Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC (Text with EEA relevance)

COMMISSION REGULATION (EC) No 2229/2004

of 3 December 2004

laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC

(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 the second subparagraph of Article 8(2) thereof,

Whereas:

(1) Directive 91/414/EEC provides for the Commission to undertake a programme of work within a period of 12 years (the programme of work) following the notification of that Directive for the gradual examination of active substances on the market two years after the date of notification of that Directive.

(2) 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[(2)] provides for the first stage of the programme of work and is still ongoing.

(3) 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[(3)] provides for the second stage of the programme of works and is also ongoing.

(4) Regulation (EC) No 451/2000 also provides for a third stage of the programme of works for an additional number of active substances not covered by the first and second stages of the programme. Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2002[(4)] also provides for the third stage of the programme of works. The third stage is also ongoing.

(5) Commission Regulation (EC) No 1112/2002 of 20 June 2002 laying down the detailed rules for the implementation of the fourth stage of the programme of work referred to

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in Article 8(2) of Council Directive 91/414/EEC[5] provides for the fourth stage of work and is ongoing. Producers wishing to support the inclusion of the active substances covered by that stage in Annex I to Directive 91/414/EEC have undertaken to provide the necessary information.

(6) By reason of the accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, it is necessary to provide the opportunity for producers in those new Member States to notify their interest to participate in stage four of the programme of work for all substances covered under that stage. It is also appropriate to organise the review of substances that were on the market in a new Member State before 1 May 2004 and which are not included in stages one to four of the programme of work.

(7) The procedures established in this Regulation should not prejudice procedures and actions to be undertaken in the framework of other Community legislation, in particular under Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances[6], where information becomes available to the Commission showing that its requirements may be satisfied.

(8) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[7] created the European Food Safety Authority (EFSA) to ensure that the Community has access to high-quality, independent and efficient scientific and technical support in order to achieve a high level of health protection in relation to legislation concerning safety of food and feed. It is therefore appropriate to provide that the EFSA should have a role in the programme of work on active substances.

(9) The relationships between producers, Member States, the Commission and the EFSA and the obligations on each of them for the implementation of the programme of work should be laid down, taking into account experience gained during the first and second stages of the programme of work, the objective of separating risk assessment from risk management and the need to organise the work in the most efficient way.

(10) Close cooperation between producers, Member States, the Commission and the EFSA and a scrupulous respect of time limits laid down is necessary to ensure the efficiency of the programme of work. Strict time limits for all elements of the fourth stage of that programme should be set in order to ensure its finalisation within an acceptable time period. For certain active substances where the dossier requirements are limited, a short deadline for submission of the dossier is appropriate in order to allow the opportunity for further information to be provided within the overall time-frame for completion of the review programme.

(11) In order to avoid duplication of work, and in particular experiments involving vertebrate animals, producers should be encouraged to submit collective dossiers.

(12) It is necessary to define the obligations of producers with regard to the formats, time periods and national authorities and the EFSA for the information to be submitted. Many

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of the active substances covered by stage four of the programme of work are produced in small volume for specialist purposes. Some are important in organic or other low input farming systems and may be expected to constitute a low risk in terms of human and environmental protection.

(13) The Commission identified in its progress Report to the European Parliament and the Council — Evaluation of the active substances of plant protection products (submitted in accordance with Article 8(2) of Council Directive 91/414/EEC on the placing of plant protection products on the market)[8] the need for special measures to be adopted in relation to low-risk compounds.

(14) A modified approach is required for this stage of the programme of work to reduce the risk that large numbers of active substances will be withdrawn for economic reasons alone. For certain groups of active substances it is, therefore, appropriate that the format and requirements for the information to be submitted are different from those developed for active substances in the previous three stages of the programme of work.

(15) In the interests of consistency of Community legislation it is necessary to ensure that the measures provided for in this Regulation are coherent with measures taken under Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[9].

(16) The notification and submission of a dossier should not be a prerequisite for the possibility, after inclusion of the active substance in Annex I to Directive 91/414/EEC, to place plant protection products on the market subject to the provisions of Article 13 of that Directive. Therefore persons who have not submitted notifications should be able to be informed at all stages of the evaluation process of the possible further requirements for continued marketing of plant protection products containing an active substance under evaluation.

(17) In order to ensure that all relevant information on the potentially dangerous effects of an active substance or its residues are considered, technical or scientific information submitted within the relevant time limits by any person should also be taken into consideration in the evaluations.

(18) Where cooperation with notifiers ceases, it is impossible to continue further evaluation efficiently and therefore the evaluation of an active substance should be terminated unless a Member State takes over.

(19) The task of evaluation should be distributed among the competent authorities of the Member States. Therefore, for each active substance a rapporteur Member State should be designated. Where appropriate the rapporteur Member State should assess the completeness checklist provided by the notifier, and examine and evaluate the information submitted. It should present to the EFSA the results of the evaluation and make a recommendation to the Commission concerning the decision to be taken with regard to the active substance concerned. For certain groups of active substances it is appropriate that the rapporteur Member States closely cooperate with other rapporteur Member States for that group. For each group it is appropriate to identify a lead rapporteur to coordinate such cooperation.

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(20) Rapporteur Member States should send draft assessment reports of their evaluations of active substances to the EFSA. The draft assessment reports should be peer reviewed by the EFSA before they are submitted to the Commission.

(21) In case of an apparent imbalance in the responsibilities borne by the Member States as rapporteur in the evaluation and assessment, it should be possible to replace the Member State originally designated as rapporteur for a particular active substance by another Member State.

(22) To ensure the proper resourcing of this stage of the programme of work, a fee should be paid to the Member States for the handling and evaluation of dossiers and draft assessment reports.

(23) The EFSA has been consulted on the proposed measures.

(24) 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:

CHAPTER I

SUBJECT MATTER AND SCOPE, DEFINITIONS AND THE DESIGNATED MEMBER STATE AUTHORITY

Article 1

Subject matter and scope

1 This Regulation lays down:

a further detailed rules for the implementation of the fourth stage of the programme of work referred to in the second subparagraph of Article 8(2) of Directive 91/414/EEC (the programme of work) with respect to the continued evaluation of the active substances notified under Regulation (EC) No 1112/2002;

b rules covering the active substances that were on the market before 1 May 2004 in the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia and which are not included in stages one to three of the programme of work and which are not covered by Regulation (EC) No 1112/2002.

2 Article 6(2) and (3) and the second paragraph of Article 6(4) of Directive 91/414/EEC shall not apply to active substances listed in Annex I to this Regulation as long as the procedures provided for in this Regulation with regard to such substances have not been finalised.

3 This Regulation shall apply without prejudice to:

a reviews by Member States of active substances listed in Annex I to this Regulation in particular pursuant to renewals of authorisations in accordance with Article 4(4) of Directive 91/414/EEC;

b reviews by the Commission in accordance with Article 5(5) of Directive 91/414/EEC;

c assessments carried out under Directive 79/117/EEC.

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Article 2

Definitions

For the purpose of this Regulation, the definitions set out in Article 2 of Directive 91/414/EEC and Article 2 of Regulation (EC) No 1112/2002 shall apply.

The following definitions shall also apply:

(a) 'notifier' means the natural or legal person who has submitted a notification in accordance with:

  (i) Regulation (EC) No 1112/2002, as listed in Annex II to this Regulation, or

  (ii) Article 4 of this Regulation;

(b) 'rapporteur Member State' means the rapporteur Member State for the active substance as set out in Annex I;

(c) 'summary dossier' means a dossier containing the information required under Article 10(2), where summaries are given of the results of the tests and studies referred to in that paragraph;

(d) 'complete dossier' means a dossier containing the information required under Article 10(3), where the results of the tests and study reports referred to in the summary dossier are given in full.

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 III shall coordinate and ensure all necessary contacts with notifiers, other Member States, the Commission and the European Food Safety Authority (EFSA) in accordance with this Regulation.

Each Member State shall give the details concerning the designated coordinating national authority to the Commission, the EFSA and the designated coordinating national authority of each other Member State and inform them of any modifications thereof.