

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	1,7-Dioxaspiro-5,5-undecan
(4Z-9Z)-7,9-Dodecadien-1-ol	1-Decanol
(7Z-11Z)-7,11-Hexadien-1-yl- acetate	2-Phenylphenol (incl. Sodium salt)
(E)-10-Dodecenyl acetate	2-Propanol
(E)-11-Tetradecenyl acetate	3,7-Dimethyl-2,6-octadien-1-ol
(E)7-(Z)9-Dodecadienyl acetate	3,7-Dimethyl-2,6-octadienal
(E,E)-8,10-Dodecadien-1-ol	4-chloro-3-methylphenol
(E/Z)-8-Dodecenyl acetate	5-Decen-1-ol
(Z)-11-Hexadecanole	5-Decen-1-yl acetate
(Z)-11-Tetradecen-1-yl-acetate	6-Benzyladenine
(Z)-13-Octadecanole	7,8-Epoxy-2-methyl-octadecane
(Z)-3-Methyl-6-isopropenyl-3,4- decadien-1yl	7-Methyl-3-methylene-7-octene-1-yl-propionate
(Z)-3-Methyl-6-isopropenyl-9-decen-1-yl acetate	Acetic acid
(Z)-5-Dodecen-1-yl acetate	Acridinic bases
(Z)-7-Tetradecanole	Alkyldimethylbenzyl ammonium chloride
(Z)-7-Tetradecenol	Alkyldimethylethylbenzyl ammonium chloride
(Z)-8-Dodecenol	Aluminium ammonium sulfate
(Z)-8-Dodecenyl acetate	Aluminium sulphate
(Z)-9-Dodecenyl acetate	Amino acids
(Z)-9-Hexadecenol	Ammonium carbonate
(Z)-9-Tetradecenyl acetate	Ammonium hydroxide
(Z)-9-Tricosene	Ammonium sulphate
(Z,E)-11-Tetradecadien-1-yl acetate	Anthraquinone
(Z,Z) Octadienyl acetate	Azadirachtin
	Barium nitrate

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 198, 22.7.1991, p. 1.

Biphenyl	Lauryldimethylbenzylammonium chloride
Bone oil	Lecithin
Boric acid	Lime phosphate
Calcium carbide	Lime sulphur
Calcium carbonate	Methyl nonyl ketone
Calcium chloride	Methyl-trans-6-nonenoate
Calcium hydroxide	Naphtalene
Calcium oxide	1-Naphtylacetamide
Carbon dioxide	1-Naphtylacetic acid
Chlorhydrate of poly(imino imido biguanidine)	2-Naphtyloxyacetamide
Chlorophylline	2-Naphtyloxyacetic acid
Choline chloride	Naphtylacetic acid ethylester
cis-7,trans-11-hexadecadienyl acetate	Nicotine
cis-Zeatin	Nitrogen
Citronellol	Octyldecyldimethyl ammonium chloride
Cystein	Onion extract
Denathonium benzoate	Oxyquinoline
Didecyl-dimethylammonium chloride	Papaine
Dioctyldimethyl ammonium chloride	Paraffin oil
Dodecyl alcohol	p-Cresyl acetate
EDTA and salts thereof	Pepper
Ethanol	Petroleum oils
Ethoxyquin	Pherodim
Farnesol	Phosphoric acid
Fatty acids including esters and salts such as ⁽¹⁾ :	Phoxim
— Decanoic acid	Plant oils such as ⁽²⁾ :
— Ethylhexanoate	— Coconut oil
— Ethyloleate	— Daphne oil
— Fatty acid potassium salt	— Etheric oils
— Pelargonic acid	— Eucalyptus oil
Fatty alcohols	— Maize oil
Folic acid	— Olive oil
Formaldehyde	— Peanut oil
Formic acid	— Pinus oil
Garlic extract	— Rape seed oil
Gelatine	— Soya oil
Gibberellic acid	— Sunflower seed oil
Gibberellin	Potassium permanganate
Glutaraldehyde	Potassium sorbate
Grease (bands, fruit trees)	Pronumone
Hydrogen peroxide	Propionic acid
Hydrolysed proteins	Pyrethrins
Indolyacetic acid	Quartz sand
Indolylbutyric acid	Quassia
Iron sulphate	Quaternary ammonium compounds
Kieselgur (Diatomaceous earth)	Quinoline derivatives
Lactic acid	Repellants (by smell) of animal or plant origin
Lauryldimethylbenzylammonium bromide	Resins and polymers
	Rock powder

⁽¹⁾ Each fatty acid has to be notified separately but not their variants.

⁽²⁾ Each plant oil has to be notified separately.

Rotenone	Sodium o-benzyl-p-chlorphenoxide
Sea-algae extract	Sodium ortho phenyl phenol
Seaweed	Sodium propionate
Sebacic acid	Sodium p-t-amyphenoxide
Serricornin	Sodium tetraborate
Silicates (sodium and potassium)	Soybean extract
Silver iodide	Soybeanoil, epoxylated
Sodium P-toluenesulphon-chloramide	Sulphur and Sulphur dioxide
Sodium carbonate	Sulphuric acid
Sodium chloride	Tar oils
Sodium hydrogen carbonate	trans-6-Nonen-1-ol
Sodium hydroxide	trans-9-Dodecyl acetate
Sodium hypochlorite	Trimedlure
Sodium lauryl sulfate	Urea
Sodium metabisulphite	Waxes

ANNEX II

All active substances (including any variants thereof such as salts, esters or amines) covered by the full notification for the fourth stage of the work programme provided for in Article 8(2) of the Directive.

Active substances (including any variants thereof) that were on the market before 25 July 1993 which:

1. are microorganisms including viruses, including the following:

Aschersonia aleyrodis

Agrotis segetum granulosis virus

Bacillus sphaericus

Bacillus thuringiensis including: (*)

— subspecies *aizawai*

— subspecies *israelensis*

— subspecies *kurstaki*

— subspecies *tenebrionis*

Beauveria bassiana

Beauveria brongniartii (syn. *B. tenella*)

Cydia pomonella granulosis virus

Mamestra brassica nuclear polyhedrosis virus

Metarhizium anisopliae

Neodiprion sertifer nuclear polyhedrosis virus

Phlebiopsis gigantea

Streptomyces griseoviridis

Tomato mosaic virus

Trichoderma harzianum

Trichoderma polysporum

Trichoderma viride

Verticillium dahliae Kleb.

Verticillium lecanii

2. are used as rodenticides (products applied in plant growing areas (agricultural field, greenhouse, forest) to protect plants or plant products temporarily stored in the plant growing areas in the open without using storage facilities), including the following:

Brodifacoum

Bromadiolone

Bromethalin

Calciferol

Calcium phosphate

Chloralose

Chlorophacinone

Cholecalciferol

Coumachlor

Coumafuryl

Coumatetralyl

Crimidine

p-Dichlorobenzene

Difenacoum

Difethialone

Diphacinone

Ethanethiol

Flocumafen

(*) Each subspecies has to be notified separately.

Fluoroacetamide

Isoval

Papaine

Phosphine and phosphine developing compounds such as:

- aluminium phosphide
- calcium phosphide
- magnesium phosphide
- zinc phosphide

Pyranocumarin

Scilliroside

Sodium cyanide

Sodium dimethylarsinate

Strychnine

Sulfaquinoxaline

Thallium sulphate

Thiourea

Tricalcium phosphate

3. are used on stored plants or plant products, including the following:

Cyanides such as:

- calcium cyanide
- hydrogen cyanide
- sodium cyanide

Phosphine and phosphine developing compounds such as:

- aluminium phosphide
- magnesium phosphide

ANNEX III

PART 1

Notification of an active substance according to Article 4 and Article 5(2)(a)*Model*

The notification must be made on paper and as a computer readable file (as made available by the body designated in Annex V).

The notification shall contain the following information:

REFERENCE NUMBER:

1. IDENTIFICATION DATA ON THE NOTIFIER

- 1.1. Manufacturer of the active substance as defined in Article 2(b) (name, address, including location of plant):
- 1.2. Name and address of the producer as defined in Article 2(a) including the name of the (natural) person responsible for the notification and further engagements resulting from this Regulation.
 - 1.2.1. (a) Telephone No:
(b) Telefax No:
(c) E-Mail Address:
 - 1.2.2. (a) Contact:
(b) Alternative:

2. INFORMATION TO FACILITATE IDENTIFICATION

- 2.1. Common name (proposed or ISO-accepted where appropriate) specifying, where relevant, any variants thereof such as salts, esters or amines produced by the manufacturer. For microorganisms the species, and where relevant, subspecies name.
- 2.2. Chemical name (IUPAC and CAS nomenclature) (where appropriate).
- 2.3. CAS, CIPAC and EEC numbers (if available).
- 2.4. Empirical and structural formula, molecular mass (where appropriate).
- 2.5. Any other information considered necessary to facilitate identification, for example method of manufacture/extraction or origin of materials from which the substance is manufactured.
- 2.6. Specification of purity of the active substance in g/kg or g/l (as appropriate).
- 2.7. Classification and labelling of the active substance in accordance with the provisions of Council Directive 67/548/EEC (OJ L 196, 16.8.1967, p. 1) (health and environment effects).

3. FURTHER INFORMATION

- 3.1. For each Member State a list of crops/uses for which plant protection products containing the active substance are currently authorised or used.
- 3.2. Further information on the active substance as set out in Annex II to the Directive points 3.1 to 3.5.
- 3.3. Date and reference number of the most recent review of the active substance in a Member State of the European Union.
- 3.4. Date and reference number of the most recent review of the active substance in an OECD-country.

4. UNDERTAKING

The notifier undertakes to submit to the designated coordinating authority of the designated rapporteur Member State the dossiers within the deadline provided for in the Regulation to be adopted according to Article 6(4) of this Regulation. Whenever the newly adopted Regulation mentions several notifiers for this active substance, the notifier agrees to make all reasonable efforts to present a single dossier collectively with the other notifiers.

The notifier undertakes to pay a fee as provided for in Article 7 at the time of the submission of the notification to the body designated in Annex V.

The notifier declares that he is aware that he will be charged a fee by Member States at the time of the submission of the full dossier for active substances covered by the Regulation meant in Article 6(4).

The notifier confirms that the above information is honest and correct.

The notifier declares that an authorisation by the manufacturer to act as his sole representative for the purpose of complying with this Regulation is enclosed if necessary.

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

PART 2

Notification of an active substance according to Article 5(2)(b)*Model*

The notification must be made both on paper and as a computer readable file (as made available by the body designated in Annex V).

The notification shall contain the following information:

REFERENCE NUMBER:

1. IDENTIFICATION DATA ON THE NOTIFIER

- 1.1. Manufacturer of the active substance as defined in Article 2(b) (name, address, including location of plant):
- 1.2. Name and address of the producer as defined in Article 2(a) including the name of the (natural) person responsible for the notification and further engagements resulting from this Regulation.
 - 1.2.1. (a) Telephone No:
(b) Telefax No:
(c) E-Mail Address:
 - 1.2.2. (a) Contact:
(b) Alternative:

2. INFORMATION TO FACILITATE IDENTIFICATION

- 2.1. Common name (proposed or ISO-accepted where appropriate) specifying, where relevant, any variants thereof such as salts, esters or amines produced by the manufacturer. For microorganisms the species, and where relevant, subspecies name.
- 2.2. Chemical name (IUPAC and CAS nomenclature) (where appropriate).
- 2.3. CAS, CIPAC and EEC numbers (if available).
- 2.4. Empirical and structural formula, molecular mass (where appropriate).
- 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 Directive 67/548/EEC (health and environment effects).

3. COMPLETENESS CHECK

A completeness check has to be presented in the format recommended at the time of entry into force of this Regulation by the Commission in the framework of the Standing Committee on the Food Chain and Animal Health, for each point of Annex II and Annex III to the Directive relevant for the limited range of representative uses of the active substance for which the notifier intends to demonstrate, on the basis of the data that will be submitted, the acceptability in relation to the assessment of the criteria referred to in Article 5 of the Directive for one or more preparations.

The notifier has to identify these representative uses.

4. LIST OF AVAILABLE STUDIES

- A list of all studies available to the notifier and which will be submitted to the rapporteur Member States as part of the dossier.
 - A detailed provisional plan including engagements for the performance of further studies in order to complete the dossier.
 - A separate list of all the studies performed since 1 August 1994 (with the exception of studies on efficacy referred to in Annex III, section 6 of the Directive).
5. For each Member State a list of crops in which plant protection products containing the active substance are currently authorised.
 6. Date and reference of the most recent review of the active substance in a Member State of the European Union.
 7. Date and reference of the most recent review of the active substance in an OECD country.

8. LIST OF ENDPOINTS

A list of all the following endpoints has to be presented relevant for the limited range of uses of the active substance for which it has to be demonstrated by the notifier, on the basis of the data that will be submitted, that for one or more preparations the requirements of the Directive in relation to the criteria referred to in its Article 5 can be met.

The end points for rodenticides and products for use on stored plants or plant products are those set out in Regulation (EC) No 451/2000, Annex IV, Part 2, Section 2, point 8:

The end points for microorganisms are as follows:

IDENTITY AND BIOLOGICAL PROPERTIES

Intended uses:

Known or new organism:

GMO:

Taxonomy:

Species, subspecies, strain:

Identification / detection:

Methods of analysis:

Mode of action:

Life cycle:

Host specificity:

Known opportunist:

Toxin production:

Resistance:

Resting stages:

Production control:

END POINTS AND RELATED INFORMATION

1. Hazard evaluation

1.1. Hazard to humans

Pathogenicity:

Infectivity:

Toxicity:

Irritation, Sensitisation:

Genotoxicity:

Medical reports:

Formulation:

1.2. Hazard to the environment

Impact on non-targets:

Formulation:

2. Exposure assessment and risk evaluation**2.1. Operator exposure**

Application method:

Operator exposure models:

2.2. Exposure of the environment

Natural occurrence, background level:

Application method:

Post release control:

2.3. Consumer exposure

Residues:

--

3. Formulation

Technical specification:

Packaging:

9. UNDERTAKING

The notifier confirms that the information submitted in points 3 and 8 of the notification is based on studies which are available to the notifier and which will be submitted to the rapporteur Member State as part of the dossier.

The notifier undertakes to submit to the designated coordinating authority of the designated rapporteur Member State the dossiers within the deadline provided for in the Regulation to be adopted according to Article 6(4) of this Regulation. Whenever the newly adopted Regulation mentions several notifiers for this active substance, the notifier agrees to make all reasonable efforts to present a single dossier collectively with the other notifiers.

The notifier undertakes to pay a fee as provided for in Article 7 at the time of the submission of the notification to the body designated in Annex V.

The notifier declares that he is aware that he will be charged a fee by Member States at the time of the submission of the full dossier for active substances covered by the Regulation meant in Article 6(4).

The notifier confirms that the above information is honest and correct.

The notifier declares that an authorisation by the manufacturer to act as his sole representative for the purpose of complying with this Regulation is enclosed if necessary.

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

ANNEX IV

PART 1

Criteria for the acceptance of notifications referred to in Article 4

A notification will only be accepted if the following is satisfied:

1. it is presented within the time limit referred to in Article 4(2).
2. it is introduced by a notifier who is a producer as defined in Article 2(a) for an active substance as defined by the Directive and which are placed on the market and used for the purpose of plant protection.
3. it is presented in the format as provided for in Annex III, part 1.
4. a fee as referred to in Article 7(1) has been paid.

PART 2

Criteria for the acceptance of notifications referred to in Article 5

A notification will only be accepted if the following is satisfied:

1. it is presented within the time limit referred to in Article 5(2).
 2. it is introduced by a notifier who is a producer as defined in Article 2(a) for an active substance as defined by the Directive and which are placed on the market and used for the purpose of plant protection.
 3. it is presented in the format as provided for in Annex III, part 2.
 4. it appears from the completeness check that the dossier currently available is sufficiently complete or a time plan to complete it is proposed.
 5. the list of endpoints is sufficiently complete.
 6. a fee as referred to in Article 7(2) has been paid.
-

ANNEX V

Designated body referred to in Articles 4 and 5

The following body is designated to perform on behalf of the Commission the tasks referred to in Article 6:

Biologische Bundesanstalt für Land und Forstwirtschaft (RENDER 4), Messeweg 11-12 D-38104 Braunschweig (website: <http://www.bba.de/english/render/htm> or e-mail: render@bba.de). The fee referred to in Article 7 has to be paid to:

account holder: Bundeskasse Halle

account No: 8000 10 20

BLZ 800 000 00, Landeszentralbank Halle

IBAN: DE 588 00 00 00 00 8000 10 20

BIC: ZBNS DE 21 800

(reference 'BBA-RENDER 4' mentioning the reference number of the notification).

This body will:

1. examine the notifications referred to in Articles 4 and 5;
2. prepare and make available to the notifiers the format of the notification referred to in Article 4(2) and Article 5(2);
3. examine the notifications and, if necessary, consult with experts from other Member States in the light of the acceptability criteria referred to in Annex IV;
4. report to the Commission at the latest within 3 months from the deadline referred to in Article 4(2) and Article 5(2) and on the acceptability of the notifications received;
5. make available to the Commission the notifications received;
6. make a detailed account available to the Commission;
7. if the total amount of fees paid by all notifiers exceeds the real cost of the examination and administrative treatment of all notifications, refund the balance to the notifiers in equal shares.

ANNEX VI

COORDINATING AUTHORITY IN THE MEMBER STATES

AUSTRIA

Bundesamt und Forschungszentrum für Landwirtschaft
Spargelfeldstraße 191
A-1226 Vienna

BELGIUM

Ministère des classes moyennes et de l'agriculture
Service qualité des matières premières et analyses
WTC 3, 8^e étage
Boulevard S. Bolivar 30
B-1000 Brussels

DENMARK

Ministry of Environment
Danish Environmental Protection Agency
Pesticide Division
Strandgade 29
DK-1401 Copenhagen K

GERMANY

Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA)
Abteilung für Pflanzenschutzmittel und Anwendungstechnik (AP)
Messeweg 11-12
D-38104 Brunswick

GREECE

Hellenic Republic
Ministry of Agriculture
General Directorate of Plant Produce
Directorate of Plant Produce Protection
Department of Pesticides
3-5 Hippokratous Street
GR-10164 Athens

SPAIN

Ministerio de Agricultura, Pesca y Alimentación
Dirección General de Agricultura
Subdirección General de Medios de Producción Agrícolas
C/ Ciudad de Barcelona, 118-120
E-28007 Madrid

FINLAND

Plant Production Inspection Centre
Pesticide Division
P.O. BOX 42
FIN-00501 Helsinki

FRANCE

Ministère de l'agriculture et de la pêche
Direction générale de l'alimentation
Sous-direction de la qualité et de la protection des végétaux
251, rue de Vaugirard
F-75732 Paris Cedex 15

IRELAND

Pesticide Control Service
Department of Agriculture, Food and Rural Development
Abbotstown Laboratory Complex
Abbotstown, Castleknock
Dublin 15
Ireland

ITALY

Ministero della Sanità
Dipartimento degli Alimenti, Nutrizione e Sanità Pubblica Veterinaria
Ufficio XIV
Piazza G. Marconi, 25
I-00144 Rome

LUXEMBOURG

Administration des services techniques de l'agriculture
Service de la protection des végétaux
Boîte postale 1904
16, route d'Esch
L-1019 Luxembourg

NETHERLANDS

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

PORTUGAL

Direcção-Geral de Protecção das Culturas,
Quinta do Marquês
P-2780-155 Oeiras

SWEDEN

National Chemicals Inspectorate
P.O. Box 1384
S-17127 Solna

UNITED KINGDOM

Pesticides Safety Directorate
Department for Environment, Food and Rural Affairs
Mallard House,
Kings Pool,
3 Peasholme Green,
York, YO1 7PX
United Kingdom