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Parliament and of the Council concerning the placing of biocidal products on the market (Text with EEA relevance) (repealed)

Article 1

Subject matter

This Regulation lays down detailed rules for the implementation of the programme of work for the systematic examination of all active substances already on the market on 14 May 2000 as active substances of biocidal products, hereinafter 'the review programme', referred to in Article 16(2) of Directive 98/8/EC.

Article 2

Definitions

For the purposes of this Regulation the definitions in Article 2 of Directive 98/8/EC and Article 2 of Regulation (EC) No 1896/2000 shall apply.

[[F1]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.**]**

Textual Amendments

F1 Substituted by 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.

Article 3

Existing active substances

1 The list of active substances identified as available on the market before 14 May 2000 as active substances of biocidal products for purposes other than those referred to in Article 2(2)(c) and (d) of Directive 98/8/EC is set out in Annex I.

2 The exhaustive list of existing active substances to be examined under the review programme is set out in Annex II.

The list includes the following active substances:

a existing active substances notified in accordance with Article 4(1) of Regulation (EC) No 1896/2000 or Article 4(2) of Commission Regulation (EC) No 1687/2002[(1)];

b existing active substances that were not notified, but in respect of which a Member State has indicated an interest in supporting their inclusion in Annex I, IA or IB to Directive 98/8/EC;

c existing active substances that were not notified, but for which a dossier was submitted to one of the Member States by 1 March 2006, which was found to comply with the requirements of Annex III to this Regulation and was accepted as complete[F1;]

[F2d existing active substances notified in accordance with Article 3b.]

The list specifies, for each existing active substance included, the product types in respect of which the substance will be examined under the review programme, as well as the Rapporteur Member State designated to carry out the evaluation.

Textual Amendments

F1 Substituted by 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.

F2 Inserted by 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.

[F2 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.**]**

Textual Amendments

F2 Inserted by 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.

[F2 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[(2)].

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.**]**

Textual Amendments

F2 Inserted by 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.

[F2 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.**]**

Textual Amendments

F2 Inserted by 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.

Article 4

Non-inclusion

1 Without prejudice to Articles 5 and 6 of this Regulation and paragraph 2 of this Article, biocidal products containing active substances not listed in Annex II to this Regulation or in Annex I or IA to Directive 98/8/EC shall no longer be placed on the market.

In the case of an active substance listed in Annex II to this Regulation, the first subparagraph shall also apply to that substance in relation to any product type not listed in that Annex.

2 Biocidal products containing active substances listed in Annex II to this Regulation for which a decision was taken not to include these active substances for certain or all of their notified product types in Annex I or IA to Directive 98/8/EC, shall no longer be placed on the market for the product types concerned, with effect from 12 months after the date of such a measure being published, unless otherwise stipulated therein.

3 Without prejudice to Articles 12(1)(b) and 15(2) of Directive 98/8/EC, from the day of entry into force of this Regulation, any active substance not listed in Annex I shall be deemed not to have been placed on the market for biocidal purposes before 14 May 2000.

[[F2]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).**]**

Textual Amendments

F2 Inserted by 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.

Article 5

Derogation for essential use

1 Member States may apply to the Commission for a derogation from Article 4(1) where they consider that an active substance is essential for them for reasons of health, safety or protection of cultural heritage or is critical for the functioning of society, and where there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health.

Applications shall be accompanied by a document stating the reasons and justifications.

2 The applications referred to in paragraph 1 shall be forwarded by the Commission to the other Member States and shall be made publicly available by electronic means.

Member States or any person may for a period of 60 days following reception of an application submit comments in writing to the Commission.

[[F3]3 Taking account of the comments received, the Commission may grant a derogation from Article 4(1) allowing the placing of the substance on the market of the requesting Member States until the date referred to in the first subparagraph of Article 16(2) of Directive 98/8/EC at the latest, provided that the Member States:

a ensure that continued use is possible only if products containing the substance are approved for the intended essential use;

b conclude that, taking into account all available information, it is reasonable to assume that continued use does not have any unacceptable effect on human or animal health or on the environment;

c impose all appropriate risk reduction measures when granting approval;

d ensure that such approved biocidal products remaining on the market after 1 September 2006 are relabelled in order to match the use conditions laid down by the Member States in accordance with this paragraph; and

e ensure that, where appropriate, alternatives for such uses are being sought by the holders of the approvals or the Member States concerned, or a dossier is being prepared for submission in accordance with the procedure laid down in Article 11 of Directive 98/8/EC at the latest two years before the date referred to in the first subparagraph of Article 16(2) of Directive 98/8/EC.**]**

4 The Member States concerned shall annually inform the Commission on the application of paragraph 3 and in particular on the actions taken pursuant to point (e).

5 Member States may at any time review the approvals of biocidal products for which the period of placing on the market has been extended in accordance with paragraph 3. Whenever there is reason to believe that any of the conditions set in points (a) to (e) of that paragraph are no longer satisfied, the Member States concerned shall without undue delay take steps to remedy the situation or if that is not possible, withdraw the approvals of the biocidal products concerned.

Textual Amendments

F3 Substituted by Commission Regulation (EU) No 298/2010 of 9 April 2010 amending Regulation (EC) No 1451/2007 as regards the extension of the duration of derogations allowing the placing of biocidal products on the market (Text with EEA relevance).

Article 6

Food and Feed

[[F3]By way of derogation from Article 4(1), Member States may allow until the date referred to in the first subparagraph of Article 16(2) of Directive 98/8/EC at the latest the placing on the market of active substances consisting solely of food or feed that are intended for use as repellents or attractants of product type 19.**]**

For the purposes of this derogation, ‘food or feed’ means any edible substance or product of plant or animal origin, whether processed, partially processed or unprocessed, which is intended or reasonably expected to be ingested by humans or animals; this category does not comprise extracts or individual substances isolated from food or feed.

Textual Amendments

F3 Substituted by Commission Regulation (EU) No 298/2010 of 9 April 2010 amending Regulation (EC) No 1451/2007 as regards the extension of the duration of derogations allowing the placing of biocidal products on the market (Text with EEA relevance).

Article 7

Examination of existing active substances under the review programme

1 The review of an active substance listed in Annex II, in respect of the product types specified, shall be undertaken by the Rapporteur Member State designated for that purpose on the basis of the complete dossier for that substance/product type combination, provided that:

a the dossier complies with the requirements set out in Annex III to this Regulation;

b the complete dossier is submitted within the period specified in Article 9 of this Regulation for the product type concerned, together with the summary dossier referred to in Article 11(1)(b) of Directive 98/8/EC and defined in Annex III to this Regulation.

An active substance listed in Annex II to this Regulation shall be reviewed exclusively in relation to the product types specified therein.

For the active substance/product type combinations referred to in Article 3(2)(c), with the exception of product types 8 and 14, the evaluation of the dossiers shall commence at the same time as the evaluation of dossiers for active substances contained in the same product types.

2 A Member State which has indicated an interest in supporting the inclusion of an active substance in Annex I, IA or IB to the Directive shall not be designated as Rapporteur Member State in respect of that substance.

3 Without prejudice to Articles 10, 11 and 12 of this Regulation, persons other than participants may apply, in accordance with Article 11 of Directive 98/8/EC, for the inclusion in Annex I, IA or IB thereto of an existing active substance/product type combination that is listed in Annex II to this Regulation. These persons shall submit in that case a complete dossier within the time period specified in Article 9 for that substance/product type combination.

Article 8

Preparation of the complete dossier

1 In the preparation of the complete dossier, all reasonable efforts shall be made, inter alia, to avoid duplication of testing on vertebrate animals and, where appropriate, to establish a collective complete dossier.

2 Before commencing compilation of the complete dossier, a participant shall:

a inform the Rapporteur Member State of any testing on vertebrate animals that it has already carried out;

b contact the Rapporteur Member State for advice as to the acceptability of justifications for waiving certain studies;

c inform the Rapporteur Member State of any intention to carry out further testing on vertebrate animals for the purposes of the complete dossier;

d when informed by the Rapporteur Member State that another participant has notified plans to carry out the same tests, make all reasonable efforts to cooperate with that participant in the performance of common testing.

Advice given by Rapporteur Member States in accordance with point (b) of the first subparagraph shall not predetermine the outcome of the completeness check under Article 13(1).

3 A Rapporteur Member State may make available the reference to any test carried out on vertebrate animals in respect of an active substance listed in Annex II to this Regulation, save where that reference is to be treated as confidential in accordance with Article 19 of Directive 98/8/EC. Such reference may include the name of the active substance concerned, the end points of the tests, and the contact address of the data owner.

4 Where a Rapporteur Member State is aware that more than one participant is seeking review of a particular active substance, it shall inform those participants accordingly.

5 Participants seeking review of the same active substance for the same product types shall undertake all reasonable efforts to submit a collective complete dossier, while fully respecting the Community rules on competition.

Where, in those circumstances, a collective dossier is not submitted, each individual dossier shall detail the efforts made to secure cooperation and the reasons for non-participation.

6 Details shall be given in the complete dossier and in the summary dossier of the efforts made to avoid duplication of testing on vertebrate animals.

7 In order to provide information on the costs entailed in applying for review and on the need for animal testing for the purposes of compiling the complete dossier, participants may submit to the Rapporteur Member State together with the complete dossiers a breakdown of the costs of the respective actions and studies carried out.

The Rapporteur Member State shall communicate that information to the Commission when submitting the competent authority report in accordance with Article 14(4).

8 Information on the costs entailed in compiling the complete dossier and on the animal testing carried out for that purpose shall be included in the report referred to in Article 18(5) of Directive 98/8/EC together with any appropriate recommendations concerning modifications of data requirements in order to reduce to a minimum the need for testing on vertebrate animals, and to ensure cost-effectiveness and proportionality.

Article 9

Submission of the complete dossier

1 Unless otherwise indicated by the Rapporteur Member State, a participant shall submit to the Rapporteur Member State one paper and one electronic copy of the complete dossier.

The participant shall also, in accordance with Article 13(3), submit one paper and one electronic copy of the summary dossier to the Commission and to each of the other Member States. However, any Member State wishing to receive copies only in electronic format or additional copies shall inform the Commission, which shall make that information publicly available by electronic means. If the Member State subsequently decides otherwise, it shall inform the Commission without undue delay,

whereupon the Commission shall update accordingly the information made publicly available.

2 For the existing active substances listed in Annex II, complete dossiers must be received by the competent authority of the Rapporteur Member State within the following periods:

a for product types 8 and 14, until 28 March 2004;

b for product types 16, 18, 19 and 21, from 1 November 2005 until 30 April 2006;

c for product types 1, 2, 3, 4, 5, 6 and 13, from 1 February 2007 until 31 July 2007;

d for product types 7, 9, 10, 11, 12, 15, 17, 20, 22 and 23, from 1 May 2008 until 31 October 2008.

[[F2]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).**]**

Textual Amendments

F2 Inserted by 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.

Article 10

Joining and replacing of participants

Where, by mutual agreement, a producer, formulator or association joins or replaces a participant for the purposes of submitting the complete dossier, all parties to the agreement shall jointly inform the Commission and the Rapporteur Member State accordingly, attaching any relevant letter of access.

The Commission shall inform accordingly any other participant seeking review of the same active substance in relation to the same product types.

Article 11

Withdrawal of participants

1 Where a participant intends to discontinue participation in the review programme, they shall inform the relevant Rapporteur Member State and the Commission accordingly, in writing and without delay, stating the reasons.

The Commission shall inform accordingly the other Member States and any other participant seeking review of the same active substance in relation to the same product type(s).

2 Where all the participants have withdrawn as regards a particular existing active substance/product type combination, the Commission shall inform the Member States thereof and shall publish that information electronically.

Article 12

Taking over the role of participant

1 Within three months of the electronic publication of the information referred to in Article 11(2), a producer, formulator, association or other person may inform the Commission of their intention to take over the role of participant as regards the existing active substance/product type combination.

Within the time period referred to in the first subparagraph, a Member State may also indicate to the Commission an interest in taking over the role of participant in order to support the inclusion in Annex I, IA or IB to Directive 98/8/EC of the existing active substance/product type combination, where there are uses which the Member State considers essential, in particular for the protection of human health, animal health or the environment.

2 The person or Member State wishing to take over the role of the participant who has withdrawn shall, within three months of informing the Commission of their intention, provide evidence to it that work to compile a complete dossier has been commissioned.

3 On the basis of the evidence referred to in paragraph 2, the Commission shall decide whether or not to allow the interested person or Member State to take over the role of participant.

Where the Commission allows the interested person or Member State to take over the role of participant, it may decide to extend, if necessary, the relevant period for the submission of a complete dossier specified in Article 9.

4 The taking over of the role of participant for a given existing active substance/product type combination may be allowed only once.

5 Where the Commission receives no response pursuant to paragraph 1, it shall take a decision not to include the existing active substance in Annex I, IA or IB to Directive 98/8/EC within the framework of the review programme for the product type(s) concerned.

Article 13

Completeness check of dossiers

1 Within three months of receiving the dossier for an existing active substance/product type combination and no later than three months after the end of the relevant time period specified in Article 9(2) of this Regulation, the Rapporteur Member State shall verify whether the dossier is to be accepted as complete in accordance with Article 11(1)(b) of Directive 98/8/EC.

Where the Rapporteur Member State has initiated consultations with other Member States and the Commission in relation to the acceptability of a dossier, the period may be prolonged until consultations have been finalised, up to a maximum of six months from receipt of the dossier.

2 A Rapporteur Member State may require, as a condition for considering a dossier to be complete, proof of advance payment, in full or in part, of the charges payable under Article 25 of Directive 98/8/EC to be provided in the dossier.

3 Where a dossier is considered to be complete, the Rapporteur Member State shall confirm acceptance of the dossier to the participant and agree to the participant forwarding the summary dossier to the Commission and the other Member States within one month of receiving the confirmation.

If a Member State in receipt of a summary dossier has legitimate reason to believe that the dossier is incomplete, it shall without delay communicate its concerns to the Rapporteur Member State, the Commission and the other Member States.

The Rapporteur Member State shall immediately take up consultations with that Member State and the Commission in order to discuss the concern expressed and resolve divergent opinions.

4 In exceptional circumstances, the Rapporteur Member State may establish a new deadline for the submission of information which, for reasons duly substantiated, the participant was unable to submit in due time.

The participant shall, within three months of being informed of the new deadline, provide evidence to the Rapporteur Member State that work to provide the missing information has been commissioned.

If the Rapporteur Member State considers that it has received sufficient evidence, it shall carry out its evaluation in accordance with Article 14 as if the dossier were complete. Otherwise, the evaluation shall not commence until the missing information is submitted.

5 Where a complete dossier is not received within the period specified in Article 9 or by a new deadline established in accordance with paragraph 4, the Rapporteur Member State shall inform the Commission, giving the reasons put forward by the participant by way of justification.

The Rapporteur Member State shall also inform the Commission in cases where a participant fails to provide the evidence required in accordance with the second subparagraph of paragraph 4. In the cases referred to in the first and second subparagraphs and if no other dossier concerns the same existing active substance/ product type combination, all participants shall be deemed to have withdrawn and Articles 11(2) and 12 shall apply *mutatis mutandis*.

Article 14

Evaluation of dossiers by the Rapporteur Member State

1 Where the Rapporteur Member State considers a dossier to be complete, it shall carry out the evaluation within twelve months of accepting the dossier in accordance with Article 11(2) of Directive 98/8/EC and shall prepare a report on that evaluation, hereinafter ‘the competent authority report’.

Without prejudice to Article 12 of Directive 98/8/EC, the Rapporteur Member State may take into account other relevant technical or scientific information regarding the properties of the active substance, metabolites or residues.

2 At the request of a participant, the Rapporteur Member State may take into account additional information relating to an active substance for which the dossier has been accepted as complete only if the following conditions are fulfilled:

a the participant informed the Rapporteur Member State, at the time of submission of the dossier, that preparation of the additional information was under way;

b the additional information is submitted no later than nine months after acceptance of the dossier in accordance with Article 13(3);

c by comparison with the data originally submitted, the additional information is equally or more reliable owing to the application of the same or higher quality standards;

d by comparison with the data originally submitted, the additional information supports a different conclusion concerning the active substance for the purposes of the recommendation under paragraph 6.

The Rapporteur Member State shall take into account additional information submitted by persons other than the participant only if that information satisfies the conditions set out in points (b), (c) and (d) of the first subparagraph.

3 Where relevant in the application of paragraph 1, in particular when additional information has been requested by a deadline established by the Rapporteur Member State, the latter may request that the participant submit updated summary dossiers to the Commission and the other Member States when the additional information is received.

All participants shall be deemed to have withdrawn and Articles 11(2) and 12 shall apply *mutatis mutandis* if:

a the additional information is not received by the deadline;

b the participant fails to provide adequate justification for further postponing the deadline;

c no other dossier concerns the same existing active substance/product type combination.

4 The Rapporteur Member State shall, without undue delay, send a copy of the competent authority report to the Commission, the other Member States and to the participant.

5 A Rapporteur Member State may decide to withhold the competent authority report if the charges payable under Article 25 of Directive 98/8/EC have not been paid in full, in which case it shall inform the participant and the Commission accordingly.

All participants shall be deemed to have withdrawn and Articles 11(2) and 12 shall apply *mutatis mutandis* if:

a full payment is not received within three months of the date of receipt of that information;

b no other dossier concerns the same existing active substance/product type combination.

6 The competent authority report shall be presented in a format to be recommended by the Commission and shall include one of the following:

a a recommendation to include the existing active substance in Annex I, IA or IB to Directive 98/8/EC, stating, where appropriate, conditions for inclusion;

b a recommendation not to include the existing active substance in Annex I, IA or IB to Directive 98/8/EC, stating the reasons.

Article 15

Commission procedures

1 When the Commission receives a competent authority report pursuant to Article 14(4) of this Regulation it shall, without undue delay, prepare the draft decision referred to in Article 27 of Directive 98/8/EC.

2 Before preparing the draft decision referred to in paragraph 1, the Commission shall, when necessary in the light of the comments received on the competent authority report, consult with experts from the Member States to address any problems remaining unresolved. Where necessary and upon a request from the Commission, the Rapporteur Member State shall prepare an updated competent authority report.

3 Where an existing active substance, despite a recommendation for inclusion pursuant to Article 14(6) of this Regulation, still gives rise to concern, as referred to in Article 10(5) of Directive 98/8/EC, the Commission may, without prejudice to Article 12 of that Directive, take into account the finalisation of the evaluation of other existing active substances applied for the same use.

4 On the basis of the documents and information referred to in Article 27(2) of Directive 98/8/EC, the Rapporteur Member State shall prepare an updated competent authority report, the first part of which shall form the assessment report. The assessment report shall be reviewed within the Standing Committee on Biocidal Products. Where several dossiers have been submitted for the same active substance/product type combination, the Rapporteur Member State shall prepare one assessment report based on the information contained in those dossiers.

Article 16

Access to information

Where a Rapporteur Member State has submitted the competent authority report in accordance with Article 14(4) of this Regulation, or where an assessment report has been finalised or updated in the Standing Committee on Biocidal Products, the Commission shall make the report or any updates thereof publicly available by electronic means, except for information that is to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

Article 17

Suspension of procedures

Where, in respect of an active substance listed in Annex II to this Regulation, the Commission presents a proposal for amending Directive 76/769/EEC or, with effect from 1 June 2009, Annex XVII of Regulation (EC) No 1907/2006 in order to prohibit its placing on the market or its use, including use for biocidal purposes, in certain or all product types, the procedures provided for in this Regulation concerning that substance for use in the product types concerned may be suspended pending a decision on that proposal.

Article 18

Repeal

Regulation (EC) No 2032/2003 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 19

Entry into force

This Regulation shall enter into force on the 20th day following 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.

(**1**) OJ L 258, 26.9.2002, p. 15.

(**2**) **[**[F2]OJ L 167, 27.6.2012, p. 1.**]**

Textual Amendments

F2 Inserted by 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.

Status:
Point in time view as at 01/09/2013.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 1451/2007 (repealed).