COMMISSION REGULATION (EU) No 188/2011

of 25 February 2011

laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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) It is necessary to adopt rules on a procedure for the submission and appraisal of applications for inclusion in Annex I to Directive 91/414/EEC of active substances which were not yet on the market 2 years after the date of notification of that Directive. In particular periods should be set for the different steps of that procedure to ensure that they are carried out rapidly.

(2) Additional information submitted after the application and the dossiers should only be taken into account if it was requested by the European Food Safety Authority, hereinafter 'the Authority', or the rapporteur Member State and submitted within the time period set.

(3) As regards applications submitted before the entry into force of this Regulation transitional measures should be provided for. In particular, it is appropriate to extend the period which may be granted to the applicant to submit additional information requested by the Authority or the rapporteur Member State. As regards such applications, it is further necessary to set periods for the circulation of the draft assessment report by the Authority and the submission of comments by the Member States, other than the rapporteur Member State, and the applicant.

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

HAS ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation lays down detailed rules for the submission and appraisal of applications for inclusion in Annex I to Directive 91/414/EEC of active substances which were not on the market on 26 July 1993.

Article 2

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 summary dossier and a complete dossier, as provided for in Article 3, or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the criteria provided for in Article 5 of that Directive.

For the purposes of this Regulation 'applicant' means the person who manufactures the active substance himself or who contracts out the manufacturing to another party or a person designated by the manufacturer as his sole representative for the purpose of compliance with this Regulation.

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.

Member States shall assess the confidentiality requests. Upon a request for access to information, the rapporteur Member State shall decide what information is to be kept confidential.

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

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

[1] OJ L 230, 19.8.1991, p. 1.

Article 3

Dossiers

1. The summary dossier shall include the following:

(a) data with respect to one or more 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 fulfilled;

(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 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 carried out the tests and studies relevant to the assessment of the criteria referred to in Article 5 of that Directive taking into account that data gaps in a dossier, as set out in Annex II or Annex III to that Directive, resulting from the proposed range of representative uses, may lead to restrictions in the inclusion in Annex I to that Directive;

(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 inclusion of the active substance concerned;

(f) an assessment of all information submitted;

(g) where relevant, a copy of an application for a residue level as referred to in Article 7 of Regulation (EC) No 396/2005 of the European Parliament and of the Council [1] or a justification for not supplying such copy of an application.

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 with a list of those tests and studies.

Article 4

Completeness check of the dossiers

1. Within 3 months from receiving the application, the rapporteur Member State shall check whether the dossiers submitted with the application contain all the elements provided for in Article 3, using the checklist referred to in Article 3(1)(d). It shall also check the requests for confidentiality referred to in Article 2(2) and the list of tests and studies submitted pursuant to Article 3(2).

2. Where one or more of the elements provided for in Article 3 are missing, the rapporteur Member State shall inform the applicant, setting a time period for their submission; such time period shall be no more than 3 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 that the application is rejected.

4. 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 European Food Safety Authority, hereinafter 'the Authority', of the completeness of the application. After receiving that notification, the applicant shall immediately forward those dossiers to the other Member States, the Commission and the Authority, including the information about those parts of the dossiers in respect of which confidentiality has been requested as referred to in Article 2(2).

5. Within 4 months from the date of receipt of the notification referred to in paragraph 4, a decision shall be adopted in accordance with Article 6(3) of Directive 91/414/EEC establishing that the dossiers submitted fulfil the requirements of Annexes II and III to that Directive, hereinafter 'completeness decision'.

Article 5

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 3 months after a completeness decision for the active substance concerned has been published.

2. The rapporteur Member State shall immediately communicate any information received from third parties to the Authority and the applicant.

3. The applicant may submit its comments on the information referred to in paragraph 2 to the rapporteur Member State and to the Authority at the latest 2 months after receiving that information.

[1] OJ L 70, 16.3.2005, p. 1.

Article 6

Assessment by the rapporteur Member State

1. Within 12 months from the date of publication of the completeness decision, the rapporteur Member State shall prepare and submit to the Commission, with a copy to the Authority, a report assessing whether the active substance can be expected to fulfil the conditions provided for in Article 5 of Directive 91/414/EEC, hereinafter referred to as 'draft assessment report'. It shall at the same time inform the applicant that the draft assessment report has been submitted and request him to immediately forward to the Authority, the other Member States and the Commission the updated dossiers, where applicable.

2. The rapporteur Member State may consult the Authority.

3. Where the rapporteur Member State needs additional information, it shall request it from the applicant setting a period of up to 6 months for it to be supplied. The rapporteur Member State shall inform the Commission and the Authority. In its assessment the rapporteur Member State shall only take into account information which was requested and submitted within the period granted.

In cases where the rapporteur Member State requests additional information, the 12-month period provided for in paragraph 1 for the submission of the draft assessment report shall be extended by the period granted by the rapporteur Member State for the submission of the additional information. If the requested information is submitted to the rapporteur Member State before the end of the period granted the extension shall correspond to the part of that period actually used.

4. Where at the end of the period referred to in the first subparagraph of paragraph 3, the applicant has not submitted all of the additional information requested in accordance with paragraph 1, the rapporteur Member State shall inform the applicant, the Commission, the other Member States and the Authority and shall state the missing elements in the draft assessment report.

5. If, after giving the applicant an opportunity to comment, the Commission determines that the applicant has failed to submit elements necessary for the assessment referred to in paragraph 1, it shall adopt a decision in accordance with Article 9(2)(b), providing that the active substance concerned is not to be included in Annex I to Directive 91/414/EEC.

Article 7

Circulation of and access to the draft assessment report

1. The Authority shall circulate the draft assessment report received from the rapporteur Member State to the applicant and the other Member States within 30 days from its receipt. Where within this 30-day period the Authority does not receive the dossier provided for in Article 6(1) it shall circulate that report as soon as it receives that dossier.

The period for the submission of written comments to the Authority from Member States and the applicant shall be 2 months.

2. The Authority shall make the draft assessment report available to the public, excluding any information in respect of which confidential treatment has been requested and justified by the applicant in accordance with Article 14 of Directive 91/414/EEC.

It shall grant a period of 2 weeks to the applicant to request confidential treatment.

Article 8

Conclusion by the Authority

1. Within 4 months from the end of the period provided for the submission of written comments, the Authority shall adopt a conclusion on whether the active substance can be expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC and shall communicate it to the applicant, the Member States and the Commission and shall make it available to the public.

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

2. The Authority shall, where appropriate, organise a consultation of experts, including experts from the rapporteur Member State.

In that case the 4-month period for the adoption of the conclusion, as set out in paragraph 1, shall be extended by 2 months.

3. Where the Authority needs additional information, it shall, in consultation with the rapporteur Member State, set a period of a maximum of 3 months for the applicant to submit that information to the Member States, the Commission and the Authority. It shall inform the applicant, the Commission and the Member States. In respect of applications for which a completeness decision was published by 31 December 2005, the maximum period shall be 5 months.

4. Within 2 months after receipt of the additional information the rapporteur Member State shall assess that information and submit an addendum to the draft assessment report to the Authority. In respect of applications for which a completeness decision was published by 31 December 2005, that period shall be 3 months.

5. Where the Authority requests additional information in accordance with paragraph 3, the period from the date of that request to the date of the submission of the addendum to the draft assessment report shall not be taken into account for the calculation of the period for the adoption of the conclusion, as provided for in paragraphs 1 and 2.

6. In its conclusion the Authority shall only take into account additional information requested by it or by the rapporteur Member State and submitted within the period granted.

7. The Authority shall establish the format for its conclusion which shall include details concerning the appraisal procedure and the properties of the active substance concerned.

Article 9

Presentation of a draft act

1. The Commission shall, at the latest 6 months after receipt of the conclusion of the Authority, submit to the Standing Committee on the Food Chain and Animal Health, hereinafter 'the Committee', a draft review report to be finalised at its meeting.

The applicant shall be given the possibility to submit comments on the draft review report within a period, of up to 30 days, set by the Commission.

2. On the basis of the draft review report and taking into account any comments submitted by the applicant within the period set by the Commission in accordance with paragraph 1, an act 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 10

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 to the public.

Article 11

Transitional measures

1. Articles 2, 3 and Article 4(1) shall not apply to applications for inclusion of active substances in Annex I to Directive 91/414/EEC for which the application was received by the rapporteur Member State by 17 March 2011 but for which no completeness check had been made by that date.

For such applications the rapporteur Member State shall perform the completeness check provided for in Article 4(1) by 18 June 2011 at the latest.

2. Articles 2, 3 and 4 shall not apply to applications for inclusion of active substances in Annex I to Directive 91/414/EEC for which the dossier was referred to the Committee in accordance with Article 6(2) of that Directive by 17 March 2011 but for which no completeness decision had been adopted by that date.

For such applications a completeness decision shall be adopted in accordance with Article 6(3) of Directive 91/414/EEC by 18 July 2011.

3. Articles 2, 3 and 4 shall not apply to applications for inclusion of active substances in Annex I to Directive 91/414/EEC for which a completeness decision was adopted but not published by 17 March 2011.

4. Articles 2 to 6 shall not apply to applications for inclusion of active substances in Annex I to Directive 91/414/EEC for which a completeness decision was published by 17 March 2011 but no draft assessment report had been submitted to the Commission by that date.

For such applications the rapporteur Member State shall prepare and submit the draft assessment report to the Commission, with a copy to the Authority by 18 March 2012. It shall at the same time inform the applicant that the draft assessment report has been submitted and request him to immediately forward to the Authority, the other Member States and the Commission the updated dossiers, where applicable. Article 6(2) to (5) shall apply *mutatis mutandis*.

5. Articles 2 to 6 and the first subparagraph of Article 7(1) shall not apply to applications for which the draft assessment report had been received by the Authority but not circulated to the applicant and the other Member States for comments by 17 March 2011.

6. By way of derogation from paragraph 5, for applications for which the draft assessment report had been submitted to the Commission and the Authority by 31 December 2009 at the latest, Articles 2 to 6 and the first subparagraph of Article 7(1) shall not apply. In such cases, the following procedure shall apply.

By 18 April 2011, the rapporteur Member State shall request the applicant to inform that Member State and the Authority, within 1 month, in case the applicant considers that information that had not been submitted for the preparation of the draft assessment report and that might influence the outcome of the assessment, is available, specifying the nature of that information and its possible influence on the assessment.

Within 2 months from receiving the reply of the applicant, the Authority shall decide whether that information might influence the outcome of the assessment. If so, the Authority shall, without undue delay, ask the rapporteur Member State to request the submission of that information by the applicant. The rapporteur Member State shall update the draft assessment report where appropriate in the light of that information.

The Authority shall set a period of up to 6 months for the rapporteur Member State to prepare and submit to the Commission that updated draft assessment report, with a copy to the Authority. It shall at the same time inform the applicant that the draft assessment report has been submitted and request him to immediately forward to the Authority, the other Member States and the Commission the updated dossiers, where applicable. Article 6(2) to (5) shall apply *mutatis mutandis*, whereby the period referred to in the first subparagraph of Article 6(3) shall not exceed 3 months.

7. The Commission shall set, and publish on its website, the dates for the circulation of the draft assessment reports referred to in paragraphs 5 and 6. Where a draft assessment report has been updated, as provided for in paragraph 6, it shall be circulated as updated. The Commission shall at the same time set, and publish on its website, the dates for the submission of comments thereon.

Article 12

Fees

1. Member States may recover the costs associated with any work they carry out within the scope of this Regulation, by means of fees or charges.

2. Member States shall ensure that the fees or charges referred to in paragraph 1:

(a) are established in a transparent manner; and

(b) correspond to the actual total cost of the work involved except if it is in public interest to lower the fees and charges.

Article 13

Other charges, levies or fees

Article 12 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 14

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.

Done at Brussels, 25 February 2011.

For the Commission
The President
José Manuel BARROSO