

**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 <sup>(1)</sup>, 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 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,

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/31/EC (OJ L 140, 1.6.2007, p. 44).

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;
- (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.

#### 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.

#### 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.

The report shall include a recommendation concerning the decision to be taken with regard to the renewal. The report shall also assess whether the new studies identified under Article 6(2) are relevant for the evaluation.

The rapporteur Member State shall send the assessment report to the Authority and the Commission by 31 May 2009 at the latest. The report shall be submitted in the format defined in accordance with the procedure referred to in Article 19(2) of Directive 91/414/EEC.

2. The rapporteur Member State may consult the Authority and request additional technical or scientific information from other Member States.

#### Article 11

##### Access to the assessment report

1. After receiving the assessment report the Authority shall communicate it to the other Member States and notifier(s) for comments. Such comments shall be sent to the Authority, which shall collate them and forward them to the Commission.

2. The Authority shall make the assessment 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 Directive 91/414/EEC.

#### Article 12

##### Evaluation of the assessment report

1. The Commission shall evaluate the assessment report and the recommendation by the rapporteur Member State and the comments received.

The Commission may consult the Authority. Such consultation may, if appropriate, include a request to arrange a peer review of the rapporteur Member State's assessment report, to take the form of a conclusion on that report.

2. In cases where the Commission consults the Authority, the Authority shall deliver its response at the latest six months after receipt of that report.

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 13

##### 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<sup>(1)</sup>, the Commission shall, at the latest six months after receipt of the assessment report or the conclusion of the Authority, submit to the Committee a draft review report to be finalised at its meeting.

That report shall be accompanied by one of the following:

(a) a draft directive to renew the inclusion of the active substance concerned in Annex I to Directive 91/414/EEC, setting out, where appropriate, the conditions and restrictions, including the period, for such inclusion; or

(b) a draft decision addressed to the Member States to withdraw the authorisations of plant protection products containing the active substance concerned, whereby the inclusion of that active substance in Annex I to Directive 91/414/EEC is not renewed, setting out the reasons for the non-inclusion.

2. The directive or decision referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 19(2) of Directive 91/414/EEC.

#### Article 14

##### Access to 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.

#### Article 15

##### Fees

1. Member States shall establish a regime obliging the notifiers to pay a fee for the administrative treatment and the evaluation of notifications as well as the dossiers related thereto, which have been submitted to them in accordance with Article 4 or Article 6 in each case where the Member State has been designated as the rapporteur Member State or co-rapporteur Member State.

2. Member States shall establish a specific fee for the evaluation of the notification.

<sup>(1)</sup> OJ L 33, 8.2.1979, p. 36.

3. For this purpose, the Member States and co-rapporteur Member States shall:

- (a) require the payment of a fee corresponding as far as possible to their costs in carrying out all the different procedures associated with the evaluation for each submission of a dossier, whether introduced by one notifier or collectively by several interested notifiers;
- (b) ensure that the amount of the fee is established in a transparent manner with a view to corresponding to the real cost of the examination and administrative treatment of a notification and a dossier; 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 is received in accordance with the instructions given by the authority in each Member State listed in Annex II and that the income from the fee is used to finance exclusively the costs actually incurred by the rapporteur Member State and co-rapporteur Member State for the evaluation and administrative treatment of the noti-

fications and the dossiers for which that Member State is rapporteur or co-rapporteur Member State or to finance general actions for the implementation of its obligations as rapporteur Member State and co-rapporteur Member State.

#### *Article 16*

#### **Other charges, levies or fees**

Article 15 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 Article 15.

#### *Article 17*

#### **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, 27 June 2007.

*For the Commission*  
Markos KYPRIANOU  
*Member of the Commission*

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## ANNEX I

**List of active substances referred to in Article 1 and their rapporteur Member States and co-rapporteur Member States**

A. Active substance	B. Rapporteur Member State	C. Co-rapporteur Member State
azoxystrobin	United Kingdom	Czech Republic
imazalil	The Netherlands	Spain
kresoxim-methyl	Belgium	Lithuania
spiroxamin	Germany	Hungary
azimsulfuron	Sweden	Slovenia
prohexadion-calcium	France	Slovakia
fluroxypyr	Ireland	Poland

## ANNEX II

## Coordinating authority in the Member States

## BELGIUM

Service Public Fédéral Santé publique, Sécurité de la chaîne alimentaire et Environnement, Eurostation  
Bloc II, 7<sup>e</sup> étage  
Place Victor Horta 40 boîte 10  
1060 Bruxelles  
Belgium

## CZECH REPUBLIC

State Phytosanitary Administration  
Section PPP  
Zemědělská 1a  
613 00 BRNO  
Czech Republic

## GERMANY

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) — Abteilung Pflanzenschutzmittel  
Messeweg 11—12  
38104 Braunschweig  
Germany

## IRELAND

Pesticide Control Service  
Department of Agriculture and Food  
Backweston Campus  
Youngs Cross  
Celbridge  
Co. Kildare  
Ireland

## SPAIN

Ministerio de Agricultura, PESCA y Alimentación  
Dirección General de Agricultura  
Subdirección General de Medios de Producción Agrícolas  
c/Alfonso XII, 62  
ES-28071 Madrid  
Spain

## FRANCE

Ministère de l'agriculture et de la pêche  
Bureau de la réglementation des produits antiparasitaires  
251, rue de Vaugirard  
F-75732 Paris Cedex 15  
France

## LITHUANIA

State Plant Protection Service  
Kalvarijų str. 62  
09304 Vilnius  
Lithuania

## HUNGARY

Central Agricultural Office  
Directorate of Plant Protection, Soil Conservation and Agri-environment  
Budaörsi út 141-145  
H-1118 Budapest  
Hungary

## THE NETHERLANDS

College voor de Toelating van Bestrijdingsmiddelen  
Postbus 217  
6700 AE Wageningen  
The Netherlands

## POLAND

Ministerstwo Rolnictwa i Rozwoju Wsi  
Departament Hodowli i Ochrony Roślin  
ul. Wspólna 30  
00-930 Warszawa  
Poland

## SLOVENIA

Ministry Of Agriculture Forestry and Food  
PHYTOSANITARY ADMINISTRATION REPUBLIC OF SLOVENIA  
Einspielerjeva 6  
SI-1000 Ljubljana  
Slovenia

## SLOVAKIA

Central Controlling and Testing Institute in Agriculture  
Department of Registration of Pesticides  
Matuskova 21  
833 16 Bratislava  
Slovakia

## SWEDEN

Kemikalieinspektionen  
P. O. Box 2  
172 13 Sundbyberg  
Sweden

## UNITED KINGDOM

Pesticides Safety Directorate  
Mallard House  
Kings Pool  
3 Peasholme Green,  
York YO1 7PX  
United Kingdom

## ANNEX III

**Notification of an active substance according to Article 4**

The notification shall be made on paper and sent by registered mail to European Commission, DG Health and Consumer Protection, unit E3, B-1049 Brussels,

The notification shall be submitted in accordance with the following model.

## MODEL

**1. Identification data on the notifier**

1.1. Name and address of the producer including the name of the natural person responsible for the notification and further engagements resulting from this Regulation:

1.1.1. (a) Telephone No:

(b) Fax No:

(c) E-mail address:

1.1.2. (a) Contact:

(b) Alternative:

**2. Information to ensure identification**

2.1. Common name (proposed or ISO-accepted) specifying, where relevant, any variants thereof such as salts, esters or amines produced by the manufacturer:

2.2. Chemical name (IUPAC and CAS nomenclature):

2.3. CAS, CIPAC and EEC numbers (if available):

2.4. Empirical and structural formula, molecular mass:

2.5. Specification of purity of the active substance in g/kg or g/l as appropriate:

2.6. Classification and labelling of the active substance in accordance with the provisions of Council Directive 67/548/EEC <sup>(1)</sup> (health and environment effects).

The notifier confirms that the above information submitted on ... (date) is honest and correct.

Signature (of the person competent to act for the company mentioned under 1.1).

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<sup>(1)</sup> OJ 196, 16.8.1967, p. 13. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850), as corrected by OJ L 136, 29.5.2007, p. 281.

## ANNEX IV

**Criteria for the admissibility of notifications referred to in Article 4**

A notification shall only be considered admissible if the following conditions are satisfied:

1. it is presented within the time limit referred to in Article 4(1);
  2. it is introduced by a notifier who is a producer of an active substance listed in Annex I;
  3. it is presented in the format as provided for in Annex III;
  4. a fee as referred to in Article 5 has been paid.
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