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)

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 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

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/50/EC (OJ L 202, 3.8.2007, p. 15).
[2] OJ L 192, 31.7.2003, p. 40.
[3] OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.7.2000, p. 27).
[4] OJ L 55, 29.2.2000, p. 25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p. 32).
[5] OJ L 224, 21.8.2002, p. 23. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19).
[6] OJ L 379, 24.12.2004, p. 13. Regulation as last amended by Regulation (EC) No 1095/2007.

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:

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) for third and fourth stage substances, by 31 December 2008.

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.

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.

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.

3. The applicant may send its comments on the submitted information to the rapporteur Member State and to the Authority at the latest 60 days after receiving it.

Article 8

Assessment by the rapporteur Member State

1. Within twelve months of the date of the application provided for in Article 3(1), the rapporteur Member State shall prepare and submit to the Commission with a copy to the Authority a report (hereinafter draft assessment report) assessing whether the active substance can be expected to meet the requirements of Article 5 of Directive 91/414/EEC. It shall at the same time inform the applicant that the draft assessment report has been submitted and request him to forward the updated dossier to the Authority, the Member States and the Commission immediately.

2. The rapporteur Member State may consult the Authority.

3. Where the rapporteur Member State needs additional information, it shall set a time period for the applicant to supply it. In that case, the twelve-month period shall be extended by the additional time period granted by the rapporteur Member State. The additional time period shall be no more than six months and shall cease at the moment when the additional information is received by the rapporteur Member State. It shall inform the Commission and the Authority. In its assessment the rapporteur Member State shall only take into account information submitted within the time period granted.

4. Where at the end of the period referred to in paragraph 3, 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 missing elements which are necessary to decide on whether the substance meets the requirements of Article 5 of Directive 91/414/EEC, it shall adopt a decision providing that the active substance in question is not to be included in Annex I to that Directive and ending the assessment of that active substance under this Regulation.

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

Article 9

Receipt of and access to the draft assessment report

The Authority shall circulate the draft assessment report received from the rapporteur Member State to the applicant, the other Member States and the Commission after receiving the dossier provided for in Article 8(1).

It shall make it available to the public, after giving the applicant two weeks to request that certain parts of the draft assessment report be kept confidential.

The Authority shall allow a period of 90 days for the submission of written comments from Member States and the applicant.

Where appropriate, the Authority shall organise a peer review, including experts from the Member States.

Article 10

Conclusion by the Authority

1. The Authority shall adopt a conclusion on whether the active substance can be expected to meet the requirements of Article 5 of Directive 91/414/EEC within 90 days of the end of the period provided for in the third paragraph of Article 9 of this Regulation and communicate it to the applicant, the Member States and the Commission.

Where appropriate, the Authority shall address in its conclusion the risk mitigation options in relation to the intended uses identified in the draft assessment report.

2. Where the Authority needs additional information, it shall, in consultation with the rapporteur Member State, set a time period of maximum 90 days for the applicant to supply it to the Authority and the rapporteur Member State. In that case, the 90-day period provided for in paragraph 1 shall be extended by the additional period granted by the Authority. It shall inform the Commission and the Member States. In its conclusion the Authority shall only take into account information submitted within the time period granted.

3. The rapporteur Member State shall assess the additional information and submit it to the Authority without delay and at the latest within 60 days after the receipt of the additional information.

4. The Commission and the Authority shall agree on a schedule for the delivery of the conclusions in order to facilitate the planning of the work. The Commission and the Authority shall agree on the format in which the conclusions of the Authority are submitted.

Article 11

Presentation of a draft directive or draft decision

1. Without prejudice to any proposal it may submit with a view to amending the Annex to Council Directive 79/117/EEC [1], the Commission shall, at the latest six months after receipt of the conclusion of the Authority or information that the applicant has failed to submit the missing elements to the dossier, submit to the Committee a draft review report to be finalised at its meeting.

The applicant shall be given the possibility to submit comments on the review report within a deadline set by the Commission.

2. On the basis of the review report provided for in paragraph 1, and taking into account any comments submitted by the applicant within the deadline set by the Commission under paragraph 1, a Directive or a Decision shall be adopted in accordance with the procedure referred to in Article 19(2) of the Directive 91/414/EEC, providing that:

(a) an active substance is included in Annex I to Directive 91/414/EEC subject to conditions and restrictions, where appropriate;

(b) an active substance is not included in Annex I to that Directive.

[1] OJ L 33, 8.2.1979, p. 36.

3. The adoption of a decision under paragraph 2(b) shall end the assessment of that active substance under this Regulation.

Article 12

Access to the review report

The finalised review report, excluding any parts which refer to confidential information contained in the dossiers and determined as such in accordance with Article 14 of the Directive 91/414/EEC, shall be made available for public consultation.

CHAPTER III

ACCELERATED PROCEDURE

Article 13

Conditions for the application of accelerated procedure

Where a second, third or fourth stage substance has been the subject of a non-inclusion Decision in accordance with Article 6(1) of Directive 91/414/EEC, and a draft assessment report has been prepared, any person who had participated as notifier in the procedure leading up to that decision or any person who in agreement with the original notifier replaced him for the purposes of this Regulation, may submit an application in accordance with the accelerated procedure provided for in Articles 14 to 19 of this Regulation. Such an application must be submitted within six months from the date of publication of the non-inclusion decision as regards third and fourth stage substances, or, within six months from the date of entry into force of this Regulation as regards second stage substances.

Article 14

Application

1. The application referred to in Article 13 shall be submitted to the Member State which acted as rapporteur during the assessment procedure which ended with the adoption of the non-inclusion Decision unless another Member State informs the Commission that it is willing to carry out the evaluation in agreement with the original rapporteur Member State.

2. When submitting his application, the applicant may, pursuant to Article 14 of Directive 91/414/EEC, request certain parts of the additional data referred to in paragraph 2 of Article 15 to be kept confidential. He shall explain for each document or each part of a document why it is to be considered as confidential.

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

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

Article 15

Substantive and procedural requirements

1. The following substantive requirements shall apply:

(a) the specification of the active substance is the same as was the subject of the non-inclusion Decision. It may only be changed insofar as this is necessary, in the light of the reasons which gave rise to the non-inclusion Decision, to permit inclusion of that substance in Annex I to Directive 91/414/EEC;

(b) the supported uses are the same as those that were the subject of the non-inclusion Decision. They may only be changed insofar as this is necessary, in the light of the reasons which gave rise to the non-inclusion Decision, to permit inclusion of that substance in Annex I to Directive 91/414/EEC;

(c) it shall be for the applicant to demonstrate that the requirements in Article 5 of Directive 91/414/EEC are fulfilled.

2. With the application the applicant shall submit the following:

(a) the additional data necessary to address the specific issues that led to the adoption of the non-inclusion Decision concerned;

(b) any additional data reflecting the current scientific and technical knowledge and in particular changes to scientific and technical knowledge since the submission of the data which led to the non-inclusion decision;

(c) a supplement to the original dossier, where appropriate;

(d) a checklist demonstrating that the dossier is complete and indicating which data are new.

Article 16

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 17

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 16 is made public.

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

3. The applicant may send its comments on the submitted information to the rapporteur Member State and to the Authority at the latest 60 days after receiving it.

Article 18

Assessment by the rapporteur Member State

1. The data referred to in Article 15(2) shall be evaluated by the rapporteur Member State referred to in Article 14(1), unless that Member State agrees with another Member State that the latter will act as rapporteur. The applicant, the Commission, the Authority and the other Member States shall be informed of this agreement.

2. Within six months after the submission of the application the rapporteur Member State shall forward to the Authority and the Commission an evaluation of the additional data in a report, (hereinafter additional report), which should reflect current scientific and technical knowledge, and if necessary, information from the original dossier taking into consideration the information available on potentially dangerous effects submitted by any third party and any comments received from the applicant in accordance with Article 17(3). The additional report shall assess whether the active substance can be expected to meet the requirements of Article 5 of the Directive 91/414/EEC. The Rapporteur Member state shall at the same time inform the applicant that the additional report had been submitted and that the updated dossier should immediately be forwarded to the Authority, the Member States and the Commission.

The rapporteur Member State may consult the Authority.

3. Where the rapporteur Member State needs additional information, which shall not concern the submission of new studies, it shall set a time period for the applicant to supply it. In that case, the six months period referred to in paragraph 2 shall be extended by the additional time period granted by the rapporteur Member State. The additional time period shall be maximum 90 days and shall cease at the moment when the additional information is received by the rapporteur Member State. It shall inform the Commission and the Authority. In its assessment the rapporteur Member State shall only take into account information submitted within the time period granted.

Article 19

Access to the additional report

1. After receiving the additional report the Authority shall communicate it immediately to the other Member States and the applicant for comments. Such comments shall be sent to the Authority within 30 days of receipt of the additional report. The Authority shall collate and forward the comments to the Commission.

2. The Authority shall make the additional report available on request or keep it available for consultation by any person, except the elements thereof which have been accepted as confidential in accordance with Article 14 of the Directive 91/414/EEC.

Article 20

Evaluation

1. The Commission shall evaluate the additional report and where relevant the draft assessment report, referred to in Article 13, and the recommendation by the rapporteur Member State and the comments received within 30 days of receipt of the collated comments from the Authority.

The Commission may consult the Authority. Such consultation may, if appropriate, include a request to arrange a peer review, including experts from the Member States.

2. In cases where the Commission consults the Authority for second stage substances, the latter shall deliver its conclusion at the latest 90 days after receipt of the request by the Commission. The Authority shall deliver its conclusion report at the latest six months after the request for stage three and four substances.

For third and fourth stage substances, where the Authority needs additional information, which shall not concern the submission of new studies, it shall set a time period of maximum 90 days for the applicant to supply it to the Authority and to the rapporteur Member State. In that case, the sixth months period referred to in the previous subparagraph shall be extended by the additional period granted by the Authority.

The rapporteur Member State shall assess the additional information and submit it to the Authority without delay and at the latest within 60 days after the receipt of the additional information.

3. The Commission and the Authority shall agree on a schedule for the delivery of the conclusions in order to facilitate the planning of the work. The Commission and the Authority shall agree on the format in which the conclusions of the Authority are submitted.

Article 21

Presentation of a draft directive or draft decision

1. Without prejudice to any proposal it may submit with a view to amending the Annex to Directive 79/117/EEC, the Commission shall, at the latest six months after receipt of the information referred to in the first subparagraph of Article 20(1), or of the conclusion of the Authority or of the information that the applicant has failed to submit the missing elements to the dossier, submit to the Committee a draft review report to be finalised at its meeting.

The applicant shall be given the possibility to submit comments on the review report within a deadline set by the Commission.

2. On the basis of the review report provided for in paragraph 1, and taking into account of any comments submitted by the applicant within the deadline set by the Commission under paragraph 1, a Directive or a Decision shall be adopted in accordance with the procedure referred to in Article 19(2) of Directive 91/414/EEC, providing that:

(a) an active substance is included in Annex I to Directive 91/414/EEC subject to conditions and restrictions, where appropriate;

(b) an active substance is not included in Annex I to that Directive.

Article 22

Access to the review report

The finalised review report, excluding any parts which refer to confidential information contained in the dossiers and determined as such in accordance with Article 14 of Directive 91/414/EEC, shall be made available for public consultation.

CHAPTER IV

GENERAL PROVISIONS

Article 23

Fees

1. Member States shall establish a regime obliging the applicants to pay a fee or charge for the administrative treatment and the evaluation of additional data or the dossiers related thereto.

2. Member States shall establish a specific fee or charge for the evaluation.

3. For this purpose, the Member States shall:

(a) require the payment of a fee or charge corresponding as far as possible to their costs in carrying out all the different procedures associated with the evaluation for each submission of additional data or dossiers;

(b) ensure that the amount of the fee or charge is established in a transparent manner with a view to corresponding to the real cost of the examination and administrative handling of additional data or dossiers; however, Member States may provide for a scale of fixed charges based on average costs for the calculation of the total fee;

(c) ensure that the fee or charge is received in accordance with the instructions given by the authority in each Member State and that the income from the fee is used to finance exclusively the costs actually incurred by the rapporteur Member State for the evaluation and administrative handling of additional data or dossiers for which that Member State is rapporteur or to finance general actions for the implementation of its obligations as a Member State resulting from this regulation.

Article 24

Other charges, levies or fees

Article 23 is without prejudice to Member States rights to maintain or introduce, in accordance with the Treaty, charges, levies or fees with regard to the authorisation, placing on the market, use and control of active substances and plant protection products other than the fee provided for in that Article.

Article 25

Entry into force

This Regulation shall enter into force on the seventh 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.

Done at Brussels, 17 January 2008.

For the Commission
Markos KYPRIANOU
Member of the Commission