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

Whereas:

(1) The Commission is to undertake a programme of work for the gradual examination of active substances that were on the market two years after the date of notification of Directive 91/414/EEC. 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 Commission Regulation (EC) No 2266/2000 ([4]). This first stage is ongoing. The second and third stages of work were 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 are also ongoing.

(2) A fourth stage of work should be provided for all the existing active substances not covered by the first, second and third stages of the programme. For certain categories of active substances, it is desirable to indicate which particular active substances or under which conditions of use they should be included in the fourth stage of the programme.

(3) A notification procedure should be provided by which interested producers can inform the Commission of their interest in securing the inclusion of an active substance in Annex I of Directive 91/414/EEC and of their undertaking to submit all the required information for a proper evaluation of, and decision on, that active substance in the light of the criteria for inclusion set out in Article 5 of the Directive. Such information would permit further prioritisation of the work programme and enable decisions to be taken on whether these substances should stay on the market after 25 July 2003 pending the outcome of the evaluation on whether their use may be expected to satisfy the requirements of Article 5 of Directive 91/414/EEC.

(4) It is necessary to define the obligations of notifiers with regard to the formats, periods and recipient authorities for the information to be submitted. Different levels of notification are appropriate for different categories of active substances. For certain categories of active substances, data requirements and evaluation criteria are developed. Therefore, it should be required that the interested producers provide detailed information relating to the current stage of completeness of their dossiers and on the endpoints and undertake to provide a full data package within a set deadline. For the remaining active substances the interested producers should provide basic information in order to identify adequately the active substance and its uses and also undertake to provide a data package within a set deadline.

(5) Notification 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 the Directive.

(6) 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]), as last amended by Commission Directive 91/188/EEC ([7]), where information becomes available to the Commission showing that its requirements may be satisfied.

(7) The Commission will, subject to the conclusions of the progress report on the programme of work to the European Parliament and the Council, referred to in the third subparagraph of Article 8(2) of Directive 91/414/EEC, adopt further detailed regulatory provisions permitting the finalisation as soon as possible of the evaluation and decision making of active substances for which the provisions of the present Regulation concerning notification are satisfied.

([1]) OJ L 230, 9.8.1991, p. 1.
([2]) OJ L 148, 6.6.2002, p. 19.
([3]) OJ L 366, 15.12.1992, p. 10.
([4]) OJ L 259, 13.10.2000, p. 27.
([5]) OJ L 55, 29.2.2000, p. 25.
([6]) OJ L 33, 8.2.1979, p. 36.
([7]) OJ L 92, 13.4.1991, p. 42.

(8) The fourth subparagraph of Article 8(2) of Directive 91/414/EEC provides for a Commission Decision not to include in Annex I active substances in cases where the requirements of Article 5 of the Directive are not satisfied or the requisite information and data have not been submitted within the prescribed time period and for Member States to withdraw authorisations of plant protection products containing such active substances. However, it may in particular cases and in the light of detailed reasons provided by Member States, be appropriate to delay such withdrawal for certain uses which are essential and for which there is no alternative to protect efficiently plants or plant products, so as to allow the development of alternatives replacing the use of withdrawn products. The necessity to re-examine these provisions will have to be demonstrated on a case-by-case basis.

(9) Where, for a particular active substance, the requirements of the present Regulation concerning notification are not satisfied, interested parties are not prevented from seeking inclusion of such active substances in Annex I of Directive 91/414/EEC, through the procedures of Article 6(2) of Directive 91/414/EEC, at a later date.

(10) It is appropriate for manufacturers to bear the costs of the evaluation needed to demonstrate that their products are safe to market and therefore a fee has to be paid to the authority designated by the Commission to examine the notifications for the active substances.

(11) 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 1

GENERAL PROVISIONS AND DEFINITIONS

Article 1

Scope

1. This Regulation lays down detailed rules for the initial implementation of the fourth stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, hereinafter referred to as the 'Directive'.

2. The initial implementation of this fourth stage concerns the notification of the active substances referred to in Annexes I and II to this Regulation with a view to their possible inclusion in a subsequent priority list of active substances with a view to their possible inclusion in Annex I to the Directive. Article 6(2), Article 6(3) and the second subparagraph of Article 6(4) of the Directive shall not apply to a substance listed or referred to in Annexes I and II as long as the procedures provided 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 in particular pursuant to renewals of authorisations in accordance with Article 4(4) of the Directive;

(b) reviews by the Commission pursuant to Article 5(5) of the Directive;

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

Article 2

Definitions

The following definitions shall apply for the purposes of this Regulation:

(a) 'Producer' means:

— for active substances produced within the Community, the manufacturer or a person established within the Community designated by the manufacturer as his/her sole representative for the purpose of compliance with this Regulation,

— for active substances produced outside the Community, the person established within the Community and designated by the manufacturer as his/her sole representative within the Community for the purpose of compliance with this Regulation,

— for active substances for which a joint notification or joint dossier is submitted, the association of producers established within the Community and designated by the producers referred to in the first or second indent for the purpose of compliance with this Regulation.

(b) 'Manufacturer' means the person who manufactures the active substance on his/her own or who contracts out to another party the manufacturing of the active substance on its behalf.

(c) 'Committee' means the Standing Committee on the Food Chain and Animal Health, established by Article 19 of the Directive.

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 the Directive to an authority or authorities.

2. In each Member State one national authority, referred to in Annex VI, shall coordinate and ensure all necessary contacts with producers, other Member States and the Commission pursuant to this Regulation. Each Member State shall inform the Commission and the designated coordinating national authority of each other Member State of any modifications to the communicated details concerning the designated coordinating national authority.

CHAPTER 2

FOURTH STAGE OF THE PROGRAMME OF WORK

Article 4

Basic notification

1. Any producer wishing to secure the inclusion of an active substance referred to in Annex I to this Regulation, in Annex I to the Directive shall so notify to the body referred to in Annex V. The Commission will regularly follow up the tasks mentioned in Annex V entrusted to the body designated in that Annex. In accordance with the procedure laid down in Article 19 of the Directive it may be decided to designate another body where it would appear that the tasks are not adequately performed.

2. Notification must be submitted for each active substance separately within three months of the date of entry into force of this Regulation in accordance with the model notification as shown in part 1 of Annex III hereto including a written commitment to present a dossier.

3. Any producer who has not notified any given active substance referred to in paragraph 1 within the deadline referred to in paragraph 2 or whose notification was rejected in accordance with the provisions of Article 6 will be permitted to participate in the review programme only collectively with one or more notifiers of the active substance (including a Member State which has notified in accordance with Article 6(2)), whose notification was accepted in accordance with Article 6, in submitting a joint dossier.

Article 5

Full notification

1. Any producer wishing to secure the inclusion of an active substance referred to in Annex II to this Regulation, in Annex I to the Directive shall so notify to the body designated in Annex V.

2. Notification must be submitted for each active substance separately, as follows:

(a) within three months of the date of entry into force of this Regulation, a first notification, in accordance with the model notification as shown in Annex III, part 1 hereto, and

(b) within six months of the date of entry into force of this Regulation, a second notification, in accordance with the model notification as shown in Annex III, part 2 hereto, including a written commitment to present a complete dossier.

3. Any producer who has not notified any given active substance referred to in paragraph 1 within the deadline referred to in paragraph 2 or whose notification was rejected in accordance with the provisions of Article 6 will be permitted to participate in the review programme only collectively with one or more notifiers of the active substance, including a Member State which has notified in accordance with Article 6(2), whose notification was accepted in accordance with Article 6, in submitting a joint dossier.

Article 6

Examination of basic notifications and full notifications

1. The Commission shall, within two months after the deadline referred to in Article 4(2) and Article 5(2)(a), inform the Committee on the notifications submitted before the deadline.

2. For any active substance for which no producer has submitted a notification, a Member State may declare its interest in securing the inclusion of that active substance in Annex I to the Directive by notifying the body designated in Annex V in accordance with Article 4 or 5. Such notifications must be submitted as soon as possible, and no later than three months after the Commission has informed the Member States that no notification was submitted for that substance. A Member State submitting a notification shall thereafter be treated as the producer for the purposes of the evaluation of the active substance concerned.

3. The Commission shall, at the latest six months after the deadlines referred to in Article 4(2) and Article 5(2), inform the Committee on the admissibility of the notifications received taking into account the criteria referred to in Annex IV, parts 1 and 2.

4. Detailed provisions concerning the submission of dossiers, the deadline(s) for their submission and the fee regime for the active substances for which an admissible notification was received shall be established by the Commission in a Regulation to be adopted in accordance with the second subparagraph of Article 8(2) of the Directive.

5. The Commission shall decide, as provided for in the fourth subparagraph of Article 8(2) of the Directive, not to include in Annex I to the Directive active substances referred to in Annex I or II to this Regulation for which no admissible notification has been submitted within the established time limit. The decision shall state the reasons for the non-inclusion. Member States shall withdraw authorisations of plant protection products containing these active substances within the period prescribed in the Decision.

CHAPTER 3

FEES

Article 7

Fees for the notification for the fourth stage of the work programme

1. Any producer submitting a notification in accordance with the provisions of Article 4 shall at the time of the submission of its notification pay a fee of EUR 750 for each active substance to the body designated in Annex V. The fee shall be used to finance exclusively the costs actually incurred for the tasks referred to in Annex V.

2. Any producer submitting a notification in accordance with the provisions of Article 5(2)(a) shall at the time of the submission of its notification pay a fee of EUR 5 000 for each active substance to the body designated in Annex V. The fee shall be used to finance exclusively the costs actually incurred for the tasks referred to in Annex V.

CHAPTER 4

FINAL PROVISION

Article 8

Temporary measures

In a decision to phase out an active substance for which no admissible notification has been submitted, pursuant to fourth subparagraph of Article 8(2) of Directive 91/414/EC the Commission may, where additional technical evidence has been provided by a Member State demonstrating an essential need for further use of that substance and the absence of any effective alternative, prescribe a phasing out period which is sufficiently long to enable suitable alternatives to be developed.

Article 9

Entry into force

This Regulation shall enter into force on 1 August 2002.

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

Done at Brussels, 20 June 2002.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

Active substances covered by the basic notification for the fourth stage of the work programme provided for in Article 8(2) of the Directive

All active substances (including any variants thereof such as salts, esters or amines) that were on the market before 25 July 1993 except those which are covered by:

— Regulation (EEC) No 3600/92,

— Regulation (EC) No 451/2000,

— Annex II to this Regulation,

Notwithstanding the above exceptions, substances which were previously considered to be covered by Directive 98/8/EC of the European Parliament and of the Council [1] but which, following clarification of the scope of the Directive, are now considered to fall within the scope of Directive 91/414/EEC and were included in Regulation (EC) No 451/2000, may be notified under Article 4. This applies in particular to substances authorised as disinfectants i.e. products applied indirectly (for example for the disinfection or the disinfestation of empty store rooms or other structures and articles like greenhouses, growing houses, containers, boxes, sacks, barrels etc.) where the purpose of the use is to destroy organisms exclusively and specifically harmful to plants or plant products and after the treatment only plants or plants products will be grown or stored in the treated structures.

All substances belonging to the following categories have to be notified even if they are not mentioned in the table further below:

— active substances of which the use is authorised in human foodstuffs or animal feeding stuffs in accordance with EU-legislation,

— active substances which are plant extracts,

— active substances which are animal products or derived thereof by simple processing,

— active substances, which are or will be exclusively used as attractants or repellants (including pheromones). Active substances, which are or will be exclusively used in traps and/or dispensers, in conformity with Council Regulation (EEC) No 2092/91 [2] concerning organic farming.

In particular all substances listed in, or falling within a category listed in the following table, should be notified in accordance with Article 5:

(4E-7Z)-4,7-Tridecadien-1-yl-acetate

(4Z-9Z)-7,9-Dodecadien-1-ol

(7Z-11Z)-7,11-Hexadien-1-yl- acetate

(E)-10-Dodecenyl acetate

(E)-11-Tetradecenyl acetate

(E)7-(Z)9-Dodecadienyl acetate

(E,E)-8,10-Dodecadien-1-ol

(E/Z)-8-Dodecenyl acetate

(Z)-11-Hexadecanole

(Z)-11-Tetradecen-1-yl-acetate

(Z)-13-Octadecanole

(Z)-3-Methyl-6-isopropenyl-3,4- decadien-1yl

(Z)-3-Methyl-6-isopropenyl--9-decen-1-yl acetate

(Z)-5-Dodecen-1-yl acetate

(Z)-7-Tetradecanole

(Z)-7-Tetradecenal

(Z)-8-Dodecenol

(Z)-8-Dodecenyl acetate

(Z)-9-Dodecenyl acetate

(Z)-9-Hexadecenal

(Z)-9-Tetradecenyl acetate

(Z)-9-Tricosene

(Z,E)-11-Tetradecadien-1-yl acetate

(Z,Z) Octadienyl acetate

1,7-Dioxaspiro-5,5-undecan

1-Decanol

2-Phenylphenol (incl. Sodium salt)

2-Propanol

3,7-Dimethyl-2,6-octadien-1-ol

3,7-Dimethyl-2,6-octadienal

4-chloro-3-methylphenol

5-Decen-1-ol

5-Decen-1-yl acetate

6-Benzyladenine

7,8-Epoxi-2-methyl-octadecane

7-Methyl-3-methylene-7-octene-1-yl-propionate

Acetic acid

Acridinic bases

Alkyldimethybenzyl ammonium chloride

Alkyldimethylethylbenzyl ammonium chloride

Aluminium ammonium sulfate

Aluminium sulphate

Amino acids

Ammonium carbonate

Ammonium hydroxide

Ammonium sulphate

Anthraquinone

Azadirachtin

Barium nitrate

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 198, 22.7.1991, p. 1.