# 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 451/2000 (Text with EEA relevance)

## 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 451/2000

## (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)], as last amended by Commission Directive 2002/48/EC[(2)], and in particular the second subparagraph of Article 8(2) thereof,

Whereas:

(1) The Commission is to undertake a programme of work for the gradual examination of active substances on the market two years after the date of notification of Directive 91/414/EEC within a period of 12 years. The first stage of this programme was laid down by 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[(3)], as last amended by Regulation (EC) No 2266/2000[(4)]. This first stage is ongoing.

(2) The second stage of work was laid down by 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[(5)], and is also ongoing.

(3) A third stage of work was provided for in Regulation (EC) No 451/2000 for an additional number of active substances not covered by the first and second stages of the programme. Producers wishing to secure the inclusion of these active substances in Annex I to Directive 91/414/EEC have provided detailed information relating to the current stage of completeness of their dossiers and on the endpoints and have undertaken to provide a full data package.

(4) For the third stage of the work programme, Article 10(3) of Regulation (EC) No 451/2000 specifies that detailed provisions concerning the submission of complete dossiers, the time limit(s) for their submission and the fee regime for the active

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substances concerned have to be established by the Commission in a Regulation to be adopted in accordance with the second subparagraph of Article 8(2) of Directive 91/414/EEC.

(5) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002[6] 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, and the scope of this involvement should be defined as soon as possible.

(6) In order to ensure that dossiers are received by the Member States in a manageable way, the active substances to be evaluated should be divided into two groups with separate time limits for the submission of dossiers.

(7) Further, at an initial stage it should be sufficient that notifiers provide only a list of the available tests and studies to the rapporteur Member States, in order to permit the Member States to establish whether a full data package is available to be submitted by the specified time limit. Where such data will not be available by the time limit, it will not be possible to complete re-evaluation of the active substance within the timetable provided for in Directive 91/414/EEC and a decision should therefore be taken immediately not to include the substance concerned in Annex I to the Directive. Authorisation of products containing such active substance should be withdrawn by Member States.

(8) The relationships between producers, Member States, the Commission and the EFSA and the obligations on each of them for the implementation of the programme should be laid down, taking into account experience gained during the first and second stages of the programme. Close cooperation between all parties involved and a scrupulous respect of time limits laid down is necessary to ensure the efficiency of the programme. Strict time limits for all elements of the third stage of the work programme should be set in order to ensure its finalisation within an acceptable time period. Where cooperation with notifiers ceases it is impossible to continue further evaluation efficiently and therefore the evaluation should be terminated.

(9) 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.

(10) It is necessary to define the obligations of notifiers with regard to the formats, time periods and recipient authorities for the information to be submitted.

(11) 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. The rapporteur Member State should assess the completeness check 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

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Commission concerning the decision to be taken with regard to the active substance concerned.

(12) Member States should send draft reports of their evaluations to the EFSA. The draft reports prepared by the rapporteur Member States should be peer reviewed by the EFSA before they are submitted to the Standing Committee on the Food Chain and Animal Health.

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

(14) 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, operators which 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.

(15) 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 prohibiting the placing on the market and use of plant-protection products containing certain active substances[(7)], as last amended by the Act of Accession of Austria, Finland and Sweden, where information becomes available to the Commission showing that its requirements may be satisfied.

(16) The use of anti-microbials from classes, which are or may be used in human or veterinary medicine for the purpose of plant protection should be discouraged. Two of the substances concerned by this Regulation — kasugamycin and streptomycine — fall into this category[(8)]. Pending eventual decisions on their inclusion in Annex I, their uses should continue to be restricted and only be permitted where essential. For the purpose of their evaluation, information on anti-microbial resistance will be required.

(17) This Regulation shall be without prejudice to Community obligations regarding methyl bromide under the Montreal Protocol.

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

(19) 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 in addition to the fee already paid for the evaluation of the notifications pursuant to Article 13 of Regulation (EC) No 451/2000.

(20) Regulation (EC) No 451/2000 provided that for the active substances covered by the third stage of the work programme, the time limit for the submission of a full data package was 25 May 2003 at the latest. That Regulation also provided that detailed provisions concerning the submission of complete dossiers would be established at a

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later stage. In order to organise the work programme efficiently, it is not necessary to submit full data packages shortly before full dossiers have to be submitted. However, to ensure that active substances without full data packages do not remain on the market, a list of available data should be submitted, while the full data packages should be submitted only in exceptional cases and on request.

(21) Regulation (EC) No 451/2000 should be amended accordingly.

(22) 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*

**Subject matter and scope**

1 This Regulation lays down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC with respect to the continued evaluation of the active substances notified under Regulation (EC) No 451/2000.

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

3 This Regulation shall apply without prejudice to:

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

b reviews by the Commission pursuant to Article 5(5) of Directive 91/414/EEC;

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

*Article 2*

**Definitions**

For the purpose of this Regulation, the definitions in Directive 91/414/EEC shall apply.

The following definitions shall also apply:

(a) ‘notifier’ means the natural or legal person who submitted a notification in accordance with the terms specified in Regulation (EC) No 451/2000 as listed in Annex II;

(b) ‘Committee’ means the Standing Committee on the Food Chain and Animal Health, referred to in Article 19 of Directive 91/414/EEC;

(c) ‘data list’ means a list of all the data which is available to be submitted in the full data package;

(d) ‘full data package’ means information and results of studies sufficient to satisfy the requirements of Annexes II and III to Directive 91/414/EEC in relation to a limited range of representative uses of the active substance concerned.

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*Article 3*

**Member State authority**

1 Member States shall allocate responsibility for the implementation of their obligations under the programme of work referred to in Article 8(2) of Directive 91/414/EEC to an authority or authorities.

2 Each Member State shall designate one national authority, referred to in Annex III, to coordinate and ensure all necessary contacts with notifiers, other Member States, the Commission and the European Food Safety Authority (EFSA) pursuant to this Regulation. Each Member State shall inform 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 of any modifications thereof.

*Article 4*

**Measures in case of imbalances**

If, during the assessment and evaluation referred to in Articles 9 and 10, it becomes apparent that there is an imbalance in the responsibilities borne and the work to be done or actually done by the Member States as rapporteurs, it may be decided, in accordance with the procedure provided for in Article 19 of Directive 91/414/EEC, to replace a Member State originally designated as rapporteur for a particular active substance by another Member State.

In such cases the original rapporteur Member State shall inform the notifiers concerned and shall transfer to the newly designated rapporteur Member State all correspondence and information which it has received as rapporteur Member State for the active substance concerned. The original Member State shall return to the notifier the fee referred to in Article 17 except for the part referred to in paragraph 2(d) thereof. The newly designated rapporteur Member State shall then require the notifiers to pay the fee referred to in Article 17 except the part referred to in paragraph 2(d) thereof.

*Article 5*

**Withdrawal or replacement of notifier**

1 If a notifier decides to end its participation in the programme of work for an active substance, it shall immediately inform the rapporteur Member State, the Commission, the EFSA and all other notifiers of the substance concerned of its decision, giving the reasons. Where a notifier ends its participation or fails to fulfil its obligations under this Regulation, the procedures provided for in Article 9 or 10 shall be terminated as regards its dossier.

2 If a notifier agrees with another producer that the notifier shall be replaced for the purposes of further participation in the programme of work under this Regulation, the notifier and such other producer shall inform the rapporteur Member State, the Commission and the EFSA by a common declaration agreeing that such other producer shall replace the original notifier in carrying out the notifier's duties pursuant to Articles 6, 7, 9, 10 or 11. They shall ensure that the other notifiers for the substance concerned are informed at the same time. The other producer in this case shall be jointly liable with the original notifier for any fees remaining