COMMISSION REGULATION (EC) No 1199/97

of 27 June 1997

amending Regulation (EEC) No 3600/92 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

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 96/68/EC [2], and in particular Article 8 (2) thereof,

Whereas the re-evaluation of active substances already on the market two years after notification of Directive 91/414/EEC under Article 8 (2) of that Directive is organized by the Commission in a collaborative and coordinated programme within which Member States undertake specific tasks contributing to the scientific and technical assessment which are the basis for regulatory decisions taken at Community level; whereas when, during the programme, Member States take national action to withdraw from the market or to restrict the use of plant protection products formulated with active substances included in this programme of work, the Commission and the other Member States should be specifically informed of the intended action and the reasons for it;

Whereas information concerning the titles and authors of test and study reports relied on by the rapporteur to make assessment, information concerning publication of the reports, the standards to which they have been conducted and the identity of those holding the data should be systematically included in the rapporteur's reports so that the information upon which the reports are based can be clearly identified and referenced and can be made available, or kept available, to interested parties for consultation and for use by the Member States' national authorities in giving effect to Article 13 of Directive 91/414/EEC; whereas Article 14 of that Directive provides that the Member States and the Commission shall accept and ensure the confidentiality of submitted information which involves industrial and commercial secrets at the warranted request of applicants; whereas, for the purposes of Article 14, confidential treatment should generally not be warranted for the abovementioned information;

Whereas the referral of the dossier and rapporteur's report on an active substance to the Standing Committee on Plant Health should be prepared by appropriate consultations of Member States' experts and notifiers;

Whereas it is necessary that any draft directive or draft decision referred to the Standing Committee on Plant Health should be directly linked to the report and recommendation made by the rapporteur Member Stater, including any modifications made following consultations; whereas the review reports should be available, through the responsible authorities of the Member States, in the Community to parties interested in the scientific and technical basis of the Commission directives or decisions;

Whereas Commission Regulation (EEC) No 3600/92 [3], as amended by Regulation (EC) No 491/95 [4] should therefore be amended accordingly;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EEC) No 3600/92 is amended as follows:

1. In Article 5, the following paragraph 4A is inserted:

'4A. From the time of the adoption of the Regulation referred to in paragraph 2, if a Member State envisages to take action to withdraw from the market or to restrict severely the use of a plant protection product containing an active substance listed in that regulation, where that action is based on information contained in the dossiers referred to in Article 6 or the

[1] OJ No L 230, 19. 8. 1991, p. 1.
[2] OJ No L 277, 30. 10. 1996, p. 25.
[3] OJ No L 366, 15. 12. 1992, p. 10.
[4] OJ No L 49, 4. 3. 1995, p. 50.

report referred to in Article 7, the Member State shall as soon as possible inform the Commission and the other Member States, citing the reasons for its intended action.'

2. Article 7 is amended as follows:

(a) in paragraph 1, the following point (d) is added:

'(d) in particular, include in the report a reference to each test and study report, for each point of Annex II to the Directive, relied on for the assessment in the form of a list of test and study reports including the title, the author(s), the date of the study or test and the date of publication, the standard to which the test or study was conducted, the holder's name and, if any, the claim made by the holder or notifier for data protection.'

(b) Paragraphs 2 and 3 are replaced by the following:

'2. From the start of the examination referred to in paragraph 1, the rapporteur Member State may request the notifiers to improve their dossiers, or add to them. Moreover, the rapporteur Member State may, from the start of this examination, consult with experts from other Member States, and may request additional technical or scientific information from other Member States in order to assist the evaluation.

3. After receiving the summary dossier and the report referred to in paragraph 1, the Commission shall refer the dossier and the report to the Committee for examination.

Before referring the dossier and report to the Committee, the Commission shall circulate the rapporteur's report to the Member States for information. The Member States shall make available at specific request or keep available for consultation by interested parties the information referred to in point (d) of paragraph 1, except the elements thereof which have been accepted as confidential in accordance with Article 14 of the Directive, as well as the name and content of the active substance.

Before the dossier and report are referred to the Committee, a consultation of experts from the Member States may be organized and the Commission may consult some or all of the notifiers of active substances specified in the regulation referred to in Article 5 (2) on the report or parts of the report on the relevant active substance.'

(c) The following paragraph 3A is inserted:

'3A. After the examination referred to in paragraph 3, the Commission shall, without prejudice to any proposal it may submit with a view to amending the Annex to Directive 79/117/EEC, present to the Committee:

(a) a draft directive to include the active substance in Annex I to the Directive, setting out where appropriate the conditions, including the time-limit, for such inclusion;

(b) a draft decision addressed to the Member States to withdraw the authorizations of plant protection products containing the active substance, pursuant to the fourth subparagraph of Article 8 (2) of the Directive, whereby that active substance is not included in Annex I to the Directive;

(c) a draft decision addressed to the Member States to suspend plant protection products containing the active substance from the market, with the option of reconsidering the inclusion of the active substance in Annex I to the Directive after submission of the results of additional trials or of additional information; or

(d) a draft decision to postpone inclusion of the active substance in Annex I to the Directive pending the submission of the results of additional trials or information.'

(d) The following paragraph 6 is added:

'6. Where the Commission presents a draft directive or a draft decision in accordance with paragraph 3A or a draft in accordance with paragraph 5, it shall at the same time present the conclusions of the Committee's examination in the format of an up-dated review report to be noted in the summary record of the meeting.

The review report, excluding any parts which refer to confidential information contained in the dossiers and determined as such in accordance with Article 14 of the Directive, shall be made available by each Member State on specific request, or shall be kept available for consultation by interested parties.'

Article 2

This Regulation shall enter into force on 30 June 1997.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 27 June 1997.

For the Commission

Franz FISCHLER

Member of the Commission