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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic 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 Article 8 (2) thereof,

Whereas the Commission is to commence a programme of work for the gradual examination of active substances available on the market two years after the date of notification of Directive 91/414/EEC;

Whereas, given the very high number of active substances on the market on that date, a selection has already been made, taking into account in a balanced manner such aspects as health and/or environmental concern, the possibility of residues in treated products, the importance of the preparations containing these substances for agriculture, any manifest data gaps (or, conversely, the presence of a complete, updated data package), and any similarity of chemical or biological properties;

Whereas the relationship between producers, Member States and the Commission and the obligations on each of the parties for the implementation of the programme should be laid down;

Whereas a notification procedure has to be provided by which interested producers have the right to inform the Commission of their interest in securing the inclusion of an active substance in Annex I to the Directive and of their undertaking to submit all the requisite 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 Directive 91/414/EEC;

Whereas it is necessary to define the obligations of notifiers with regard to the formats, the periods and the recipient authorities for the information to be submitted; whereas the administrative consequences which shall follow if these obligations are not satisfied have to be defined;

Whereas technical or scientific information about the potentially dangerous effects of an active substance or its residues submitted within the relevant time-limits by any other interested parties should also be taken into consideration for this evaluation;

Whereas the evaluation studies should be distributed among the competent authorities of the Member States; whereas, therefore, for each active substance a rapporteur Member State should be designated to examine and evaluate the information submitted, in close consultation with experts from other Member States, and to present to the Commission the results of the assessment and a recommendation that a decision be taken with regard to the active substance concerned;

Whereas the proceedings established under this Regulation should not prejudice proceedings to be undertaken in the framework of other Community legislations;

Whereas, in order to avoid duplication of work, and in particular experiments involving vertebrate animals, specific provisions have to be provided to stimulate producers to submit collective dossiers;

Whereas the procedures under the Regulation should not prejudice the possibility of investigation and prohibitory action under Council Directive 79/117/EEC [2], as last amended by Commission Directive 91/188/EEC [3], where information becomes available to the Commission showing that the requirements for prohibition provided for in Directive 79/117/EEC may be satisfied; whereas at the time of adoption of this Regulation such information regarding Atrazin and Quintozene is under particular examination;

Whereas procedural and administrative measures have to be taken at this time in order to ensure that the evaluation of active substances can effectively start from the date of implementation of Directive 91/414/EEC;

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

1. This Regulation lays down detailed rules for the implementation of the first stage of the programme of work referred to in Article 8 (2) of Directive 91/414/EEC (hereinafter referred to as 'the Directive'). The first stage involves an assessment of the substances listed in Annex I to this Regulation with a view to their possible inclusion

[1] OJ No L 230, 19. 8. 1991, p. 1, as corrected in OJ No L 170, 25. 6. 1992, p. 40.

[2] OJ No L 33, 8. 2. 1979, p. 36.
[3] OJ No L 92, 13. 4. 1991, p. 42.

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

2. This Regulation shall apply without prejudice to :

(a) reviews conducted by Member States, and in particular reviews with a view to authorization renewals under 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

1. For the purpose of this Regulation, 'plant protection products', 'substances', 'active substances', 'preparations' and 'authorization of a plant protection product' shall have the meanings set out in Article 2 of the Directive.

2. The following definitions shall also apply for the purpose of this Regulation :

(a) 'Producers' means

— for active substances produced within the Community, the manufacturer or a person established within the Community designated by the manufacturer as his sole representative,

— for active substances produced outside the Community, the person established within the Community and designated by the manufacturer as his sole representative or, whenever such person has not been designated, the importer(s) into the Community of the active substance, either on its own or in a preparation ;

(b) 'Committee' means the Standing Committee on Plant Health, referred to in Article 19 of the Directive.

Article 3

Member States shall designate an authority to coordinate cooperation with producers, other Member States and the Commission, and generally for the implementation of the programme of work referred to in Article 8 (2) of the Directive. They shall inform the Commission of the name of the designated authority.

Article 4

1. Any producer wishing to secure the inclusion of an active substance referred to in Annex I hereto, or any salts, esters or amines thereof, in Annex I to the Directive, shall so notify the Commission within six months of the date of entry into force of this Regulation.

Without prejudice to the foregoing subparagraph, producers of an active substance listed in Annex I are also bound to inform the Commission within the same period when they no longer seek its inclusion in Annex I to the Directive.

2. Notification must be made to the Commission, DG VI, rue de la Loi 200, B-1049 Brussels, in accordance with the notification as shown in Annex II hereto, completed and containing the undertaking referred to in part 5 of the specimen notification.

3. Any producer who has not notified in time any given active substance referred to in paragraph 1 will be permitted to participate in the programme referred to in Article 1 only collectively with other notifiers of that active substance or, in the case referred to in paragraph 4 hereof, in assisting the notifying Member State, with the agreement of the original notifiers.

4. The Commission shall inform the Member States through the Committee when, for any given active substance, no producer has presented a notification in accordance with paragraph 2. Member States shall be able to declare their interest in securing the inclusion of the active substance in Annex I to the Directive, by means of the specimen notification shown in Annex II hereto. Notification must be sent to the Commission as quickly as possible, and no later than six months after the Member States have been informed by the Commission. The Member State having presented the notification shall carry out the duties of a producer as set out in Articles 5 to 8 hereof.

5. When, following the above procedure, no producer or Member State has notified an interest in obtaining the inclusion of a given active substance in Annex I to the Directive, a decision not to include that active substance may be taken in accordance with the final subparagraph of Article 8 (2) of the Directive.

Article 5

1. The Commission shall examine with the Committee the notifications referred to in Article 4 (2) and (4).

2. Following the examination referred to in paragraph 1, decisions shall be adopted on the following, according to the procedure under Article 19 of the Directive, in the form of a regulation :

(a) the list of active substances adopted for assessment with a view to their possible inclusion in Annex I to the Directive ;

(b) designation of a rapporteur Member State for each active substance included in the list referred to in (a).

3. In the list referred to in paragraph 2 (a), certain substances with similar structures or chemical properties may be grouped together; if an active substance has been notified with different compositions which may lead to different toxicological properties or have different environmental effects, these may be listed separately.

4. For each substance adopted for assessment, the regulation referred to in paragraph 2 shall give:

— the names of all producers who have presented a notification in accordance with Article 2 (1), or, where appropriate, the Member States which have presented a notification under Article 4 (4),

— the name of the Member State designated as rapporteur,

— the deadline for the submission to the rapporteur Member State of the dossiers referred to in Article 6 hereof, generally laying down a period of 12 months for the compilation of the documents, and for the submission by any interested parties of technical or scientific information with regard to the potentially dangerous effects of the substance or its residues on human and/or animal health and/or on the environment.

5. When, during the reassessment referred to in Articles 6, 7 and 8 hereof, an imbalance becomes apparent in the responsibilities borne by the Member States as rapporteurs, it may be decided, using the procedure under Article 19 of the Directive, to designate a different Member State as rapporteur for a particular substance.

Article 6

1. Within the time-limit referred to in the third indent of Article 5 (4), the notifiers specified in the regulation referred to in that Article must, individually or collectively, send to the designated authority of the rapporteur Member State, for any given active substance:

(a) the summary dossier referred to in paragraph 2 hereof; and

(b) the complete dossier referred to in paragraph 3 hereof.

They shall also send this information to the experts as referred to in Article 7 (2), and, if so requested, to the competent authority referred to in Article 3 of each Member State.

Where for any substance the regulation as envisaged in Article 5 (4) indicates several notifications, the notifiers concerned shall take all reasonable steps to present collectively the dossiers referred to in the first subparagraph. Where a dossier was not presented by all notifiers concerned, it shall mention the efforts made and the reasons why certain producers have not participated.

2. The summary dossier shall include the following:

(a) a copy of the notification; in the case of a joint application made by several producers, a copy of the notifications presented in accordance with Article 4 and the name of the person designated by the producers concerned as being responsible for the joint dossier and the processing of the dossier in accordance with this Regulation;

(b) the recommended conditions for the use of an active substance, to be considered in relation to its inclusion in Annex I to the Directive;

(c) for each point of Annex II to the Directive, the available summaries and results of trials, the name of the person or institute that has carried out the trials; the same information for each point of Annex III to the Directive relevant to the assessment of the criteria referred to in Article 5 of the Directive and for one or more preparations which are representative for the conditions of use referred to in subparagraph (b);

(d) when the information referred to in certain points of subparagraph (c) is not available:

— either, in accordance with the introductory provisions of Annexes II and III of the Directive, the scientific or technical reasons demonstrating that the information is not necessary for the assessment of the active substance according to the criteria referred to in Article 5 of the Directive,

— or an undertaking by the producer or producers submitting the dossier that the missing information will be sent at a later date; a detailed timetable and documents showing that the undertaking can be fulfilled must be submitted.

3. The complete dossier shall contain the protocols and the complete study reports concerning all the information referred to in paragraph 2 (c).

4. Where, for any given active substance, the dossiers referred to in paragraph 1 are not sent within the time-limit laid down in Article 5 (4) or where the dossiers sent clearly do not satisfy the requirements laid down in paragraphs 2 and 3 hereof, the rapporteur Member State shall inform the Commission, giving the reasons pleaded by the notifiers.

5. On the basis of the report of the rapporteur Member State referred to in paragraph 4, the Commission shall present to the Committee a draft decision not to include the active substance in Annex I, in accordance with the final subparagraph of Article 8 (2) of the Directive, unless :

— a new time-limit has been granted for the submission of a dossier fulfilling the requirements of paragraphs 2 and 3 ; a new time-limit willl only be granted where the delay is proved to have been caused by efforts to present collective dossiers or by *force majeure*,

— a Member State informs the Commission of its wish to secure the inclusion of the active substance concerned in Annex I to the Directive and its readiness to ensure the composition of the dossiers as referred to in paragraph 1 hereof and to carry out the duties of notifier as set out in Articles 7 and 8 hereof.

Article 7

1. For each active substance for which it has been designated rapporteur, the Member State shall :

(a) examine the dossiers referred to in Article 6 (2) and (3), in the order in which they are received from the notifier or notifiers concerned, as well as any information as referred to in the third indent of Article 5 (4) and any other available information ; if several dossiers are presented for one active substance, the dossier presented last will determine the order of its examination ;

(b) immediately after examining a dossier, ensure that notifiers submit the updated summary dossier to the other Member States and to the Commission ;

(c) send the Commission, as quickly as possible and at the latest 12 months after receipt of a dossier as referred to in Article 6 (2) and (3), a report of its assessment of the dossier, including a recommendation :

— to include the active substance in Annex I to the Directive, stating the conditions for its inclusion, or

— to remove the active substance from the market, or

— to suspend the active substance from the market, with the option of reconsidering the inclusion of the active substance in Annex I after submission of the results of additional trials or of additional information specified in the report, or

— to postpone any decision on possible inclusion pending the submission of the results of additional trials or information specified in the report.

2. From the start of the examination referred to in paragraph 1 (a), the rapporteur Member State may request the notifiers to improve the dossier, or add to it. Moreover, the rapporteur Member State shall, during this examination, consult with experts from other Member States, accepted by the Commission on a proposal from the Member States concerned, with regard to the whole or certain parts of the dossier.

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 Standing Committee on Plant Health for examination.

After that examination, 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 either a draft directive to include the active substance in Annex I to the Directive, setting out (where appropriate) the conditions for such inclusion, or else a draft decision pursuant to the final subparagraph of Article 8 (2) of the Directive, whereby that active substance is not included in Annex I thereto.

4. However, where, following the examination referred to in paragraph 3, the submission of the results of certain additional trials or of additional information is required, the Commission shall determine :

— the time-limit within which the results or information concerned must be submitted to the rapporteur Member State and the experts designated according to paragraph 2 above,

— the time-limit within which the notifiers concerned must communicate to the rapporteur Member State and to the Commission their undertaking to submit the required results or information within the time-limit laid down in the first indent.

5. The Commission shall submit to the Committee a draft decision for non-inclusion in Annex I to the Directive. In accordance with the final subparagraph of Article 8 (2) thereof, where :

— the notifiers concerned have not communicated their undertaking to submit the required results within the time limit referred to in the second indent of paragraph 4,

— the rapporteur Member State has informed the Commission that the results referred to in the first indent of paragraph 4 have not been submitted within the time limit laid down.

Article 8

1. After receiving the results of the additional trials or the additional information, the rapporteur Member State must :

(a) examine it in conjunction with the results of the dossier already submitted for the substance concerned ;

(b) immediately after such examination, ensure that the summary of the additional trials and the results of those trials or the additional information are sent by the notifier to the other Member States and to the Commission ;

(c) communicate as quickly as possible, and within nine months at the latest following receipt of the results or information, to the Commission, the report of its assessment of the whole dossier including a recommendation :

— to include the active substance in Annex I stating the conditions for such inclusion,

— where the substance is already included in Annex I, to maintain or amend the conditions for inclusion, or

— to remove the active substance from the market, or

— to suspend the active substance from the market, with the option of reconsidering the inclusion of the active substance in Annex I after submission of certain additional trials or information in order to clarify any inconclusive points resulting from the additional trials or information submitted in accordance with Article 7 (4);

— or, where the results of the additional trials or information do not permit definite conclusions to be drawn, to postpone the decision pending the submission of certain further trials in order to clarify any inconclusive points resulting from the additional trials submitted in accordance with Article 7 (4).

2. The procedure provided for in Article 7 (2) is applicable to the examinations referred to in paragraph 1 (a) hereof.

3. After receiving the summary and report referred to in paragraph 1, the Commission shall refer them to the Committee for examination in the light of the examination already carried out in accordance with the first subparagraph of Article 7 (3).

After this examination, 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 either a draft decision to include the active substance in Annex I to the Directive, setting out (where appropriate) the conditions for such inclusion, or else a draft decision pursuant to the final subparagraph of Article 8 (2) of the Directive, whereby that active substance is not included in Annex I thereto. In the case of an active substance already listed in the said Annex, the draft decision may amend the conditions governing inclusion.

4. Where, following the examination by the Committee referred to in the first subparagraph of paragraph 3 above, the results of further trials appear necessary, Article 7 (4) and (5) and Article 8 (1) shall apply. In such cases, the Commission shall give the notifiers concerned its detailed reasons for requesting additional trials.

Article 9

Where, in respect of a substance mentioned in Annex A, the Commission presents a proposal for a total prohibition under Directive 79/117/EEC, the periods provided in this Regulation shall be suspended until a decision on this proposal has been taken. Where the Council decides on the total prohibition of the substance in the Annex to Directive 79/117/EEC, the procedure under this Regulation will be terminated.

Article 10

This Regulation shall enter into force on 1 February 1993.

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

Done at Brussels, 11 December 1992.

For the Commission

Ray MAC SHARRY

Member of the Commission

ANNEX I

LIST OF SUBSTANCES COVERED BY THE FIRST STAGE OF THE WORK PROGRAMME PROVIDED FOR IN ARTICLE 8 (2) OF DIRECTIVE 91/414/EEC

Name

1. Acephate
2. Metamidophos
3. Aldicarb
4. Amitraz
5. Azinphos-ethyl
6. Azinphos-methyl
7. Carbendazim
8. Benomyl
9. Thiophanate-methyl
10. Chlorpyriphos
11. Chlorpyriphos-methyl
12. Cyfluthrin
13. Beta-cyfluthrin
14. Cyhalothrin
15. Lambda-cyhalothrin
16. Cypermethrin
17. Alpha-cypermethrin
18. DNOC
19. Deltamethrin
20. Dinoterb
21. Endosulfan
22. Fenthion
23. Fenvalerate
24. Esfenvalerate
25. Lindane
26. Parathion
27. Parathion-methyl
28. Permethrin

---

29. Benalaxyl
30. Metalaxyl
31. Chlorothalonil
32. Dinocap
33. Fenarimol
34. Fentin acetate
35. Fentin hydroxide
36. Flusilazole
37. Imazalil
38. Mancozeb
39. Maneb
40. Zineb
41. Metiram
42. Propineb
43. Thiram
44. Ferbam
45. Ziram
46. Propiconazole
47. Pyrazophos
48. Quintozene
49. Thiabendazole
50. Vinclozolin
51. Procymidone
52. Iprodione
53. Chlozolinate

---

54. Chlorpropham
55. Propham
56. Daminozide
57. Maleic hydrazide
58. Tecnazene

---

59. Alachlor
60. Amitrole (Aminotriazole)
61. Atrazine
62. Simazine
63. Bentazone
64. Chlorotoluron
65. 2,4-D
66. 2,4-DB
67. Ethofumesate
68. Fluroxypyr
69. Glyphosate
70. Ioxynil
71. Bromoxynil
72. Isoproturon
73. MCPA
74. MCPB
75. Mecoprop
76. Mecoprop-P
77. Metsulfuron
78. Tifensulfuron
79. Triasulfuron
80. Molinate
81. Monolinuron
82. Linuron
83. Paraquat
84. Diquat
85. Pendimethalin
86. Desmedipham
87. Phenmedipham
88. Propyzamide
89. Pyridate
90. Warfarin

ANNEX II

MODEL

Notification of an active substance according to Article 4 (1) of Regulation (EEC) No 3600/92

1. *Identification data on the notifier*

1.1 Manufacturer of the active substance (name, address, including location of plant):

1.2 Notifying company (name, address, etc.) (if different from 1.1):

1.2.a. Acting as:

— sole representative designated by the manufacturer,

— importer not designated as sole representative of the manufacturer.

1.3 Name of the (physical) person responsible for the notification and further engagements resulting from Regulation (EEC) No 3600/92.

1.3.1. Address for correspondence:

1.3.2. (a) Telephone No:
(b) Telex No:
(c) Telefax No:

1.3.3. (a) Contact:
(b) Alternative:

2. *Information to facilitate identification*

2.1 Common name proposed or ISO-accepted, and synonyms, specifying, where relevant, any salts or esters produced by the manufacturer.

2.2 Chemical name (IUPAC nomenclature).

2.3 Manufacturer's development code number(s).

2.4 CAS, CIPAC and EEC numbers (if available).

2.5 Empirical and structural formula, molecular mass.

2.6 Specification of purity of the active substance in g/kg or g/l as appropriate.

2.7 Identity of isomers, impurities and additives (e.g. stabilizers), together with the structural formula and the possible range expressed in g/kg or g/l.

3. *Information on use conditions to be covered by the inclusion in Annex I and supported by the applicant*

3.1 Function, e.g. fungicide, herbicide, insecticide, repellant, growth regulator.

3.2 Field of use envisaged, e.g. field, glasshouse, food or feed storage, home garden.

3.3 Any specific health, agricultural, plant health or environmental conditions under which the active substance may or should not be used.

3.4 Harmful organisms controlled and crops or products protected or treated.

4. *Information on authorized uses known to the notifier*

4.1 Countries where there is registration (EC).

4.2 Contries where there is registration (non EC).

4.3 Registered uses in EC, including all relevant conditions.

4.4 Formulations Name, type (GIFAP/FAO code) and content of active substance (in g/kg or g/l).

5. *Undertaking to submit dossier*

The notification confirms that the above information is honest and correct. He agrees to submit to the competent authorities of the designated reporting Member State the dossiers as set out in Article 6 of Regulation (EEC) No 3600/92 within a period of 12 months of the Commission decision provided for in Article 5 (4) of this Regulation. Whenever this decision mentions several notifiers for this active substance, the notifier will undertake all reasonable efforts to present a single dossier collectively with the other notifiers.

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