# COMMISSION REGULATION (EU) No 613/2013

## of 25 June 2013

## amending Regulation (EC) No 1451/2007 as regards additional active substances of biocidal products to be examined under the review programme

THE EUROPEAN COMMISSION,

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

Having regard to 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 [1], and in particular Article 16(2) thereof,

Whereas:

(1) 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 [2] sets out, in Annex II, an exhaustive list of existing active substances to be evaluated under the work programme for the systematic examination of active substances already on the market (hereinafter referred to as the 'review programme') and prohibits the placing on the market of biocidal products containing active substance/product-type combinations which are not listed in that Annex or in Annex I or IA to Directive 98/8/EC, or for which the Commission has taken a non-inclusion decision.

(2) The list in Annex II to Regulation (EC) No 1451/2007 includes existing active substance/product-type combinations which were notified in accordance with Article 4(1) of Commission Regulation (EC) No 1896/2000 of 7 September 2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products [3], in which a Member State has indicated an interest in accordance with Article 5(3) of Regulation (EC) No 1896/2000, or for which a dossier was submitted by 1 March 2006 and accepted as complete.

(3) The definitions of 'biocidal products' in point (a) of Article 2(1) of Directive 98/8/EC and of active substance in point (d) of Article 2(1) of that Directive, and the product-type descriptions in Annex V to that Directive, have been interpreted differently. In some cases, the common understanding shared between the Commission and the competent authorities designated in accordance with Article 26 of Directive 98/8/EC has changed over time. In particular, the judgment of the Court of Justice of the European Union of 1 March 2012 in case C-420/10, *Söll GmbH* v *Tetra GmbH* [4], clarified that the concept of 'biocidal products' must be interpreted as including certain products which act only by indirect means on the target harmful organisms.

(4) Persons relying on guidance notes published, or written advice given, by the Commission or by a competent authority designated in accordance with Article 26 of Directive 98/8/EC may therefore have failed to notify the existing active substance/product-type combination in a product placed on the market, or to take over the role of participant, in the objectively justified belief that the product is excluded from the scope of Directive 98/8/EC or that it falls under a different product-type.

(5) Those persons should have the possibility of submitting a dossier for examination under the review programme in such cases, subject, where relevant, to prior notification, in order to avoid the market withdrawal of products for which a justified interpretation as regards its character as a biocidal product or its correct product-type is subsequently contested by Member States or the Commission.

(6) In addition, in cases where, for the same reasons, active substances have not yet been identified as existing, Annex I to Regulation (EC) No 1451/2007 should be updated to correctly reflect all existing active substances.

(7) The situation of persons wishing to notify an active substance/product-type combination on the basis of this Regulation will be similar to that of persons wishing to take over the role of participant in accordance with Article 12 of Regulation (EC) No 1451/2007. It is therefore appropriate to provide for similar procedure and deadlines for informing stakeholders and allowing declarations of intention to the Commission.

(8) Furthermore, it is appropriate to align the deadlines and other requirements for notification with those set out in Article 4(1) of Regulation (EC) No 1896/2000 for the first notifications of existing active substances to the extent possible, while taking account of the current working methods of the European Chemicals Agency established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council [5].

(9) In cases where no Rapporteur Member State has been designated for the active substance concerned by a notification, and in order to ensure that the substance will be evaluated for approval, confirmation is to be required from the notifier that a competent authority agrees to evaluate the forthcoming application for approval of the active substance.

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 325, 11.12.2007, p. 3.
[3] OJ L 228, 8.9.2000, p. 6.
[4] Not yet published in the European Court Reports.
[5] OJ L 396, 30.12.2006, p. 1.

(10) Regulation (EC) No 1451/2007 should therefore be amended accordingly.

(11) In order to ensure a smooth transition from Directive 98/8/EC 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], certain parts of this Regulation should apply from the same date as Regulation (EU) No 528/2012.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

*Article 1*

Regulation (EC) No 1451/2007 is amended as follows:

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

'In addition, "participant" means a person which has submitted a notification that has been accepted by the Commission in accordance with Article 4(2) of Regulation (EC) No 1896/2000 or with Article 3c(1) of this Regulation, or a Member State which has indicated an interest in accordance with Article 5(3) of Regulation (EC) No 1896/2000.';

(2) in Article 3(2), the following point (d) is added:

'(d) existing active substances notified in accordance with Article 3b.';

(3) the following Article 3a is inserted:

'*Article 3a*

**Procedure for the declaration of intention to notify**

1. A person or a Member State considering that a biocidal product being placed on the market and containing only existing active substances is covered by Directive 98/8/EC and falls under one or more product-types for which Article 4 prohibits the placing on the market may submit a request to the Commission to allow the notification of the active substances contained in that product for the relevant product-types.

The request shall indicate the relevant active substance/product-type combinations, and a justification for the failure to submit a notification in accordance with Article 4(1) of Regulation (EC) No 1896/2000, or to indicate an interest in accordance with Article 5(3) of that Regulation, or to take over the role of participant in accordance with Article 12 of this Regulation, or to submit a complete dossier in accordance with Article 9(1) of this Regulation.

2. Upon receipt of a request in accordance with paragraph 1, the Commission shall consult Member States on whether the request is acceptable.

The request shall be acceptable if the biocidal product is covered by Directive 98/8/EC and falls under one or more product-types for which Article 4 of this Regulation prohibits the placing on the market and, prior to submitting that request, the applicant held an objectively justified belief, induced by guidance published or written advice given by the Commission or by a competent authority designated in accordance with Article 26 of Directive 98/8/EC, that the product was excluded from the scope of Directive 98/8/EC or that it fell under a different product-type.

However, the request shall not be acceptable if the active substance/product-type combination concerned has already been the subject of a decision not to include it in Annex I or IA to Directive 98/8/EC based on an assessment report reviewed by the Standing Committee on Biocidal Products in accordance with Article 15(4) of this Regulation.

3. Where, following a consultation in accordance with paragraph 2, the Commission finds the request acceptable, it shall accept it and allow the notification of the active substance for the relevant product-types.

However, where the dossier submitted to the Rapporteur Member State for the relevant active substance already contains all the data required for the evaluation of the relevant product-types for which Article 4 prohibits the placing on the market, and the participant which has submitted that dossier wishes to be considered as having notified the active substance for those product-types, the Rapporteur Member State shall inform the Commission thereof, and no additional notification shall be allowed pursuant to the first subparagraph.

The Commission shall inform the Member States thereof and publish that information electronically.

4. A person intending to notify the active substance/product-type combination included in the electronic publication referred to in the third subparagraph of paragraph 3 shall declare that intention to the Commission no later than three months from the date of that electronic publication.';

(4) the following Article 3b is inserted:

'*Article 3b*

**Notification procedure**

1. Following the declaration of intention to notify, the person referred to in Article 3a(4) shall submit a notification of the active substance/product-type combination to the European Chemicals Agency established by Regulation (EC) No 1907/2006 (hereinafter referred to as the 'Agency') no later than 18 months from the date of the electronic publication referred to in the third subparagraph of Article 3a(3).

The notification shall be made through the Register for Biocidal Products referred to in Article 71 of Regulation (EU) No 528/2012 of the European Parliament and of the Council (*).

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

2. The notification shall be submitted in IUCLID format. It shall contain all the information referred to in points 1 to 3 and the table in Annex II to Regulation (EC) No 1896/2000, and proof 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 the electronic publication referred to in the third subparagraph of Article 3a(3).

3. Unless a Rapporteur Member State has already been designated for the active substance in question, the notifier shall indicate to which competent authority of a Member State it intends to submit a dossier, 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 the Regulation adopted pursuant to Article 80(1) of Regulation (EU) No 528/2012. 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 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 thereof.

6. Appeals against decisions of the Agency taken pursuant to paragraph 4 or paragraph 5 shall lie with the Board of Appeal established by Regulation (EC) No 1907/2006. Article 92(1) and (2), and Articles 93 and 94 of Regulation (EC) No 1907/2006 shall apply to such appeal procedures. An appeal shall have suspensive effect.

7. The Agency shall without delay inform the Commission of whether the notification complies with the requirements of paragraph 2 or has been rejected.

(*) OJ L 167, 27.6.2012, p. 1.';

(5) the following Article 3c is inserted:

'*Article 3c*

**Inclusion in, or exclusion from, the review programme**

1. Where an active substance is considered notified in accordance with the second subparagraph of Article 3a(3), or where the Agency informs the Commission in accordance with Article 3b(7) that a notification complies with the requirements of Article 3b(2), the Commission shall accept the notification and:

(a) where the active substance/product-type combination concerned is not included in Annex II to this Regulation, include the active substance/product-type combination therein and, where relevant, the active substance in Annex I to this Regulation;

(b) where the active substance/product-type combination concerned is included in Annex II to this Regulation but has been the subject of a Commission decision not to include it in Annex I or IA of Directive 98/8/EC, annul that decision.

2. Where a declaration of intention to notify has not been received within the deadline referred to in Article 3a(4), where a notification has not been received within the deadline referred to in Article 3b(1), or where the Agency informs the Commission in accordance with Article 3b(7) that a notification submitted in accordance with Article 3b(1) has been rejected, the Commission shall inform the Member States thereof and publish that information electronically.';

(6) in Article 4, the following paragraph 4 is added:

'4. By way of derogation from paragraphs 1 and 2, biocidal products containing an active substance for which the Commission has published electronically the relevant information in accordance with the third subparagraph of Article 3a(3) for the relevant product-types may be placed on the market in accordance with Article 16(1) of Directive 98/8/EC until the date when the Commission has taken a decision to include the active substance/product-type combination in Annex II in accordance with point (a) of Article 3c(1) or to annul a previous non-inclusion decision in accordance with point (b) of Article 3c(1), or for a period of six months from the date when the Commission has published electronically the relevant information in accordance with Article 3c(2).';

(7) in Article 9, the following paragraph 3 is added:

'3. By way of derogation from paragraph 2, for active substance/product-type combinations listed in Annex II in accordance with point (a) of Article 3c(1), or for which a decision has been annulled in accordance with point (b) of Article 3c(1), applications for approval of an active substance in accordance with Article 7 of Regulation (EU) No 528/2012 shall be submitted no later than two years from the date of the decision adopted in accordance with points (a) or (b) of Article 3c(1).'.

*Article 2*

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

However, points 2, 4 and 7 of Article 1 shall apply from 1 September 2013.

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

Done at Brussels, 25 June 2013.

*For the Commission*
*The President*
José Manuel BARROSO