Commission Regulation (EC) No 737/2007 of 27 June 2007 on laying down the procedure for the renewal of the inclusion of a first 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 (EC) No 737/2007

of 27 June 2007

on laying down the procedure for the renewal of the inclusion of a first 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 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 Articles 6(1) and (5) thereof,

Whereas:

(1) Directive 91/414/EEC provides that on request, the inclusion of a substance can be renewed once or more for a period not exceeding 10 years.

(2) The Commission has received a request from certain producers requesting a renewal for the seven active substances first included in Annex I of Directive 91/414/EEC.

(3) A procedure should be provided for by which all interested producers have the right to inform the Commission of their interest in securing the inclusion of an active substance in Annex I to Directive 91/414/EEC

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

(5) The names and addresses of the producers whose notification has been found admissible should be published by the Commission in order to ensure that contacts can be made for presenting joint dossiers.

(6) The relationship between producers, Member States, the European Food Safety Authority, hereinafter the 'Authority', and the Commission and the obligation on each of the parties for the implementation of the procedure should be laid down.

(7) Technical or scientific information about an active substance, in particular with regard to its potentially dangerous effects or its residues, submitted within the relevant time limits by any other interested parties should be taken into consideration in the evaluations.

(8) The information submitted should include new data relevant to the active substance and new risk assessments to reflect any changes in data requirements under Annexes II and III to Directive 91/414/EEC, and any changes in scientific or technical knowledge since

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the active substance was first included in Annex I to Directive 91/414/EEC, as reflected in guidance documents from the Commission's services and relevant opinions from the Scientific Committee on Plants (SCP) or the Authority. The range of uses submitted should reflect the representative use pattern. The producer should demonstrate, on the basis of the data submitted, that for one or more preparations the requirements of Directive 91/414/EEC in relation to the criteria referred to in its Article 5 can be met.

(9) It should be established that rapporteur Member States should send reports of their evaluations to the Authority and the Commission as quickly as possible.

(10) The assessment reports prepared by the rapporteur Member States may, where necessary, be the subject of an examination by experts of other Member States within a programme coordinated by the Authority before they are submitted to the Standing Committee on the Food Chain and Animal Health.

(11) The rules on data protection under Article 13 of Directive 91/414/EEC are intended to provide an incentive to notifiers 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, notifiers 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/EEC.

(12) 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 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

Definition

For the purposes of this Regulation:

(a) 'producer' 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 the Directive 91/414/EEC;

(c) 'Notifier' has the meaning given by Article 4(1) of this Regulation;

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(d) 'Original dossier', in relation to an active substance, means the dossier on the basis of which the active substance was included in Annex I to Directive 91/414/EEC.

Article 3

Designated Member State authority

1 Each Member State shall designate an authority or authorities to carry out the obligations of the Member States as defined in this Regulation.

2 The national authorities listed in Annex II shall coordinate and ensure all necessary contacts with notifiers, other Member States, the Commission and the Authority, in accordance with this Regulation.

Each Member State shall communicate modifications concerning the designated national coordinating authority to the Commission, the Authority and the designated coordinating authority of the other Member States.

Article 4

Notification

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 such as salts, esters or amines, shall send a notification, for each active substance separately, to the rapporteur Member State listed in column B of that Annex and to the co-rapporteur Member State listed in column C of that Annex by 6 October 2007 at the latest, using the model in Annex III. Such a producer is referred to hereinafter as 'the notifier'.

A copy of the notification shall be sent to the Commission.

2 A joint notification may be submitted by an association of producers designated by the producers for the purpose of compliance with this Regulation.

3 A producer who has not submitted a notification for the active substance concerned by 6 October 2007 at the latest or whose notification was rejected as inadmissible, shall not participate in the rest of the procedure, except together with another producer who has submitted an admissible notification.

Article 5

Admissibility of notifications and publication data concerning notifiers

1 For each active substance the rapporteur Member State shall examine the notifications referred to in Article 4(1) and, at the latest one month after the date referred to in that paragraph, assess the admissibility of the notifications received, taking into account the criteria referred to in Annex IV. It shall communicate its assessment to the Commission, which shall decide which notifications are admissible, taking account of the rapporteur Member State's assessment.

2 The Commission shall publish, for each active substance, the names and the addresses of the notifiers concerned.

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Article 6

Submission of data

1 By 31 August 2008 at the latest, the notifiers concerned shall submit the following to the rapporteur Member State and the co-rapporteur Member State:

a a copy of the notification and, in the case of a joint notification in accordance with Article 4(2), the name of the person designated by the producers concerned as being responsible for the joint dossier and the processing of the dossier in accordance with this Regulation;

b any new data compared to the original dossier relevant to the active substance and any new risk assessments to reflect changes in data requirements under Annexes II and III to Directive 91/414/EEC, or any changes in scientific and technical knowledge since the active substance concerned was first included in Annex I to Directive 91/414/EEC;

c a checklist demonstrating that the dossier is complete, indicating which data are new.

2 Where the dossier contains studies which are more recent than those found in the original dossier, the notifier must explain for each new study why it is relevant.

3 The range of uses submitted should reflect a representative use pattern. The data submitted by the notifier shall demonstrate that, for one or more preparations, the active substance meets the requirements set out in Article 5(1) of Directive 91/414/EEC.

4 Where for an active substance listed in Annex I there are several notifications, the notifiers concerned shall take all reasonable steps to submit the data collectively. Where the data are not submitted jointly by all notifiers concerned, the notification shall mention the efforts made and the reasons why certain notifiers have not participated. For active substances notified by more than one notifier, those notifiers shall for each study involving vertebrate animals, give detailed explanation on the attempts made to avoid duplication of testing and give, if applicable, the reasons and a justification for conducting a duplicate study.

5 If requested by the Authority or a Member State, the notifier shall make available the original dossier and subsequent updates submitted for the first inclusion in Annex I to Directive 91/414/EEC.

Article 7

Subsequent submission

1 Without prejudice to Article 7 of Directive 91/414/EEC, the rapporteur Member State shall not accept the submission of additional information after 31 August 2008.

2 By way of derogation from paragraph 1, the rapporteur Member State may request additional information setting a time period for its submission ending on 31 March 2009 at the latest. The rapporteur Member State shall inform the Commission and the Authority of any such request it makes.

Information which has not been requested, or which has not been submitted before 31 March 2009, shall not be taken into account.

3 The rapporteur Member State shall inform the Commission and the Authority of cases where it receives information from the notifier, which it is required not to take into account under the provisions of this article.

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Article 8

End of participation

1 When a notifier decides to end its participation in the renewal procedure for an active substance, he shall inform the rapporteur Member State, co-rapporteur Member State, the Commission and the other notifiers for the substance concerned, mentioning the reasons.

Where a notifier ends his participation or fails to fulfil his obligations provided for in this Regulation, the procedures provided for in Articles 10 to 14 shall not be continued for his dossier. In particular, where a notifier does not submit, where requested, the dossier referred to in Article 6(5), his participation will be considered to have ended.

2 When a notifier agrees with another producer that the notifier shall be replaced for the purposes of further participation in the renewal procedure, the notifier and the other producer shall inform the rapporteur Member State, co-rapporteur Member State and the Commission by a common declaration, agreeing that the other producer shall replace the notifier in carrying out the duties under this Regulation. They shall inform any other notifiers for the substance concerned at the same time. In such a case, the other producer may be liable for any fees remaining payable under the regime established by the rapporteur Member State pursuant to Article 15.

Article 9

Submission of information by third parties

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 by 31 May 2008 at the latest.

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

The notifier may send its comments on the submitted information to the rapporteur Member State at the latest by 31 August 2008.

Article 10

Assessment by the rapporteur Member State

1 The rapporteur Member State shall assess the new data and risk assessments submitted under Article 6(1), 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 notifier in accordance with Article 9.

The rapporteur Member State shall prepare an assessment report in consultation with the co-rapporteur Member State, setting out, where relevant, the points on which the co-rapporteur Member State did not agree.