Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I (Text with EEA relevance)

COMMISSION REGULATION (EC) No 33/2008

of 17 January 2008

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[(1)], and in particular Article 6(5) thereof,

Whereas:

(1) Article 8(2) of the Directive 91/414/EEC provides that the Commission undertakes a programme of work for the gradual examination of active substances on the market two years after the date of notification of this Directive. This programme has been divided into four phases, the last of which is due to expire on 31 December 2008 in accordance with Commission Decision 2003/565/EC of 25 July 2003 extending the time period provided for in Article 8(2) of Council Directive 91/414/EEC[(2)].

(2) The first stage of this programme was laid down by Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market[(3)]. The second and third stages of work were laid down by Commission Regulation (EC) No 451/2000 of 28 February 2000 laying down the detailed rules for the implementation of the second and third stages of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC[(4)] and Commission Regulation (EC) No 1490/2002[(5)]. The fourth stage was laid down by Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down the detailed rules for the implementation of the fourth stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC[(6)].

(3) For the inclusion of active substances in Annex I to Directive 91/414/EEC which were part of the first, second, third and fourth programme of work as referred to in Article 8(2) of that Directive it is necessary to provide for detailed rules for the re-submission of applications which avoid duplication of work, maintain a high safety

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 33/2008. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

standard and ensure that a decision is taken quickly. Furthermore, the relationship between applicants, Member States, the European Food Safety Authority, hereinafter 'the Authority', and the Commission and the obligations on each of the parties for the application of the procedure should be laid down.

(4) For the substances included in the first stage the dossiers were submitted in 1995 and 1996. No peer review was carried out by the Authority. Given the age of the original dossiers and the changes in scientific knowledge, reflected in guidance documents from the Commission services, a complete and up to date dossier should be required for these substances and the Authority should in principle carry out a peer review. The same provisions should in principle apply for substances of stage 2, 3 and 4 of the review programme but in cases where a draft assessment report has been prepared and an application is submitted within a reasonable time after the decision providing that the substance was not to be included in Annex I to Directive 91/414/EEC an accelerated procedure may be implemented.

(5) For substances covered by the second stage strict deadlines applied and therefore it was necessary to decide on the basis of the available information peer reviewed by the Authority. In a number of cases issues were identified which led to the substance not being included in Annex I to Directive 91/414/EEC. For those substances the original dossiers were submitted at the latest in April 2002. Authority peer reviews were carried out between 2003 and 2006 and therefore the dossiers are up to date. In some of these cases only a limited number of studies might be required to form a complete dossier for re-submission of applications concerning possible Annex I inclusions, based on the same or more restricted supported uses. It is appropriate to provide for an accelerated procedure for re-submission and peer review in cases where the dossier was compiled and discussed recently. The same should apply to third and fourth stage substances of the review programme for which the procedures were last amended in Regulation (EC) No 1095/2007.

(6) Additional data should only be taken into account if they are submitted within the time period set.

(7) The possibility to submit a new application for the same substance at any time should be provided for.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

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CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Scope

This Regulation lays down detailed rules for the submission and evaluation of applications for inclusion in Annex I to Directive 91/414/EEC of active substances which have been evaluated by the Commission within the framework of the review programme provided for in Article 8(2) of that Directive but which, by the dates set out in points (a), (b) and (c), had not been included into Annex I to that Directive:

(a) for first stage substances, by 31 December 2006, or in the case of metalaxyl, by 30 June 2010;

(b) for second stage substances, by 30 September 2007;

(c) **[**[F1]for third and fourth stage substances, by 31 December 2009.**]**

Textual Amendments

F1 Substituted by Commission Regulation (EU) No 78/2010 of 27 January 2010 amending Regulation (EC) No 33/2008 as regards the scope and the period granted under the regular procedure to the Authority for the adoption of its conclusions concerning the inclusion of certain active substances in Annex I to Directive 91/414/EEC (Text with EEA relevance).

Article 2

Definitions

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

(a) ‘applicant’ means the person who manufactures the active substance on his own or who contracts the manufacturing to another party or a person designated by the manufacturer as his sole representative for the purpose of compliance with this Regulation;

(b) ‘committee’ means the Standing Committee on the Food Chain and Animal Health, referred to in Article 19 of Directive 91/414/EEC;

(c) ‘first stage substances’ means active substances listed in Annex I to Regulation (EEC) No 3600/92;

(d) ‘second stage substances’ means active substances listed in Annex I to Regulation (EC) No 451/2000;

(e) ‘third stage substances’ means active substances listed in Annex I to Regulation (EC) No 1490/2002;

(f) ‘fourth stage substances’ means active substances listed in Annex I to Regulation (EC) No 2229/2004.

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CHAPTER II

REGULAR PROCEDURE

Article 3

Application

1 An applicant wishing to secure the inclusion in Annex I to Directive 91/414/EEC of an active substance covered by Article 1 shall submit an application for that active substance to a Member State (hereinafter referred to as rapporteur Member State) together with a complete dossier, including a summary dossier, as provided for in Article 4 demonstrating that the active substance fulfils the requirements provided for in Article 5 of that Directive. It shall be for the applicant to demonstrate that these requirements are fulfilled.

2 When submitting his application, the applicant may, pursuant to Article 14 of Directive 91/414/EEC, request certain parts of the dossiers referred to in paragraph 1 of this Article to be kept confidential. The applicant shall explain for each document or each part of a document why it is to be considered as confidential.

The applicant shall at the same time submit any claims for data protection pursant to Article 13 of Directive 91/414/EEC.

The applicant shall submit separately the information to be kept confidential.

Article 4

Dossiers

1 The summary dossier shall include the following:

a data with respect to a limited range of representative uses of at least one plant protection product containing the active substance, demonstrating that the requirements of Article 5 of Directive 91/414/EEC are met;

b for each point of the data requirements for the active substance referred to in Annex II to Directive 91/414/EEC, the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried out the tests and studies;

c for each point of the data requirements for the plant protection product referred to in Annex III to Directive 91/414/EEC, the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried out the tests and studies relevant to the assessment of the requirements referred to in Article 5 of that Directive taking into account that data gaps in the Annex II or Annex III dossier, resulting from the proposed limited range of representative uses, may lead to restrictions in the Annex I inclusion;

d a checklist demonstrating that the dossier provided for in paragraph 2 is complete;

e the reasons why the test and study reports submitted are necessary for first inclusion of the active substance;

f an assessment of all information submitted.

2 The complete dossier shall contain the full text of the individual test and study reports concerning all the information referred to in points (b) and (c) of paragraph 1.

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Article 5

Completeness check of the dossier

1 Within 30 days of receiving the application, the rapporteur Member State shall check whether the dossiers submitted with the application contain all the elements provided for in Article 4, using the checklist referred to in Article 4(1)(d).

2 Where one or more of the elements provided for in Article 4 are missing, the Member State shall inform the applicant, setting a time period for their submission; such time period shall be no more than six months.

3 Where at the end of the period, referred to in paragraph 2, the applicant has not submitted the missing elements, the rapporteur Member State shall inform the applicant, the Commission and the other Member States. If, after giving the applicant an opportunity to comment, the Commission determines that the applicant has failed to submit the missing elements, it shall adopt a decision providing that the active substance concerned is not to be included in Annex I to Directive 91/414/EEC. Such a decision shall end the assessment of that active substance under this Regulation.

4 A new application for the same substance may be submitted at any time.

5 Where the dossiers submitted with the application contain all the elements provided for in Article 3, the rapporteur Member State shall notify the applicant, the Commission, the other Member States and the Authority of the completeness of the application.

Article 6

Publication of information

For applications for which completeness has been established the Commission shall make public the following information:

(a) the name of the active substance;

(b) the date of application;

(c) the name and address of applicants;

(d) the rapporteur Member State.

Article 7

Submission of information by third parties

1 Any person or Member State wishing to submit to the rapporteur Member State information which might contribute to the assessment, in particular with regard to the potentially dangerous effects of the active substance or its residues on human and animal health and on the environment shall do so, without prejudice to Article 7 of Directive 91/414/EEC, no later than 90 days after the information referred to in Article 6 is made public.

2 The rapporteur Member State shall submit without delay any information received to the Authority and the applicant.