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Parliament and of the Council concerning the placing of biocidal products on the market (Text with EEA relevance) (repealed)

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(Text with EEA relevance) (repealed)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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) Pursuant to Directive 98/8/EC, Member States may only authorise the placing on the market of biocidal products containing active substances included in Annex I, IA or IB to that Directive. However, under the transitional measures provided for in Article 16(1) of Directive 98/8/EC Member States may allow the placing on the market of biocidal products containing active substances not listed in Annex I, IA or IB to Directive 98/8/EC which were already on the market on 14 May 2000, hereinafter 'existing active substances'. Pursuant to paragraph 2 of that same Article, a 10-year programme of work is to be carried out for the review of all existing active substances. This programme of work was intended to identify the existing active substances and determine those to be evaluated under the review programme with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC.

(2) The initial phase of the programme was laid down in 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[(2)].

(3) Under Regulation (EC) No 1896/2000, existing active substances for use in biocidal products had to be identified, and those to be evaluated with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC in one or more product types had to be notified no later than 28 March 2002.

(4) Commission Regulation (EC) No 2032/2003 of 4 November 2003 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, and amending Regulation (EC) No 1896/2000[3] established a list of existing active substances. That list covered active substances that had been identified in accordance with Article 3(1) or Article 5(2) of Regulation (EC) No 1896/2000 or in respect of which equivalent information had been submitted in a notification in accordance with Article 4(1) of that Regulation.

(5) Regulation (EC) No 2032/2003 also established, in Annex II, an exhaustive list of existing active substances to be evaluated under the review programme. That list covered active substances in respect of which at least one notification had been accepted in accordance with Article 4(2) of Regulation (EC) No 1896/2000 or in which a Member State had expressed an interest in accordance with Article 5(3) of that Regulation. That list specified the product types concerned.

(6) Regulation (EC) No 2032/2003 allowed for a number of active substances or substance/product type combinations that were not originally covered by the review programme, to be examined on the same conditions as the active substances evaluated under the review programme, provided that interested operators submitted complete dossiers before 1 March 2006.

(7) Article 4(2) of Regulation (EC) No 2032/2003 set 1 September 2006 as the date from which products containing active substances not examined under the review programme should be withdrawn from the market.

(8) Article 4(3) of Regulation (EC) No 2032/2003 provided that the existing active substances that had not been identified by the persons using them in biocidal products were to be deemed not to have been placed on the market for biocidal purposes before 14 May 2000. However, this assimilation to new active substances should not be taken to mean that the unlawfully non-identified existing active substances may benefit from a provisional authorisation or from the longer data protection period reserved to genuinely new active substances. Whereas a clarification in that sense should be added to that provision.

(9) Regulation (EC) No 2032/2003 introduced the possibility for Member States to apply for a derogation for biocidal products containing identified existing active substances that are not examined under the review programme, which Member States claim are essential for reasons of health, safety, or protection of cultural heritage or critical for the functioning of society in the absence of technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment or health. Such derogation is granted to the requesting Member States only if the requests are justified, if continued use does not give rise to concerns for human health and the environment, and if, where appropriate, alternatives are being developed. It is appropriate to continue to allow Member States to apply for such a derogation, including in respect of an active substance which it has been decided not to include in Annex I, IA or IB to Directive 98/8/EC. Since the review programme referred to in Article 16(2) of Directive 98/8/EC runs only until 14 May 2010, any such derogation should not continue beyond that date.

(10) Certain substances or products that are normally consumed by humans or animals for their subsistence may also be used to attract or to repel harmful organisms. For these substances, there is general agreement that the authorisation/registration requirements of Directive 98/8/EC seem unjustified and that they should be expressly excluded from its scope. Considering that a revision of Directive 98/8/EC will take a significant amount of time during which the viability of those products on the market might be irreversibly affected, it is appropriate to postpone their withdrawal from the market until 14 May 2010.

(11) A Member State which has indicated an interest in seeking review of a particular active substance should not be designated Rapporteur Member State for that substance.

(12) In order to avoid duplication of work, and in particular to reduce testing involving vertebrate animals, the requirements concerning preparation and submission of the complete dossier should be such as to encourage those whose notifications have been accepted, hereinafter 'participants', to act collectively, in particular by submitting collective dossiers. It should be possible for the Rapporteur Member State to make available the reference to any test involving vertebrate animals that has been carried out in respect of a notified existing active substance unless that reference is confidential under Article 19 of Directive 98/8/EC. Also, in order to gain experience on the appropriateness of data requirements and to ensure that the review of active substances is carried out in a cost-effective way, participants should be encouraged to provide information on the costs of compiling a dossier and on the need to carry out tests on vertebrate animals.

(13) In order to avoid delays, participants should start discussions as early as possible with Rapporteur Member States in order to resolve uncertainties in relation to data requirements. Applicants, other than participants, who wish to apply in accordance with Article 11 of Directive 98/8/EC for inclusion in Annex I, IA or IB thereto of an active substance/product type combination being evaluated under the review programme should submit complete dossiers for that combination no earlier or no later than participants so as not to disturb the smooth functioning of the review programme or create a disadvantage to the participants.

(14) The requirements concerning the content and format of dossiers and the number of dossiers to be submitted should be defined.

(15) Provision should be made for cases in which a participant is joined by a producer, formulator or association and in which a participant withdraws from the review programme.

(16) Producers, formulators or associations should within certain time limits have the opportunity of taking over the role of participant for an existing active substance/product type combination in respect of which all participants have withdrawn or none of the dossiers meets the requirements. Subject to the same time-limits, it should also be possible in certain circumstances for Member States to indicate an interest and act as a participant for the inclusion in Annex I, IA or IB to Directive 98/8/EC of such a combination.

(17) In order to discourage abuse of the opportunity to maintain an active substance on the market while it is examined under the review programme, it should be possible for another person or a Member State to take over the role of participant only once in relation to a given active substance/product type combination. For the same purpose, a person or Member State taking over the role of participant should provide within a certain period evidence of commencing work on a complete dossier.

(18) Time limits should be specified within which the Rapporteur Member States must verify the completeness of the dossiers. It should be possible, in exceptional circumstances, for the Rapporteur Member States to establish a new deadline for the submission of parts of a dossier, in particular where the participant has demonstrated that it was impossible to submit information in due time or in order to resolve uncertainties regarding data requirements that remain despite earlier discussions between the participant and the Rapporteur Member State.

(19) For each existing active substance, the Rapporteur Member State should examine and evaluate the dossier and present the results to the Commission and the other Member States in the form of a competent authority report and a recommendation as to the decision to be taken with regard to the active substance concerned. In order not to prolong decision-making unnecessarily, the Rapporteur Member State should at the same time consider carefully the need for additional studies. For the same reason, Rapporteur Member States should be obliged to take into consideration information submitted after acceptance of the dossier only under specified conditions.

(20) The competent authority reports should be examined by the other Member States before the assessment reports are submitted to the Standing Committee on Biocidal Products.

(21) Where, despite a recommendation for inclusion of an active substance in Annex I, IA or IB to Directive 98/8/EC, concerns as referred to in Article 10(5) of that Directive remain, it should be possible for the Commission to take into account, but without prejudice to Article 12 of that Directive, the finalisation of the evaluation on other existing active substances applied for the same use. Provision should be made for Rapporteur Member States to update competent authority reports where necessary.

(22) In order to ensure better access to information, assessment reports should be drafted on the basis of the reports submitted by the competent authorities of the Member States and should be covered by the same rules regarding access to information as the reports of the competent authorities. The assessment reports should be derived from the original competent authority report as amended in the light of all the documents, comments and information taken into account during the evaluation process.

(23) It should be possible to suspend the procedures provided for in this Regulation in the light of the application of other Community acts, in particular as regards Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations[(4)], and after 1 June 2009, as regards Title VIII and Annex XVII of Regulation (EC) No 1907/2006.

(24) In order to ensure the most efficient course of the review programme, a number of active substance/product type combinations have been reassigned to different rapporteur Member States. These developments should be reflected in Annex II of this Regulation.

(25) Regulation (EC) No 2032/2003 has been amended on several occasions[(5)] in order to take into consideration the accession of new Member States, lessons learned from the implementation to date of the review programme, and in particular in order to provide for the non-inclusion in Annex I, IA or IB to Directive 98/8/EC of a number of active substances, either because the requisite information was not submitted within the prescribed period or in cases where the requirements of Article 10 of the said Directive were not satisfied. This practice of constantly updating Regulation (EC) No 2032/2003 in order to follow the evolution of the review programme has proven ineffectual and time-consuming; furthermore it could create confusion to stakeholders as to which rules apply and which active substances are currently under review. In the interest of clarity, it is preferable to repeal and replace Regulation (EC) No 2032/2003 by a new simplified act which will lay down the rules for the review programme, and that the Commission should adopt separate acts for the future non-inclusion decisions.

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

HAS ADOPTED THIS REGULATION:

(**1**) OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2007/47/EC (OJ L 247, 21.9.2007, p. 21).

(**2**) OJ L 228, 8.9.2000, p. 6. Regulation as amended by Regulation (EC) No 2032/2003 (OJ L 307, 24.11.2003, p. 1).

(**3**) OJ L 307, 24.11.2003, p. 1. Regulation as last amended by Regulation (EC) No 1849/2006 (OJ L 355, 15.12.2006, p. 63).

(**4**) OJ L 262, 27.9.1976, p. 201. Directive as last amended by Directive 2007/51/EC of the European Parliament and of the Council (OJ L 257, 3.10.2007, p. 13).

(**5**) By Regulation (EC) No 1048/2005 (OJ L 178, 9.7.2005, p. 1); and Regulation (EC) No 1849/2006, (OJ L 355, 15.12.2006, p. 63).

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), Introductory Text.