Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (Text with EEA relevance)

COMMISSION REGULATION (EU) No 1141/2010

of 7 December 2010

laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances

(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) Directive 91/414/EEC provides that, on request, the inclusion of an active substance may be renewed.

(2) The Commission has received letters from several producers requesting a renewal for active substances included in Annex I to Directive 91/414/EEC and for which the inclusion period is to expire in 2011 and 2012.

(3) It is necessary to provide for a procedure for the submission and appraisal of applications for the renewal of the inclusion in Annex I to Directive 91/414/EEC of those active substances.

(4) Periods should be set for the different steps of that procedure to ensure that they are carried out rapidly.

(5) Producers wishing to secure the renewal of active substances covered by this Regulation should be required to apply to the relevant rapporteur Member State.

(6) Where two or more applications for the same active substance have been submitted separately and fulfil the requirements, the rapporteur Member States should communicate the updated contact details of each applicant to the other applicants to facilitate the submission of joint dossiers and to avoid, whenever possible, duplication of studies involving vertebrate animals.

(7) In order to ensure the efficiency of renewal procedures, rapporteur Member States should organise, prior to the submission of the dossiers, a meeting to discuss the state of the art of the active substance and consider whether and, if necessary, how the dossiers submitted for the first inclusion are to be updated.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. 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*

(8) The dossiers submitted for renewal should include new data relevant to the active substance and new risk assessments to reflect any changes in data requirements and any changes in scientific or technical knowledge since the active substance was first included in Annex I to Directive 91/414/EEC, as reflected in guidance documents published by the Commission and in relevant opinions from the Scientific Committee on Plants or the European Food Safety Authority (hereinafter 'the Authority'). The range of uses submitted should reflect the representative uses. The applicant should demonstrate, on the basis of the data submitted, that for one or more preparations the requirements of Article 5 of Directive 91/414/EEC will be fulfilled.

(9) The applicants should list separately vertebrate studies to be submitted with the dossier and the rapporteur Member States should make such lists available on request to promote early discussions on the sharing of vertebrates data to avoid duplication of vertebrate studies.

(10) Technical or scientific information about an active substance, in particular with regard to potentially dangerous effects, submitted within the relevant period by third parties should be taken into consideration in the evaluations. The applicants should be given the opportunity to comment on such information.

(11) The renewal assessment reports prepared by the rapporteur Member States may, where necessary, be the subject of a consultation of experts organised by the Authority on request of the Commission before they are submitted to the Standing Committee on the Food Chain and Animal Health.

(12) The rules on data protection of Article 13 of Directive 91/414/EEC are intended to provide an incentive to applicants to assemble the detailed studies required under Annexes II and III to that Directive. However, data protection should not be extended artificially by the production of new studies which are not needed to decide on the renewal of an active substance. To this end, applicants should be required to identify explicitly which studies are new compared to the original dossier used for the first inclusion of the substance in Annex I to Directive 91/414/EC and to provide justification for their submission.

(13) In view of the particular situation, where parts of the renewal procedure still take place while Directive 91/414/EEC applies while the decisions on the renewals will be taken under Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[(2)], applicants are encouraged, as regards the format of the updating statement and the format and content of the dossier, to pay particular attention to the specific guidance documents published by the Commission.

(14) 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:

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Article 1

Scope

This Regulation lays down the procedure for the renewal of the inclusion in Annex I to Directive 91/414/EEC of the active substances listed in Annex I to this Regulation.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

(a) 'producer' means the person who manufactures the active substance on his own 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;

(b) 'applicant' means a producer who applies for the renewal of the inclusion of an active substance referred to in column A of Annex I;

(c) 'rapporteur Member State' means the Member State which evaluates an active substance, as listed in column B of Annex I for the respective active substance;

(d) 'co-rapporteur Member State' means a Member State which cooperates in the evaluation carried out by the rapporteur Member State, as listed in column C of Annex I for the respective active substance;

(e) 'inclusion' means inclusion of an active substance in Annex I to Directive 91/414/EEC;

(f) 'renewal' means renewal of the inclusion of an active substance in Annex I to Directive 91/414/EEC.

Article 3

Coordinating authority of the Member State

Each Member State shall appoint an authority, hereinafter 'the coordinating authority', which coordinates and ensures contacts with applicants, other Member States, the Commission and the European Food Safety Authority, hereinafter 'the Authority', in accordance with this Regulation. Each Member State shall communicate the name and the contact details of its coordinating authority and any modifications to the Commission.

The Commission shall publish a list including the names and the contact details of the coordinating authorities of the Member States. It shall keep that list updated according to the modifications communicated to it.

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Article 4

Submission of application

1 A producer wishing to renew the inclusion in Annex I to Directive 91/414/EEC of an active substance referred to in column A of Annex I to this Regulation, or any variants thereof, shall, for each active substance separately, submit an application to the rapporteur Member State and to the co-rapporteur Member State by 28 March 2011 at the latest.

2 When submitting an application, the applicant may, pursuant to Article 14 of Directive 91/414/EEC, request certain parts of the information to be kept confidential. It shall present such parts of the application separately, setting out the reasons for requesting confidentiality.

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

3 The applicant shall send a copy of the application, without the updating statement referred to in Article 5(2), to the Commission and to the Authority.

4 Where several producers wish to renew the inclusion of the same active substance in Annex I to Directive 91/414/EEC, a joint application may be submitted by a joint representative.

5 Where applicable, a fee, as referred to in Article 19, shall be paid upon submission of an application.

Article 5

Format and content of application

1 An application shall be submitted in the format set out in Annex II.

2 The application shall state which sections of the dossiers submitted for the first inclusion of the active substance require updating with new information.

Hereinafter, that part of the application is referred to as ‘the updating statement’.

3 The updating statement shall list the new information the applicant intends to submit and demonstrate that such information is necessary, because of data requirements or criteria which were not applicable at the time of the first inclusion of the active substance or because of changes in the representative uses or because the application is for an amended renewal.

The updating statement shall separately list new studies the applicant intends to submit on vertebrate animals.

4 Upon request from any interested party, the rapporteur Member State shall make available the information listed by the applicant as referred to in paragraph 3.

Article 6

Checking of application

1 Within 1 month of receipt of the application, the rapporteur Member State shall check whether the application fulfils the requirements of Articles 4 and 5.

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2 Where the rapporteur Member State considers that the application fulfils the requirements of Articles 4 and 5, it shall, within the period of 1 month provided for in paragraph 1, inform the applicant, the Commission and the Authority of the date of receipt and that the application fulfils the requirements.

3 Where the rapporteur Member State considers that the application does not fulfil the requirements of Articles 4 and 5, it shall, within the period of 1 month provided for in paragraph 1, inform the applicant of the date of receipt and explain which requirements have not been fulfilled. It shall at the same time set the applicant a period of 14 days to render the application compliant. That period shall extend the period of 1 month provided for in paragraph 1. Where, at the end of the period set for rendering the application compliant, the rapporteur Member States considers that the application fulfils the requirements of Articles 4 and 5, paragraph 2 shall apply.

Where, at the end of the period set for rendering the application compliant, the rapporteur Member States considers that the application still does not fulfil the requirements of Articles 4 and 5, it shall, stating its reasons, immediately so inform the applicant, the Commission and the Authority.

Upon receiving the communication from the rapporteur Member State, the Commission shall, taking into account the view of the rapporteur Member State, decide whether the application fulfils the requirements of Articles 4 and 5 and inform the rapporteur Member State, the other Member States and the Authority of its decision. The rapporteur Member State shall immediately inform the applicant of that decision.

4 Where for an active substance no application fulfils the requirements of Articles 4 and 5, in accordance with Directive 91/414/EEC, the active substance shall be removed from Annex I to that Directive. Its non-inclusion and the withdrawal of the authorisations of plant-protection products containing that active substance shall be provided for.

5 Where two or more applications for the same active substance have been submitted separately and each is considered to fulfil the requirements of Articles 4 and 5, the rapporteur Member State shall communicate the contact details of each applicant to the other applicants.

6 The Commission shall publish, for each active substance, the names and the addresses of the applicants whose applications are considered to fulfil the requirements of Articles 4 and 5.

Article 7

Pre-submission contacts

Where an application fulfils the requirements of Articles 4 and 5, the applicant may request a meeting with the rapporteur Member State and the co-rapporteur Member State to discuss the updating statement. If requested, such pre-submission contacts shall take place prior to the submission of supplementary dossiers, as provided for in Article 9.

Article 8

Access to the application

Upon request from any interested party, the rapporteur Member State shall make available the application, excluding any information for which confidential treatment has been requested and is justified pursuant to Article 14 of Directive 91/414/EEC.