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)

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 Since that Directive has been repealed and replaced by Regulation (EU) No 528/2012, the detailed rules for the continuation of the review programme should be adapted to the provisions of that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

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case C-420/10[(4)], or on authoritative guidance from the Commission or Member States' competent authorities, which is subsequently reviewed.

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

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

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

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

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

(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

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granted once, thereby already causing delay to the review programme, and unless the Agency has already begun working on its opinion.

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

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

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

HAS ADOPTED THIS REGULATION:

CHAPTER 1

SUBJECT MATTER AND DEFINITIONS

Article 1

Subject matter

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

Article 2

Definitions

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

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

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

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

— a Directive on inclusion in Annex I or IA to Directive 98/8/EC,

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

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

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

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

CHAPTER 2

PROCESS FOR EVALUATION OF DOSSIERS

Article 3

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

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

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

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

Article 4

Acceptance of applications

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

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

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

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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.

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;