemate;[2,4-Dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1R)-trans-chrysanthemate (Imiprothrin)	UK	428-790-6	72963-72-5															х			
790	5-chloro-2-(4-chlorphenoxy)phenol (DCPP)	AT	429-290-0	3380-30-1	X	X		X														
807	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine (Clothianidin)	DE	433-460-1	210880-92-5															Х			_ -

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Official Journal of the European Union

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
952	Bacillus sphaericus 2362, strain ABTS-1743	IT	Micro- organism	143447-72-7															х			
955	Bacillus thuringiensis subsp. israelensis, strain SA3A	ΙΤ	Micro- organism	Not applic- able															x			
957	Bacillus subtilis	DE	Micro- organism	Not applic- able			x															
928	Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)	FR	Mixture	55965-84-9		X		X		x					X	X	X					
939	Active Chlorine: manufactured by the reaction of hypochlorous acid and sodium hypochlorite produced in situ	SK	Mixture	Not applic- able		X	X	X	х													
813	Peroxyoctanoic acid	FR	Not applic- able	33734-57-5		X	x	x														l
1014	Silver zeolite	SE	Not applic- able	Not applic- able		x		X	х		х		X									
849	3-phenoxybenzyl (1R)-cis,trans-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclo-propanecarboxylate (d-Phenothrin)	ΙE	Not applic- able	188023-86-1															X			
931	Amines, N-C ₁₂ -C ₁₄ (even-numbered)-alkyl-trimethylenedi-, reaction products with chloroacetic acid (Ampholyt 20)	IE	Not applic- able	139734-65-9		X	X	X														
152	Reaction products of 5,5-dimethylhydantoin, 5-ethyl-5-methylhydantoin with bromine and chlorine (DCDMH)	NL	Not avail- able	Not available											х							<u> </u>

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Official Journal of the European Union

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
459	Reaction mass of titanium dioxide and silver chloride	SE	Not avail- able	Not available	х	X				х	х		х	х	х							
777	Reaction products of 5,5-dimethylhydantoin, 5-ethyl-5-methylhydantoin with chlorine (DCEMH)	NL	Not avail- able	Not available											Х							
810	Silver phosphate glass	SE	Not avail- able	308069-39-8		X					x		X									
824	Silver zinc zeolite	SE	Not avail- able	130328-20-0		Х		Х	х		х		Х									
1013	Silver copper zeolite	SE	Not avail- able	130328-19-7		Х		Х	х		х		Х									
1017	Silver adsorbed on silicon dioxide (as a nanomaterial in the form of a stable aggregate with primary particles in the nanoscale)	SE	Not avail- able	Not available									X									
1019	Silicon dioxide (as a nanomaterial formed by aggregates and agglomerates)	FR	Not avail- able	68909-20-6															Х			
831	Silicium dioxide (Silicium dioxide/Kieselguhr)	FR	Plant protection product	61790-53-2															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															Х			

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Official Journal of the European Union

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	
855	(RS)-3-Allyl-2-methyl-4-oxocyclopent-2-enyl (1R,3R)-2,2-dimethyl-3-(2-methyl-prop-1-enyl)-cyclopropanecarboxylate (mixture of 2 isomers 1R trans: 1R/S only 1:3) (Esbiothrin)	DE	Plant protection product	260359-57-7															х				
848	N-((6-Chloro-3-pyridinyl)methyl)-N'-cyano-N-methylethanimidamide (Acetamiprid)	BE	Plant protection product	160430-64-8															х				
835	Esfenvalerate/(S)alphaCyano-3-phenox-ybenzyl (S)-2-(4-chlorophenyl)-3-methylbutyrate (Esfenvalerate)	PT	Plant protection product	66230-04-4															х				
836	[1.alpha.(S*),3.alpha.]-(.alpha.)-cyano-(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dichlorovinyl)-2,2-dimethyl-cyclopropanecarboxylate (alpha-Cypermethrin)	BE	Plant protection product	67375-30-8															х				
843	4-bromo-2-(4-chlorophenyl)-1-ethoxy- methyl-5-trifluoromethylpyrrole-3-carbo- nitrile (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								
863	Monohydro chloride of polymer of N,N'''-1,6-hexanediylbis[N'-cyanoguanidine] (EINECS 240-032-4) and hexamethylenediamine (EINECS 204-679-6)/ Polyhexamethylene biguanide (monomer: 1,5-bis(trimethylen)-guanylguanidinium monohydrochloride) (PHMB)	FR	Polymer	27083-27-8/ 32289-58-0	х	х	Х	х	х	х			х		х								

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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	
868	Poly(hexamethylenebiguanide)	FR	Polymer	91403-50-8	х	х	x	х					X		X								
869	Poly(oxy-1,2-ethanediyl), .alpha[2-(didecylmethylammonio)ethyl]omegahydroxy-, propanoate (salt) (Bardap 26)	IT	Polymer	94667-33-1		X		х				X		X									
872	N-Didecyl-N-dipolyethoxyammonium borate/Didecylpolyoxethylammonium borate (Polymeric betaine)	EL	Polymer	214710-34-6								Х											

PART 2

Active substance/product-type combinations not supported on 4 August 2014

This part of this Annex includes

- the substance/product-type combinations listed in the table below, including any nanomaterial forms,
- any nanomaterial forms of all substance/product-type combinations listed in the table in part 1, except those listed in that table, and
- any nanomaterial forms of all active substance/product-type combinations approved by 4 August 2014, except those explicitly approved.

The substance/product-type combinations and nanomaterials included in this part will be the subject of a non-approval decision pursuant to Article 20 if no person makes a notification within 12 months of the entry into force of this Regulation pursuant to Article 14(3), or if such a notification is rejected pursuant to Article 17(4) or 17(5).

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
1021	1,3-dichloro-5,5-dimethylhydantoin (redefined as per entry 152)	NL	204-258-7	118-52-5											X							
166	Cetalkonium chloride (see entry 948)		204-526-3	122-18-9																		
167	Benzyldimethyl(octadecyl)ammonium chloride (see entry 948)		204-527-9	122-19-0																		

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
213	Benzododecinium chloride (see entry 948)		205-351-5	139-07-1																		
214	Miristalkonium chloride (see entry 948)		205-352-0	139-08-2																		
227	2-thiazol-4-yl-1H-benzoimidazole (Thiabendazole)	ES	205-725-8	148-79-8		X																
331	Didecyldimethylammonium bromide (see entry 949)		219-234-1	2390-68-3																		
384	Dimethyldioctylammonium chloride (see entry 949)		226-901-0	5538-94-3																		
399	Benzyldodecyldimethylammonium bromide (see entry 948)		230-698-4	7281-04-1																		
401	Silver	SE	231-131-3	7440-22-4									X									<u> </u>
418	Silicon dioxide — amorphous	FR	231-545-4	7631-86-9															X			
449	Copper sulphate	FR	231-847-6	7758-98-7		х																
1016	Silver chloride	SE	232-033-3	7783-90-6	х	х				Х	х		х	х	х							
554	p-[(diiodomethyl)sulphonyl]toluene	UK	243-468-3	20018-09-1		х																
587	Decyldimethyloctylammonium chloride (see entry 949)		251-035-5	32426-11-2																		
601	Benzyldimethyloleylammonium chloride (see entry 948)		253-363-4	37139-99-4																		
615	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Permethrin)	IE	258-067-9	52645-53-1									Х									

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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
637	Quaternary ammonium compounds, benzylcoco alkyldimethyl, chlorides (see entry 948)		263-080-8	61789-71-7																		
638	Quaternary ammonium compounds, dicocoalkyl dimethyl, chlorides (see entry 949)		263-087-6	61789-77-3																		
639	Quaternary ammonium compounds, bis (hydrogenated tallow alkyl)dimethyl, chlorides (see entry 949)		263-090-2	61789-80-8																		
647	Quaternary ammonium compounds, benzyl-C ₈₋₁₈ -alkyldimethyl, chlorides (see entry 948)		264-151-6	63449-41-2																		
668	Quaternary ammonium compounds, di-C ₆₋₁₂ -alkyldimethyl, chlorides (see entry 949)		269-925-7	68391-06-0																		
670	Quaternary ammonium compounds, benzyl- C_{8-16} -alkyldimethyl, chlorides (see entry 948)		270-324-7	68424-84-0																		
689	Quaternary ammonium compounds, benzyl-C ₁₀₋₁₆ -alkyldimethyl, chlorides (see entry 948)		273-544-1	68989-00-4																		
692	Amines, C ₁₀₋₁₆ -alkyldimethyl, N-oxides	PT	274-687-2	70592-80-2		Х																
697	Quaternary ammonium compounds, di- C_{8-18} -alkyldimethyl, chlorides (see entry 949)		277-453-8	73398-64-8																		
1000	Dihydrogen bis[monoperoxyphthalato-(2-)-O1,OO1]magnesate(2-) hexahydrate	PL	279-013-0	14915-85-4		х																

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Official Journal of the European Union

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	
998	Margosa extract other than from the kernels of <i>Azadirachta indica</i> extracted with water and further processed with organic solvents.	DE	283-644-7	84696-25-3															х				
741	Quaternary ammonium compounds, benzyl- C_{8-18} -alkyldimethyl, bromides (see entry 948)		293-522-5	91080-29-4																			
1020	1,3-dichloro-5-ethyl-5-methylimidazoli- dine-2,4-dione (redefined as per entry 777)	NL	401-570-7	89415-87-2											Х								
778	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol (Tebuconazole)	DK	403-640-2	107534-96-3									х										
805	Reaction product of dimethyl adipate, dimethyl glutarate, dimethyl succinate with hydrogen peroxide (Perestane)	HU	432-790-1	Not applic- able		х																	
923	Alkyl-benzyl-dimethylammonium chloride/Benzalkonium chloride (see entry 948)		Mixture	8001-54-5																			
949	Quaternary ammonium compounds (dialkyldimethyl (alkyl from C ₆ -C ₁₈ , saturated and unsaturated, and tallow alkyl, coco alkyl, and soya alkyl) chlorides, bromides, or methylsulphates) (DDAC)	IT	Mixture of EINECS listed substances	Not applic- able	X	х	х	х				х		X	х	х							
950	Quaternary ammonium compounds (alkyltrimethyl (alkyl from C ₈ -C ₁₈ , saturated and unsaturated, and tallow alkyl, coco alkyl, and soya alkyl) chlorides, bromides, or methylsulphates) (TMAC)	ΙΤ	Mixture of EINECS listed substances	Not applic- able								х											

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Official Journal of the European Union

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
948	Quaternary ammonium compounds (benzylalkyldimethyl (alkyl from C ₈ -C ₂₂ , saturated and unsaturated, tallow alkyl, coco alkyl, and soya alkyl) chlorides, bromides, or hydroxides) (BKC)	IT	Mixture of EINECS listed substances	Not applic- able	X	Х	х	х				х		X	Х	Х						
849	3-phenoxybenzyl (1R)-cis,trans-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclo-propanecarboxylate (d-Phenothrin)	ΙE	Not applic- able	188023-86-1															X			
1001	Quaternary ammonium compounds, benzyl-C ₁₂₋₁₆ -alkyldimethyl, chlorides (other than the substance covered by entry 671)	IT	Not applic- able	Not applic- able	х	х	х	х				х		Х	х	х						х
1002	Quaternary ammonium compounds, benzyl-C ₁₂₋₁₈ -alkyldimethyl, chlorides (other than the substance covered by entry 667)	IT	Not applic- able	Not applic- able	X	X	X	X						X	X	X						Х
1003	Quaternary ammonium compounds, C ₁₂₋₁₄ -alkyl[(ethylphenyl)methyl]dimethyl, chlorides (other than the substance covered by entry 725)	ΙΤ	Not applic- able	Not applic- able	х	X	X	X						X	X	X						X
1005	Quaternary ammonium compounds, benzyl-C ₁₂₋₁₄ -alkyldimethyl, chlorides (other than the substance covered by entry 724)	IT	Not applicable	Not applic- able	х	х	х	х						х	х	х						x
1006	Silver-zinc-aluminium-boronphosphate glass/Glass oxide, silver- and zinc-containing	SE	Not applic- able	398477-47-9		X					х		Х									
1009	Quaternary ammonium compounds, di- C_{8-10} -alkyldimethyl, chlorides (other than the substance covered by entry 673)	IT	Not applic- able	Not applic- able	Х	Х	х	х	Х	х				Х	Х	Х						

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Official Journal of the European Union

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
1011	Quaternary ammonium compounds, coco alkyltrimethyl, chlorides (other than the substance covered by entry 635)	IT	Not applic- able	Not applic- able								X										
1012	Aluminium sodium silicate-silver zinc complex/Silver-Zinc-Zeolite	SE	Not applic- able	130328-20-0		Х					х		х									
598	(±)-1-(.betaallyloxy-2,4-dichloropheny-lethyl)imidazole (Technical grade imazalil)	DE	Plant protection product	73790-28-0			X															

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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 and10	31.12.2020	31.3.2021
11, 12, 15, 17, 20 and 22	31.12.2022	31.9.2023

COMMISSION REGULATION (EU) No 1063/2014

of 7 October 2014

establishing a prohibition of fishing for whiting in VIII by vessels flying the flag of Belgium

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy (1), and in particular Article 36(2) thereof,

Whereas:

- (1) Council Regulation (EU) No 43/2014 (2), lays down quotas for 2014.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2014.
- (3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

Article 1

Quota exhaustion

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2014 shall be deemed to be exhausted from the date set out in that Annex.

Article 2

Prohibitions

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

Article 3

Entry into force

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

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

Done at Brussels, 7 October 2014.

For the Commission,

On behalf of the President,

Lowri EVANS

Director-General for Maritime Affairs and Fisheries

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

^(*) Council Regulation (EU) No 43/2014 of 20 January 2014 fixing for 2014 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, to Union vessels, in certain non-Union waters (OJ L 24, 28.1.2014, p. 1).

No	42/TQ43	
Member State	Belgium	
Stock	WHG/08.	
Species	Whiting (Merlangius merlangus)	
Zone	VIII	
Closing date	13.9.2014	

COMMISSION REGULATION (EU) No 1064/2014

of 7 October 2014

establishing a prohibition of fishing for common sole in VIIf and VIIg by vessels flying the flag of United Kingdom

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy (1), and in particular Article 36(2) thereof,

Whereas:

- (1) Council Regulation (EU) No 43/2014 (2), lays down quotas for 2014.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2014.
- (3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

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Quota exhaustion

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Article 2

Prohibitions

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Entry into force

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

Done at Brussels, 7 October 2014.

For the Commission,
On behalf of the President,
Lowri EVANS
Director-General for Maritime Affairs and Fisheries

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

^(*) Council Regulation (EU) No 43/2014 of 20 January 2014 fixing for 2014 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, to Union vessels, in certain non-Union waters (OJ L 24, 28.1.2014, p. 1).

No	41/TQ43
Member State	United Kingdom
Stock	SOL/7FG.
Species	Common sole (Solea solea)
Zone	VIIf and VIIg
Closing date	11.9.2014

COMMISSION REGULATION (EU) No 1065/2014

of 7 October 2014

establishing a prohibition of fishing for plaice in VIII, IX and X; Union waters of CECAF 34.1.1 by vessels flying the flag of Belgium

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy (1), and in particular Article 36(2) thereof,

Whereas.

- (1) Council Regulation (EU) No 43/2014 (2) lays down quotas for 2014.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2014.
- (3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

Article 1

Quota exhaustion

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Article 2

Prohibitions

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

Article 3

Entry into force

This Regulation shall enter into force on the 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, 7 October 2014.

For the Commission,
On behalf of the President,
Lowri EVANS
Director-General for Maritime Affairs and Fisheries

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

^(*) Council Regulation (EU) No 43/2014 of 20 January 2014 fixing for 2014 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, to Union vessels, in certain non-Union waters (OJ L 24, 28.1.2014, p. 1).

No	43/TQ43
Member State	Belgium
Stock	PLE/8/3411
Species	Plaice (Pleuronectes Platessa)
Zone	VIII, IX and X; Union waters of CECAF 34.1.1
Closing date	13.9.2014

COMMISSION IMPLEMENTING REGULATION (EU) No 1066/2014

of 9 October 2014

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (1),

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors (²), and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.
- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the Official Journal of the European Union,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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, 9 October 2014.

For the Commission,

On behalf of the President,

Jerzy PLEWA

Director-General for Agriculture and Rural Development

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²) OJ L 157, 15.6.2011, p. 1.

 $\label{eq:annex} ANNEX$ Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (¹)	Standard import value
0702 00 00	MA	305,5
	MK	57,4
	XS	75,9
	ZZ	146,3
0707 00 05	MK	29,8
	TR	95,4
	ZZ	62,6
0709 93 10	TR	118,0
	ZZ	118,0
0805 50 10	AR	113,6
	BR	84,6
	CL	104,9
	IL	102,2
	TR	126,7
	UY	58,0
	ZA	138,9
	ZZ	104,1
0806 10 10	BR	151,1
	MK	31,8
	TR	134,4
	ZZ	105,8
0808 10 80	BA	57,3
	BR	51,7
	CL	76,3
	NZ	132,8
	US	192,8
	ZA	121,0
	ZZ	105,3
0808 30 90	CN	95,2
	TR	124,7
	ZZ	110,0

⁽¹) Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 8 October 2014

amending Annexes I and II to Decision 2004/558/EC as regards the approval of a control programme for eradicating infectious bovine rhinotracheitis in Belgium and the infectious bovine rhinotracheitis-free status of the Federal State of Thuringia in Germany

(notified under document C(2014) 7113)

(Text with EEA relevance)

(2014/703/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (1), and in particular Articles 9(2) and 10(2) thereto,

Whereas:

- (1) Directive 64/432/EEC lays down rules for trade within the Union in bovine animals. Article 9 thereof provides that a Member State which has a compulsory national control programme for one of the contagious diseases listed in Annex E(II) thereto, may submit its programme to the Commission for approval. That list includes infectious bovine rhinotracheitis. Infectious bovine rhinotracheitis is the description of the most prominent clinical signs of the infection with the bovine herpes virus type 1 (BHV1).
- (2) Article 9 of Directive 64/432/EEC also provides for the definition of the additional guarantees which may be required in intra-Union trade.
- (3) In addition, Article 10 of Directive 64/432/EEC provides that where a Member State considers that its territory or part thereof is free from one of the diseases listed in Annex E(II) to that Directive, it is to present appropriate supporting documentation to the Commission. That Article also provides for the definition of the additional guarantees which may be required in intra-Union trade.
- (4) Commission Decision 2004/558/EC (²) approves the programmes for the control and eradication of BHV1 presented by the Member States listed in Annex I thereto for the regions listed in that Annex and for which additional guarantees apply in accordance with Article 9 of Directive 64/432/EEC.
- (5) In addition, Annex II to Decision 2004/558/EC lists the regions of the Member States that are considered free of BHV1 and to which additional guarantees apply in accordance with Article 10 of Directive 64/432/EEC.
- (6) Belgium has submitted to the Commission a programme with the aim of eradicating BHV1 infection in the whole of its territory. That programme complies with the criteria set out in Article 9(1) of Directive 64/432/EEC. That programme also provides for rules for the national movement of bovine animals which are equivalent to those previously implemented in certain Member States or regions thereof, which were successful in eradicating the disease in those Member States or regions.

The programme presented by Belgium and the additional guarantees presented in accordance with Article 9 of Directive 64/432/EEC should be approved.

(7) Annex I to Decision 2004/558/EC should therefore be amended accordingly.

⁽¹⁾ OJ 121, 29.7.1964, p. 1977/64.

^(*) Commission Decision 2004/558/EC of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (OJ L 249, 23.7.2004, p. 20).

- (8) All regions of Germany, with the exception of the Federal State of Bavaria, are currently listed in Annex I to Decision 2004/558/EC. The Federal State of Bavaria is free of BHV1 and is therefore listed in Annex II to that Decision.
- (9) Germany has now submitted to the Commission supporting documentation for the Federal State of Thuringia to be considered free of BHV1 and for the additional guarantees in accordance with Article 10 of Directive 64/432/EEC.

Following the evaluation of the supporting documentation submitted by that Member State, the Federal State of Thuringia should no longer be listed in Annex I to Decision 2004/558/EC, but instead be listed in Annex II thereto and the application of the additional guarantees in accordance with Article 10 of Directive 64/432/EEC should be extended to it.

- (10) Annex II to Decision 2004/558/EC should therefore be amended accordingly.
- (11) Decision 2004/558/EC should therefore be amended accordingly.
- (12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Annexes I and II to Decision 2004/558/EC are replaced by the text in Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 8 October 2014.

For the Commission
Tonio BORG
Member of the Commission

Annexes I and II to Decision 2004/558/EC are replaced by the following:

'ANNEX I

Member States	Regions of Member States to which the additional guarantees for infectious bovine rhinotracheitis apply in accordance with Article 9 of Directive 64/432/EEC				
Belgium	All regions				
Czech Republic	All regions				
Germany	All regions, except the Federal State of Bavaria and the Federal State of Thuringia				
Italy	Region Friuli-Venezia Giulia Region Valle d'Aosta Autonomous Province of Trento				

ANNEX II

Member States	Regions of Member States to which the additional guarantees for infectious bovine rhinotracheitis apply in accordance with Article 10 of Directive 64/432/EEC			
Denmark	All regions			
Germany	The Federal State of Bavaria The Federal State of Thuringia			
Italy	The Autonomous Province of Bolzano			
Austria	All regions			
Finland	All regions			
Sweden	All regions'			

COMMISSION IMPLEMENTING DECISION

of 8 October 2014

amending Decision 2009/821/EC as regards the list of border inspection posts

(notified under document C(2014) 7139)

(Text with EEA relevance)

(2014/704/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (¹), and in particular Article 20(1) and (3) thereof,

Having regard to Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (2), and in particular the second sentence of the second subparagraph of Article 6(4) and Article 6(5) thereof,

Having regard to Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (3), and in particular Article 6(2) thereof,

Whereas:

- (1) Commission Decision 2009/821/EC (4) lays down a list of border inspection posts approved in accordance with Directives 91/496/EEC and 97/78/EC. That list is set out in Annex I to that Decision.
- (2) Denmark has communicated that the border inspection post at Kolding should be deleted from the list of entries for that Member State. Germany has communicated that the border inspection post at Düsseldorf should be deleted from the list of entries for that Member State. The lists of entries for those Member States as set out in Annex I to Decision 2009/821/EC should therefore be amended accordingly.
- (3) Following communication from Spain and the Netherlands, the entries for the border inspection posts at Barcelona, Gran Canaria and Tenerife Sur airports in Spain and at Rotterdam port in the Netherlands should be amended in the list set out in Annex I to Decision 2009/821/EC.
- (4) Following a satisfactory audit carried out by the Commission audit service (formerly referred to as Commission inspection service), the Food and Veterinary Office (FVO), the border inspection post at Nuuk in Greenland can be approved for all categories of products not intended for human consumption. The relevant entry for that border inspection post as set out in Annex I to Decision 2009/821/EC should therefore be amended accordingly.
- (5) The FVO carried out audits in Croatia, following which it made some recommendations to that Member State. Those recommendations were satisfactorily addressed by Croatia with an action plan and with the amendment of the approval categories of the border inspection post at Rijeka. The entry for that border inspection post set out in Annex I to Decision 2009/821/EC should therefore be amended accordingly.
- (6) Decision 2009/821/EC should therefore be amended accordingly.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 224, 18.8.1990, p. 29.

⁽²⁾ OJ L 268, 24.9.1991, p. 56.

⁽³⁾ OJ L 24, 30.1.1998, p. 9.

^(*) Commission Decision 2009/821/EC of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in TRACES (OJ L 296, 12.11.2009, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

Annex I to Decision 2009/821/EC is amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 8 October 2014.

For the Commission
Tonio BORG
Member of the Commission

Annex I to Decision 2009/821/EC is amended as follows:

- (1) in the part concerning Denmark, the entry for the port at Kolding is deleted.
- (2) in the part concerning Germany, the entry for the airport at Düsseldorf is deleted.
- (3) the part concerning Spain is amended as follows:
 - (a) the entry for the airport at Barcelona is replaced by the following:

	(a)	the entry for the airport at Barcelona is replaced by the following:						
						Iberia	HC(2), NHC-T(CH)(2), NHC-NT(2)	0
	'Barcelona	ES BCN	14	A	Swissport	HC(2), NHC(2)	0	
		_				WFS	HC-T(CH)(2)'	
	(b)	the entry for	the airport a	t Grai	n Can	aria is replaced by the follow	ving:	
		'Gran Canaria	a ES LPA	4	A		HC(2), NHC-NT(2) (*)	O (*)'
	(c) the entry for the airport at Tenerife Sur is replaced by the following:						ng:	
			ES TFS	4	A	Productos	HC(2) (*), NHC(2)	
		'Tenerife Sur	ES IFS	4 A	Α	Animales		U (*), E (*), O'
(4)	(4) in the part concerning Greenland, the entry for the port at Nuuk is replaced by the following:							
	ʻNu	uk	GL GOH 1	P			HC(1)(2)(15), NHC(2)(15)'	
(5) in the part concerning Croatia, the entry for the po			for the port at Rijeka is repl	aced by the following:				
	'Rij	ijeka HR RJK 1		P			HC(2), NHC-T(FR)(2), NHC- NT(2)'	
(6)	in the part concerning the Netherlands, the entry for the port at Rotterdam is replaced by the following:							
		otterdam	NL RTM 1	P	Е	Eurofrigo Karimatastraat	HC, NHC-T(FR), NHC-NT	
						Eurofrigo, Abel Tasman- traat	НС	
	'Ro				F	rigocare Rotterdam B.V.	HC(2)	
					(Coldstore Wibaco B.V.	HC-T(FR)(2), HC-NT(2)	
					K	Gloosterboer Delta Terminal	HC(2)'	



