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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

(OJ L 55, 29.2.2000, p. 25)

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COMMISSION REGULATION (EC) No 451/2000

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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

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 1999/80/EC [2], and in particular Article 8(2), second subparagraph, thereof,

Whereas:

(1) The Commission is to undertake a work programme for the gradual examination of active substances on the market two years after the date of notification of Directive 91/414/EEC within a period of 12 years. The first stage of the 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 work programme referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market [3], as last amended by Regulation (EC) No 1972/1999 [4]. The first stage is ongoing. It is necessary to continue and speed up the examination of the remaining active substances, taking into account experience from the first stage.

(2) Given the very high number of existing active substances on the market still to be evaluated, a programme in several phases must be established. Experience has shown that the evaluation and decision-making on an active substance is a time-consuming process. It is therefore not yet possible to provide for a detailed evaluation of all the existing active substances.

(3) Therefore the second stage will provide for the detailed evaluation of a number of active substances comparable to the number covered in the first stage whilst the third stage will prepare for the subsequent evaluation of active substances. For certain categories of active substances further harmonisation is required concerning the dossier to be provided and the evaluation to be carried out. Those categories should therefore not be included in the current proposed work programme but should be covered by further stages for their evaluation with a view to their possible inclusion in Annex I to Directive 91/414/EEC.

(4) For the second stage a selection should be made taking into account, in a balanced manner, such aspects as health and/or environmental concern, possibility of leaving residues in treated products, importance of the preparations containing these substances for agriculture, any manifest data gaps and any similarity of chemical or biological properties.

(5) The relationships 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, taking into account experience gained during the first stage of the programme. Close cooperation between all parties involved is necessary to increase the efficiency of the programme.

(6) Technical or scientific information about an active substance, in particular with regard to its potentially dangerous effects or its residues, submitted within the relevant time limits by any other

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[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 210, 10.8.1999, p. 13.
[3] OJ L 366, 15.12.1992, p. 10.
[4] OJ L 244, 16.9.1999, p. 41.

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interested parties should also be taken into consideration in the evaluations.

(7) A notification procedure should 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 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 Directive 91/414/EEC. Therefore the information submitted should include information on a limited range of representative uses for which the notifier must demonstrate, on the basis of the data submitted, that for one or more preparations the requirements of Directive 91/414/EEC in relation to the criteria referred to in its Article 5 can be met.

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

(9) The task of evaluation should be distributed among the competent authorities of the Member States. Therefore, for each active substance a rapporteur Member State should be designated to examine and evaluate the information submitted and to present to the Commission the results of the evaluation and a recommendation for a decision to be taken with regard to the active substance concerned.

(10) Rapporteur Member States should first examine dossiers received, assess the completeness check provided by the notifiers and report to the Commission. It should be established that Member States should send draft reports of their evaluations to the Commission generally within 12 months after the dossiers submitted by notifiers have been considered complete.

(11) The draft reports prepared by the rapporteur Member States should, where necessary, be the subject of preliminary examination by experts of other Member States within a programme coordinated by the Commission before they are submitted to the Standing Committee on Plant Health.

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

(13) The notification and submission of a dossier should not be a prerequisite for the possibility after inclusion of the active substance in Annex I to Directive 91/414/EEC to place plant protection products on the market subject to the provisions of Article 13 of Directive 91/414/EEC. Therefore, it should be possible for operators which have not presented notifications to be informed at all stages of the possible further requirements for continued marketing of plant protection products containing an active substance under evaluation.

(14) The procedures provided for 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 [1], as last amended by Commission Directive 91/188/EEC [2], where information becomes available to the Commission showing that its requirements may be satisfied.

(15) Directive 91/414/EEC provides in Article 8(2), second subparagraph, a 12-year period for the work programme concerning the evaluation of existing active substances. The 12-year period may be extended by the Commission subject to the conclusions of a

[1] OJ L 33, 8.2.1979, p. 36.
[2] OJ L 92, 13.4.1991, p. 42.

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progress report, referred to in Article 8(2), third subparagraph, on the programme to the European Parliament and the Council. On the expiry of the time limit, whether or not it was extended, Member States will have to withdraw authorisations of plant protection products containing the active substances which were not included in Annex I to Directive 91/414/EEC.

The Commission, subject to the conclusions of that report, will adopt further detailed regulatory provisions serving to finalise as soon as possible the evaluation and decision making of active substances for which the provisions of the present Regulation concerning notification and submission of complete dossiers axe satisfied.

Article 8(2), fourth subparagraph, 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 Directive 91/414/EEC are not satisfied or the requisite information and data have not been submitted within the prescribed time period and for the withdrawal by Member States of authorisations of plant protection products containing such active substances. However, subject to the conclusions of the said report and if necessary, it may be appropriate to re-examine these provisions for certain uses which are essential and for which there is no alternative to protect efficiently plants or plant products such as to allow the development of alternatives replacing the use of withdrawn products. The necessity of re-examining those provisions will have to be demonstrated on a case-by-case basis.

(16) If, for a particular active substance, the requirements of the present Regulation concerning notification and submission of complete dossiers are not satisfied, interested parties are not prevented from seeking inclusion of such active substances in Annex I to Directive 91/414/EEC, in accordance with the procedures under Article 6(2) of Directive 91/414/EEC, at a later date.

(17) A third stage of work is envisaged for all the active substances not covered by the first and second stage of the programme. Producers wishing to secure the inclusion of such active substances in Annex I to Directive 91/414/EEC should provide detailed information relating to the current stage of completeness of their dossiers and on the endpoints, which would be useful for further prioritisation of the work programme, and undertake to provide a full data package. It is also appropriate to indicate now the time limit for submission of the full data package.

(18) It is necessary to inform the producers as early as possible about future stages of the re-evaluation programme by publishing the active substances which will be included in the third stage of the programme in order to facilitate the submission of collective dossiers and the preparation of the necessary studies and data.

(19) In order to ensure the proper implementation of this work programme, a fee should be paid to the rapporteur Member States for the detailed evaluation of notifications and dossiers. The cost structure in the Member States is not the same. It is therefore not possible to harmonise completely the amount of such fees. A fee should also be paid to the authority designated by the Commission to examine the notifications for the active substances covered by the third stage.

(20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plant Health,

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HAS ADOPTED THIS REGULATION:

CHAPTER 1

GENERAL PROVISIONS AND DEFINITIONS

Article 1

Scope

1. This Regulation lays down detailed rules for the implementation of the second and third stages of the work programme referred to in Article 8(2) of Directive 91/414/EEC, hereinafter referred to as 'the Directive'.

2. The second stage concerns the evaluation of the active substances listed in Annex I to this Regulation with a view to their possible inclusion in Annex I to the Directive.

3. The third stage concerns the reporting of the active substances referred to in Annex II to this Regulation with a view to their possible inclusion at a later stage in a subsequent priority list of active substances with a view to their possible inclusion in Annex I to the Directive.

4. Article 6(2), Article 6(3) and the second subparagraph of Article 6(4) of the Directive shall not apply to a substance listed in Annexes I and II to this Regulation as long as the procedures provided for in this Regulation with regard to that substance have not been finalised.

5. 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

1. For the purpose of this Regulation, plant protection products, substances, active substances, preparations and authorisations of plant protection products shall have the meanings defined in Article 2 of the Directive.

2. For the purpose of this Regulation, the following definitions shall also apply:

(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 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 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 own or who contracts out to another party the manufacturing of the active substance on his behalf;

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

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Article 3

Member State authority

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

2. In each Member State one authority, which is referred to in Annex III, 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 authority of each other Member State of any modifications to the communicated details concerning the designated coordinating authority.

CHAPTER 2

SECOND STAGE OF THE WORK PROGRAMME

Article 4

Notification

1. Any producer wishing to secure the inclusion of an active substance referred to in Annex I to this Regulation, or any variants thereof such as salts, esters or amines, in Annex I to the Directive shall so notify, for each active substance separately, the rapporteur Member State designated in Annex I to this Regulation within six months after the date of entry into force of this Regulation.

2. Notification must be made on paper and sent by registered mail to the coordinating authority in the rapporteur Member State, referred to in Annex III to this Regulation, in accordance with the model notification as shown in Part 1 of Annex IV to this Regulation. A copy of the notification shall be sent to the European Commission, Health and Consumer Protection DG, Rue de la Loi/Wetstraat 200, B-1049 Brussels.

3. Any producer who has not notified any given active substance referred to in paragraph 1 within the time limit referred to in that paragraph or whose notification was rejected in accordance with the provisions of Article 5(2) shall be permitted to participate in this programme only collectively with one or more notifiers of the active substance, whose notification was accepted in accordance with Article 5(2), in submitting a joint dossier.

Article 5

Examination of notifications and request for submission of dossiers to designated rapporteur Member States

1. For each active substance for which a Member State has been designated rapporteur, it shall examine the notifications referred to in Article 4(2) and, at the latest three months after the time limit referred to in Article 4(1), report to the Commission on the admissibility of the notifications received taking into account the criteria as referred to in Annex V, Part 1.

2. The Commission shall refer the reports referred to in paragraph 1 within three months from the receipt thereof to the committee for further examination concerning their admissibility, taking into account the criteria as referred to in Annex V, Part 1.

Following that examination, a regulation shall be adopted in accordance with the procedure laid down in Article 19 of the Directive establishing the list of active substances, adopted for evaluation with a view to their possible inclusion in Annex I to the Directive. Only active substances for which at least one notification was considered admissible in accordance with the provisions of the first subparagraph shall be included in that Regulation.

3. In the list referred to in paragraph 2, certain active substances with similar structures or chemical properties may be grouped together;

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if an active substance has been notified with different compositions which may lead to different toxicological properties or have different environmental effects, those compositions may be listed separately.

4. For each active substance adopted for assessment, the Regulation referred to in paragraph 2 shall specify:

(a) the names and addresses of all notifiers who have made notifications in accordance with Article 4(1) and (2) and which have been considered to be admissible following their examination in accordance with the first subparagraph of paragraph 2;

(b) the name of the Member State designated as rapporteur; this will be the same Member State as the one designated in Annex I unless an imbalance has become apparent in the number of active substances attributed to the different Member States;

(c) the time limit for the submission to the rapporteur Member State of the dossiers referred to in Article 6, which shall be a period of 12 months;

(d) the same time limit for the submission to the rapporteur Member States by any interested parties of relevant information which may contribute to the evaluation, in particular with regard to the potentially dangerous effects of the active substance or its residues on human and animal health and on the environment.

5. From the time of the adoption of the Regulation referred to in paragraph 2, if a Member State envisages taking 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 report referred to in Article 8, the Member State shall inform the Commission and the other Members States as soon as possible, citing the reasons for its intended action.

6. When, during the assessment and evaluation referred to in Articles 6 and 7, an imbalance becomes apparent in the responsibilities borne by the Member States as rapporteurs, it may be decided, in accordance with the procedure laid down in Article 19 of the Directive, to replace a Member State originally designated as rapporteur for a particular active substance by another Member State.

In such cases, the original rapporteur Member State shall inform the notifiers concerned and shall transfer to the newly designated rapporteur Member State all correspondence and information which it has received as rapporteur Member State for the active substance concerned. The original Member State shall return the fee referred to in Article 12, except the part referred to in Article 12(2)(d) to the notifiers concerned. The newly designated rapporteur Member State shall then require the notifiers to pay the fee referred to in Article 12, except the part referred to in Article 12(2)(d).

7. When a notifier decides to end its participation in the work programme for an active substance, he shall inform at the same time the rapporteur Member State, the Commission and the other notifiers for the substance concerned, mentioning the reasons. Where a notifier ends his participation or fails to fulfil his obligations provided for in this Regulation, the procedures provided for in Article 7 or Article 8 shall not be continued for his dossier.

When a notifier agrees with another producer that the notifier shall be replaced for the purposes of further participation in the work programmes under this Regulation, the notifier and the other producer shall inform the rapporteur Member State and the Commission by a common declaration, agreeing that the other producer shall replace the original notifier in carrying out the notifier's duties as set out in Articles 6, 7 and 8; they shall ensure that the other notifiers for the substance concerned are informed at the same time. In such a case, the other producer may be liable for any fees remaining payable under the regime established by the rapporteur Member State pursuant to Article 12.

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Article 6

Submission of dossiers by notifiers

1. Within the time limit referred to in Article 5(4)(c), for each active substance the notifiers specified in the Regulation referred to in that Article shall, individually or collectively, submit to the designated authority of the rapporteur Member State for any given active substance the complete dossier referred to in paragraph 3, including the summary dossier referred to in paragraph 2.

Where for any substance the Regulation referred to in Article 5 indicates several notifications, the notifiers concerned shall take all reasonable steps to present collectively the dossiers as 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 made 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) a limited range of representative uses of the active substance for which it has to be demonstrated by the notifier, on the basis of the data submitted, that for one or more preparations the requirements of the Directive in relation to the criteria referred to in Article 5 thereof can be met;

(c) — for each point of Annex II to the Directive, the summaries and results of studies and trials, and 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 for one or more preparations which are representative for the uses referred to in subparagraph (b) taking into account the fact that data gaps in the information of the Annex II dossier resulting from the proposed limited range of representative uses of the active substance may lead to restrictions in the inclusion in Annex I to the Directive,

— for studies not yet fully completed, the evidence that these studies have been commissioned at the latest three months after the entry into force of this Regulation with an undertaking that they will be submitted at the latest within 12 months after the time limit referred to in Article 5(4)(c);

(d) a check by the notifier of the completeness of the dossier.

3. The complete dossier shall contain physically the individual test and study reports concerning all the information referred to in paragraph 2(c), or the protocols and the undertakings referred to in paragraph 2(c) where work is in progress.

4. Member States shall determine the number of copies and the format of the dossiers referred to to in paragraphs 2 and 3 to be submitted by the notifiers. In determining the format of the dossier, Member States shall take the utmost account of the recommendations made by the Commission in the framework of the Standing Committee on Plant Health.

5. Where, for any given active substance, the dossiers referred to in paragraph 1 are not sent within the time limit referred to in Article 5 (4)(c), the rapporteur Member State shall inform the Commission at the latest within three months, giving the reasons pleaded by the notifiers.

6. On the basis of the report of the rapporteur Member State referred to in paragraph 5, a new time limit shall only be established in accordance with the procedure laid down in Article 19 of the Directive in

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the Regulation referred to in Article 5 for the submission of a dossier fulfilling the requirements of paragraphs 2 and 3 where the delay is demonstrated to have been caused by *force majeure*.

7. After that examination, the Commission shall decide, as provided for in Article 8(2), fourth subparagraph, of the Directive, not to include in Annex I to the Directive an active substance for which no notification or no dossier has been submitted within the prescribed time limit mentioning the reasons for the non-inclusion. Member States shall withdraw by 25 July 2003 authorisations of plant protection products containing those active substances.

Article 7

Completeness check of dossiers

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) and assess the completeness check(s) provided by the notifiers;

(b) at the latest six months after the receipt of all dossiers for an active substance, report to the Commission on the completeness of the dossiers; for those active substances for which one or more dossiers are considered to be complete within the meaning of Article 6(2) and (3), the rapporteur Member State shall perform the evaluation as referred to in Article 8, unless the Commission informs the rapporteur Member State within two months that the dossier is not to be considered complete. For those active substances for which the dossier is to be completed, as provided for under Article 6(2)(c), third indent, the report must confirm the date by which the dossier is to be completed and from which the evaluation as referred to in Article 8 will begin.

2. For those active substances for which a rapporteur Member State or the Commission consider that no dossier is complete within the meaning of Article 6(2) and (3), the Commission shall, within three months after the receipt of the report of the rapporteur Member State referred to in paragraph (1)(b), refer that report to the committee. In accordance with the procedure laid down in Article 19 of the Directive it shall be decided whether a dossier is considered complete within the meaning of Article 6(2) and (3). Where the dossier is considered complete, the rapporteur Member State shall perform the evaluation referred to in Article 8.

3. After that examination, the Commission shall decide, as provided for in Article 8(2), fourth subparagraph, of the Directive, not to include in Annex I to the Directive active substances for which no complete dossier has been submitted within the prescribed time limit mentioning the reasons for the non-inclusion. Member States shall withdraw by 25 July 2003 authorisations of plant protection products containing those active substances.

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Article 8

Evaluation of dossiers by rapporteur Member States and the EFSA

1. The rapporteur Member State shall evaluate and report only on those active substances for which at least one dossier has been determined to be complete in accordance with Article 6(2) and (3). For such active substances it shall evaluate and report only on the complete dossiers and for the other dossiers it shall check the identity and impurities of the active substance. The rapporteur Member State shall take into consideration the information available on potentially dangerous effects in the other dossiers submitted by any notifier or by any third party in accordance with the provisions of Article 5(4)(d). It shall send a draft report of its assessment of the dossier to the European Food Safety Authority (EFSA) as quickly as possible, and at the latest 12 months after the dossier was determined to be complete. The draft assessment report shall be submitted in the format recommended in

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accordance with the procedure provided for in Article 19 of the Directive.

At the same time, the rapporteur Member State shall make a recommendation to the Commission either:

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

— not to include the active substance in Annex I to the Directive, stating the reasons for the non-inclusion.

The rapporteur Member State shall in particular include in the draft assessment report a reference to each test and study report, for each point of Annex II and Annex III to the Directive, relied on for the assessment. This reference shall be made in the form of a list of test and study reports including the title, the author(s), the date of the study or test report 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. It shall also mention for the other notified sources of the active substances for which the dossier was considered not to be complete whether it can be concluded that such active substances are comparable within the meaning of Article 13(5) of the Directive.

2. Without prejudice to Article 7 of the Directive, submission of new studies shall not be accepted, except for the studies as referred to in Article 6(2)(c), third indent. The rapporteur Member State may request the notifiers to submit further data which are necessary to clarify the dossier. When doing so the rapporteur Member State shall set a time limit within which the information should be provided; this time limit shall not affect the time limit for the submission of the report referred to in paragraph 1.

The rapporteur Member State may, from the start of this examination, consult with experts from the EFSA and may request additional technical or scientific information from other Member States to assist the evaluation. The rapporteur Member State may perform the evaluation together with a co-rapporteur Member State.

The rapporteur Member State shall request the notifiers to submit an updated summary dossier to the EFSA, the other Member States and on request to the Commission at the same time as the rapporteur's draft assessment report is sent to the EFSA.

The Member States, the EFSA or the Commission may request through the rapporteur Member State that notifiers also send them the updated complete dossiers or parts thereof.

3. As soon as it becomes evident to a rapporteur Member State that it will be unable to comply with the time limit specified in paragraph 1 for the submission of the draft assessment report to the EFSA, it shall inform the Commission and the EFSA and give the reasons for the delay. All Member States shall provide to the Commission and the EFSA a report of their progress on the evaluation of the active substances for which they are rapporteur. Such report has to be made by 30 April 2003.

4. After receiving the updated summary dossier and the draft assessment report referred to in paragraph 1, the EFSA shall, within 30 days, acknowledge receipt of the report to the rapporteur Member State. In exceptional cases where the draft assessment report clearly does not fulfil the requirements concerning the format recommended by the Commission, the Commission shall agree with the EFSA and the rapporteur Member State on a period for resubmission of an amended report. This period shall not exceed four months.

5. The EFSA shall circulate the rapporteur's draft assessment report to the Member States and may organise a consultation of experts including the rapporteur Member State. The EFSA may consult some or all of the notifiers of active substances specified in Annex I on the report or parts of the report on the relevant active substance.

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Without prejudice to Article 7 of the Directive, submission of new studies shall not be accepted. The rapporteur Member State, with the agreement of the EFSA, may request the notifiers to submit within specified periods further data considered by the rapporteur member state of the EFSA necessary to clarify the dossier.

6. The EFSA shall make available at specific request or keep available for consultation by any person the following:

(a) the information referred to in the last subparagraph of paragraph 1, except the elements thereof which have been accepted as confidential in accordance with Article 14 of the Directive;

(b) the name of the active substance;

(c) the content of the pure active substance in the manufactured material;

(d) the list of any data required for consideration of the possible inclusion of the active substance into Annex I to the Directive, first as contained in the rapporteur's report and secondly as finalised by the EFSA;

(e) the draft assessment report, except the elements thereof which have been accepted as confidential in accordance with Article 14 of the Directive.

7. The EFSA shall evaluate the rapporteur's draft assessment report and deliver its opinion on whether the active substance can be expected to meet the safety requirements of the Directive to the Commission at the latest one year after receipt of the rapporteur Member State draft assessment report. Where appropriate, the EFSA shall give its opinion on the available options claimed to meet the safety requirements. The Commission and the EFSA shall agree on a schedule for the delivery of the opinions in order to facilitate the planning of the work. The Commission and the EFSA shall agree on the format in which the opinion of the EFSA is submitted.

8. At the latest six months after receipt of the EFSA opinion referred to in paragraph 7, the Commission shall submit the draft review report. Without prejudice to any proposal it may submit with a view to amending the Annex to Directive 79/117/EEC, and on the basis of the finalised review report it shall submit 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, or

(b) a draft decision addressed to the Member States to withdraw the authorisations 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, mentioning the reasons for the non-inclusion.

The directive or decision shall be adopted in accordance with the procedure provided for in Article 19 of the Directive.

9. Where the Commission submits a draft directive or a draft decision in accordance with paragraph 8, it shall at the same time submit the conclusions of the Committee's examination in the format of a finalised review report to be noted in the summary record of the meeting.

The finalised 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 for public consultation.

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Article 9

Suspension of evaluation

Where, in respect of a substance mentioned in Annex I to this Regulation, the Commission presents a proposal for a total prohibition under Directive 79/117/EEC, the time limits provided for in this Regulation

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shall be suspended until a decision on that proposal has been taken. Where the Council decides on the total prohibition of the substance under Directive 79/117/EEC, the procedure under this Regulation shall be terminated.

CHAPTER 3

THIRD STAGE OF THE WORK PROGRAMME

Article 10

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 the body referred to in Annex VII to this Regulation. The Commission shall give regular follow-up of the tasks mentioned in Annex VII to this Regulation entrusted to the body referred to in that Annex. In accordance with the procedure laid down in Article 19 of the Directive it may be decided to designate another body if it appears that the tasks are not adequately performed.

2. Notifications shall 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 Section 1 of the model notification as shown in Annex IV, Part 2 hereto;

and

(b) within nine months of the date of entry into force of this Regulation, a second notification in accordance with Sections 1 and 2 of the model notification as shown in Annex IV, Part 2 hereto, including a written commitment to present a complete dossier.

3. Detailed provisions concerning the submission of such dossiers, the time limit(s) for their submission and the fee regime for the active substances concerned shall be established by the Commission in a Regulation to be adopted in accordance with Article 8(2), second subparagraph, of the Directive.

4. ►M1 The time limit for the submission of a list of available studies shall be 23 May 2003. A full data package shall be available on 23 May 2003 at the latest. ◄ The full data package shall contain physically the individual test and study reports concerning all the information referred to in Article 6(2)(c), first and second indents. Nevertheless, in the Regulation referred to in paragraph 3, a later time limit may be established in exceptional cases for the results of long-term studies, not expected to be fully completed by that date, provided that the data package contains:

— evidence that such studies have been commissioned at the latest within 12 months of the date of the entry into force of this Regulation,

— a due scientific justification,

— the protocol and a progress report of the study.

5. Any producer who has not notified any given active substance referred to in paragraph 1 within the time limits referred to in paragraph 2 or whose notification was rejected in accordance with Article 11 will be permitted to participate in the review programme only collectively with one or more notifiers of the active substance, whose notification was considered admissible in accordance with Article 11, in submitting a joint dossier.

Article 11

Examination of notifications

1. The Commission shall, within three months after the time limit referred to in Article 10(2)(b), inform the committee of the notifications received in time. At the latest eight months after the receipt of the notifications, the commission will report to the Committee for

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further examination on the admissibility of the notifications received taking into account the criteria as referred to in Annex V, Part 2.

2. The Commission shall decide, as provided for in Article 8(2), fourth subparagraph of the Directive, not to include in Annex I to the Directive active substances referred to in Annex II to this Regulation for which no admissible notification or no full data package has been submitted within the prescribed time limit mentioning the reasons for the non-inclusion. ►M1 Member States shall withdraw by 25 July 2003 authorisations of plant-protection products containing active substances for which no admissible notification has been submitted. Authorisations of plant-protection products containing active substances for which no list of available studies has been submitted or for which no full data package is available shall be withdrawn by the deadline referred to in the Decision on the non-inclusion of the active substance concerned. ◄

CHAPTER 4

FEES

Article 12

Fees for the second priority list

▼M2

1. Member States shall establish a regime obliging notifiers to pay a fee or charge for the administrative treatment and evaluation of notifications and dossiers.

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2. For this purpose, the Member States shall:

▼M2

(a) require the payment of a fee or charge for each notification and for each submission of a dossier;

▼B

(b) ensure that the amount of the fee is established in a transparent manner with a view to corresponding to the real cost of the examination and administrative treatment of a notification and a dossier; however, Member States may provide for a scale of fixed charges based on average costs for the calculation of the total fee;

▼M2

(c) ensure that the fee or charge is received in accordance with the instructions given by the organisation in each Member State listed in Annex VI and that the income from the fee or charge is used to finance exclusively the costs actually incurred by the Member State for the evaluation and administrative treatment of the notifications and the dossiers for which that Member State is rapporteur or to finance general activities of the Member States resulting from Articles 7 and 8;

▼B

(d) require that a first part of the fee, covering the costs of the rapporteur Member State's obligations resulting from Article 5(1) and Article 7, is paid at the time of the submission of the notification referred to in Article 4; this part shall not be refundable under any circumstances.

Article 13

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

Any producers submitting a notification in accordance with Article 10 shall at the time of the submission of their first notification, as referred to in Article 10(2)(a), pay a fee of EUR 5 000 for each active substance to the body referred to in Annex VII. The fee shall be used to finance exclusively the costs actually incurred for the tasks referred to in Annex VII.

▼B

Article 14

Other charges, levies or fees

Articles 12 and 13 are without prejudice to Member States' rights to maintain or introduce, in accordance with the Treaty, charges, levies or fees with regard to the authorisation, placing on the market, use and control of active substances and plant protection products other than the fee provided for in Articles 12 and 13.

CHAPTER 5

FINAL PROVISIONS

Article 15

Temporary measures

The Commission shall report to the committee on the conclusions of its progress report, referred to in Article 8(2), third subparagraph, of the Directive.

If necessary and on a case-by-case basis, the Commission may take appropriate temporary measures as provided for by Article 8(2), third subparagraph, of the Directive for uses for which additional technical evidence has been provided demonstrating the essential need for further use of the active substance and that there is no efficient alternative.

Article 16

Entry into force

This Regulation shall enter into force on 1 March 2000.

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

▼B

ANNEX I

List of active substances to be covered by the second stage of the work programme provided for in Article 8(2) of the Directive with the designated rapporteur Member State

Name

PART A: ANTICHOLINESTERASE ACTIVE SUBSTANCES

Organophosphates	Rapporteur Member State
Azamethiphos	United Kingdom
Ampropylfos	Sweden
Bromophos	Austria
Bromophos-ethyl	Austria
Cadusafos	Greece
Carbophenothion	Luxembourg
Chlorfenvinphos	Italy
Tetrachlorvinphos	Italy
Chlormephos	Spain
Chlorthiophos	Spain
Demeton-S-methyl	France
Demeton-S-methyl-sulphone	France
Oxydemeton-methyl	France
Dialifos	France
Diazinon	Portugal
Dichlofenthion	The Netherlands
Dichlorvos	Italy
Dicrotophos	Italy
Monocrotophos	Italy
Dimefox	Germany
Dimethoate	United Kingdom
Omethoate	United Kingdom
Formothion	United Kingdom
Dioxathion	France
Disulfoton	Greece
Ditalimfos	Austria
Ethephon	The Netherlands
Ethion	France
Ethoate-methyl	Italy
Ethoprophos	United Kingdom
Etrimfos	United Kingdom
Fenamiphos	The Netherlands
Fenitrothion	Denmark
Fonofos	Ireland
Isazofos	France
Isoxathion	Spain
Heptenophos	Austria
Idofenphos	France
Isofenphos	Austria
Malathion	Finland
Mecarbam	Spain

▼B

Organophosphates	Rapporteur Member State
Mephosfolan	Ireland
Methidathion	Portugal
Mevinphos	Sweden
Naled	France
Phorate	United Kingdom
Phosalone	Austria
Phosmet	Spain
Phosphamidon	Germany
Phoxim	Belgium
Pirimiphos-ethyl	United Kingdom
Pirimiphos-methyl	United Kingdom
Profenofos	Germany
Propetamphos	Luxembourg
Prothiofos	Spain
Prothoate	Greece
Pyraclofos	Spain
Pyridaphenthion	Italy
Quinalphos	France
Sulprofos	Spain
Sulfotep	Finland
Temephos	Ireland
Terbufos	Austria
Thiometon	The Netherlands
Thionazin	Italy
Tolclofos-methyl	►M1 Sweden ◄
Triazophos	Greece
Trichlorfon	Portugal
Trichloronat	Finland
Vamidothion	Portugal

Carbamates	Rapporteur Member State
Bendiocarb	United Kingdom
Benfuracarb	Belgium
Carbofuran	Belgium
Carbosulfan	Belgium
Furathiocarb	Belgium
Butocarboxim	Germany
Butoxycarboxim	Germany
Carbaryl	Spain
Dioxacarb	Denmark
Ethiofencarb	Germany
Formetanate	Italy
Methiocarb	Germany
Methomyl	United Kingdom
Thiodicarb	United Kingdom
Oxamyl	Ireland
Pirimicarb	Portugal

▼B

Carbamates	Rapporteur Member State
Promecarb	Portugal
Propamocarb	Sweden
Prothiocarb	Sweden
Propoxur	Belgium
Thiofanox	France
Triazamate	United Kingdom

PART B

1,3-dichloropropene	Spain
1,3-dichloropropene (cis)	Spain
Captan	Italy
Folpet	Italy
Clodinafop	The Netherlands
Clopyralid	Finland
Cyanazine	Sweden
Cyprodinil	France
Dichlorprop	Denmark
Dichlorprop-P	Denmark
Dimethenamid	Germany
Dimethomorph	Germany
Diuron	Denmark
Fipronil	France
Fosetyl	France
Glufosinate	Sweden
Haloxyfop	Denmark
Haloxyfop-R	Denmark
Metconazole	Belgium
Methoxychlor	Italy
Metolachlor	Belgium
Metribuzin	Germany
Prometryn	Greece
Pyrimethanil	Portugal
Rimsulfuron	Germany
Terbutryne	Germany
Tolylfluanid	Finland
Tribenuron	Sweden
Triclopyr	Ireland
Trifluralin	Greece
Trinexapac	The Netherlands
Triticonazole	Austria

PART C

Barban	Belgium
Bromocyclen	Denmark
Bronopol	Germany
Chloral-semi-acetal	Germany

▼B

Chloral-bis-acylal	Germany
Chlorfenprop	Greece
Chlorobenzilate	Spain
Chloroxuron	Spain
P-chloronitrobenzene	Spain
DADZ(Zinc-diethyldithiocarbamate)	France
Di-allate	France
Difenoxuron	Ireland
(2-dithiocyanomethylthio)benzothiazol	Italy
Fluorodifen	Italy
Furfural	Luxembourg
Isocarbamide	The Netherlands
Naphthylacetic acid hydrazide	Austria
Noruron	Portugal
Pentachlorophenol	Finland
4-t-pentylphenol	Sweden
Propazine	United Kingdom
Sodium diacetoneketogulonate	United Kingdom
Sodium dimethyldithiocarbamate	United Kingdom
2,4,5-T	France

▼B

ANNEX II

Active substances covered by the third 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 with the exception of the following active substances:

1. the active substances listed in the Annex to Regulation (EEC) No 3600/92;
2. the active substances listed in Annex I to this Regulation;
3. active substances which are micro-organisms including viruses;
4. active substances of which the use is authorised in human foodstuffs or animal feeding stuffs in accordance with EU legislation;
5. active substances which are plant extracts;
6. active substances which are animal products or derived thereof by simple processing;
7. 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 dispenses, in conformity with Council Regulation (EEC) No 2092/91 ([1]) concerning organic farming;
8. active substances which are or will be exclusively used as rodenticides;
9. active substances which are or will exclusively be used on stored plants or plant products;
10. the following commodity substances:

    aluminium sulphate

    calcium chloride

    CO_2

    EDTA and salts thereof

    ethanol

    grease (bands, fruit trees)

    fatty alcohols

    iron sulphate

    lime phosphate

    lime sulphur

    nitrogen

    paraffin oil

    petroleum oils

    potassium permanganate

    propionic acid

    resins and polymers

    sodium chloride

    sodium hydroxide

    sulphur and sulphur dioxide

    sulphuric acid

    waxes.

([1]) OJ L 36, 10.2.1998, p. 16.

▼B

ANNEX III

Coordinating authority in the Member States

AUSTRIA

Bundesamt und Forschungszentrum für Landwirtschaft
Spargelfeldstraße 191
A-1226 Wien

BELGIUM

Ministère des classes moyennes et de l'agriculture,
Service 'Qualité des matières premières et analyses'
WTC 3, 8e étage
Boulevard Simon Bolivar 30
B-1000 Bruxelles

Ministerie van Middenstand en Landbouw
Dienst Kwaliteit van de grondstoffen en analyses
WTC 3, 8e verdieping
Simon Bolivarlaan 30
B-1000 Brussel

DENMARK

Ministry of Environment and Energy
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 Braunschweig

GREECE

Hellenic Republic
Ministry of Agriculture
General Directorate of Plant Produce
Directorate of Plant Produce Protection
Department of Pesticides
3-4 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
Service de la protection des végétaux
251, rue de Vaugirard
F-75732 Paris Cedex 15

▼B

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 Roma

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
Postbus 217
6700 AE Wageningen
Nederland

PORTUGAL

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

SWEDEN

Kemikalieinspektionen
Box 1384
S-171 27 Solna

UNITED KINGDOM

Pesticides Safety Directorate
Ministry of Agriculture, Fisheries and Food
Mallard House
Kings Pool
3 Peasholme Green,
York YO1 7PX
United Kingdom

▼B

ANNEX IV

PART 1

Notification of an active substance according to Article 4

MODEL

The notification must be made on paper and sent by registered mail.

The notification shall contain the following information:

1. *Identification data on the notifier*

   1.1. Manufacturer of the active substance as defined in Article 2(2)(a) (name, address, including location of plant):

   1.2. Name and address of the producer as defined in Article 2(2)(a) including the name of the (physical) person responsible for the notification and further engagements resulting from this Regulation:

   1.2.1. (a) Telephone No:

   (b) Fax 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) specifying, where relevant, any variants thereof such as salts, esters or amines produced by the manufacturer:

   2.2. Chemical name (IUPAC and CAS nomenclature):

   2.3. CAS, CIPAC and EEC numbers (if available):

   2.4. Empirical and structural formula, molecular mass:

   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 Council Directive 67/548/EEC (health and environment effects) (OJ 196, 16.8.1967, p. 1):

3. *Undertaking*

   The notifier undertakes to submit to the designated coordinating authority of the designated rapporteur Member State the dossiers as set out in Article 6 of this Regulation within the time limit provided for in the regulation to be adopted according to Article 5(2). Whenever this 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 the remaining part of the fee as provided for in Article 12(2) in accordance with the instructions given by the organisation of the designated rapporteur Member State referred to in Annex VI at the time of the submission of the full dossier for active substances covered by the regulation meant in Article 5(2). In case a new rapporteur Member State is designated in accordance with Article 5(6), the notifier undertakes to pay the remaining part of the fee as provided for in Article 12(2) to the newly designated rapporteur Member State in accordance with the instructions given by the organisation of the newly designated rapporteur Member State referred to in Annex VI.

   The notifier confirms that he has paid the first part of the fee as provided for in Article 12(2)(d) at the time of the submission of the notification in accordance with the instructions of the organisation of the designated rapporteur Member State referred to in Annex VI, or undertakes to pay it immediately where the designated rapporteur Member State has instructed him to wait with the payment until requested to do so.

   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.

   The notifier confirms that the above information submitted on ..... (date) is honest and correct.

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

▼B

PART 2

Notification of an active substance according to Article 10

MODEL

The notification shall be presented in two sections:

Sections 1 and 2 have to be submitted both on paper and as a computer readable file. The detailed format will be defined by the body designated in Annex VII in consultation with the Commission.

SECTION 1

Reference No:

1. *Identification data on the notifier*

   1.1. Manufacturer of the active substance as defined in Article 2(2)(a) (name, address, including location of plant):

   1.2. Name and address of the producer as defined in Article 2(2)(a) including the name of the (physical) person responsible for the notification and further engagements resulting from this Regulation:

   1.2.1. (a) Telephone No:

   (b) Fax 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) specifying, where relevant, any variants thereof such as salts, esters or amines produced by the manufacturer:

   2.2. Chemical name (IUPAC and CAS nomenclature):

   2.3. CAS, CIPAC and EEC numbers (if available):

   2.4. Empirical and structural formula, molecular mass:

   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. *Undertaking*

   The notifier confirms that the information submitted in Section 2, 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 referred to in Article 11(3).

   The notifier undertakes to submit to the designated coordinating authority of the designated rapporteur Member State the dossiers within the time limit provided for in the Regulation to be adopted according to Article 10(3) of this Regulation. Whenever this 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 13 at the time of the submission of the notification to the body designated in Annex VII.

   The notifier declares that he is aware that he will be charged a fee by a designated rapporteur Member State at the time of the submission of the full dossier for active substances covered by the Regulation meant in Article 11.

   The notifier confirmes that the above information and the information which is submitted on . . . . . (date) as Section 2 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 inclosed if necessary.

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

▼B

SECTION 2

Reference No:

The notifier has to resubmit in points 1 and 2 the same information as already submitted as part of his notification in accordance with Section 1, points 1 and 2. Changes, if any, should be clearly marked.

1. *Identification data on the notifier*

   1.1. Manufacturer of the active substance as defined in Article 2(2)(a) (name, address, including location of plant):

   1.2. Name and address of the producer as defined in Article 2(2)(a) including the name of the (physical) person responsible for the notification and further engagements resulting from this Regulation:

   1.2.1. (a) Telephone No:

   (b) Fax 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) specifying, where relevant, any variants thereof such as salts, esters or amines produced by the manufacturer:

   2.2. Chemical name (IUPAC and CAS nomenclature):

   2.3. CAS, CIPAC and EEC numbers (if available):

   2.4. Empirical and structural formula, molecular mass:

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

   2.6. Classification and lebelling 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 Plant 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 of the most recent review of the active substance in a Member State of the European Union.

7. Date 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:

▼B

IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES

Common name (ISO)	
Chemical name (IUPAC)	
Chemical name (CA)	
CIPAC No	
CAS No	
EEC No	
FAO specification	
Minimum purity	
Molecular formula	
Molecular mass	
Structural formula	
Melting point	
Boiling point	
Appearance	
Relative density	
Vapour pressure	
Henry's law constant	
Solubility in water	
Solubility in organic solvents	
Partition coefficient (log P_{OW})	
Hydrolytic stability (DT_{50})	
Dissociation constant	
Quantum yield of direct photo transformation in water at Σ > 290 nm	
Flammability	
Explosive properties	
UV/VIS absorption (max.)	
Photostability (DT_{50})	

TOXICOLOGY AND METABOLISM

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption	
Distribution	
Potential for accumulation	
Rate and extent of excretion	
Toxicologically significant compounds	
Metabolism in animals	

▼B

Acute toxicity	
Rat oral [1]	
Rat LD_{50} dermal	
Rat LC_{50} inhalation	
Skin irritation	
Eye irritation	
Skin sensitisation (test method used and result)	
Short term toxicity	
Target/critical effect	
Lowest relevant oral NOAEL/NOEL	
Lowest relevant dermal NOAEL/NOEL	
Lowest relevant inhalation NOAEL/NOEL	
Genotoxicity	
Long-term toxicity and carcinogenicity	
Target/critical effect	
Lowest relevant NOAEL	
Carcinogenicity	
Reproductive toxicity	
Target/critical effect — reproduction	
Lowest relevant reproductive NOAEL/NOEL	
Target/critical effect — developmental toxicity	
Lowest relevant developmental NOAEL/NOEL	
Delayed neurotoxicity	
Other toxicological studies	
Medical data	

[1] May include a point estimate or a range estimate.

▼B

Summary	Value	Study	Safety factor
ADI			
AOEL systemic			
AOEL inhalation			
AOEL dermal			
ArfD (acute reference dose)			

Dermal absorption	

FATE AND BEHAVIOUR IN THE ENVIRONMENT

Fate and behaviour in soil

Route of degradation

Aerobic

Mineralisation after 100 days	
Non-extractable residues after 100 days	
Relevant metabolites: name and/or code % of applied rate (range and maximum)	

Supplemental studies

Anaerobic	
Soil photolysis	
Remarks	

Rate of degradation [1]

Laboratory studies

DT_{50}lab (20 °C, aerobic)	
DT_{90}lab (20 °C, aerobic)	
DT_{50}lab (10 °C, aerobic)	
DT_{50}lab (20 °C, anaerobic)	

[1] Specify method of calculation and order of reaction.

▼B

Field studies (1)

DT_{50f} from soil dissipation studies	
DT_{90f} from soil dissipation studies	
Soil accumulation studies	
Soil residue studies	

Remarks

For example, effect of soil pH on degradation rate	

Adsorption/desorption

K_f	
K_d	
K_{oc}	
PH dependence	

Mobility

Laboratory studies

Column leaching	
Aged residue leaching	

Field studies

Lysimeter/field leaching studies	

Remarks	

Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation	
Relevant metabolites	
Photolytic degradation	
Relevant metabolites	

(1) Specify country or region.

▼B

Biological degradation

Readily biodegradable	
Water/sediment study: DT_{50} water DT_{90} water DT_{50} whole system DT_{90} whole system Distribution in water/sediment systems (active substance) Distribution in water/sediment systems (metabolites)	
Accumulation in water and/or sediment	

Degradation in the saturated zone	
Remarks	

Fate and behaviour in air

Volatility

Vapour pressure	
Henry's law constant	

Photolytic degradation

Direct photolysis in air	
Photochemical oxidative degradation in air DT_{50}	
Remarks	

ECOTOXICOLOGY

Terrestrial vertebrates

Acute toxicity to mammals	
Longterm toxicity to mammals	
Acute toxicity to birds	
Dietary toxicity to birds	
Reproductive toxicity to birds	
Semi-field/field study	

(1) Specify country or region.

▼B

Aquatic organisms

Acute toxicity to fish	
Long-term toxicity to fish	
Bioaccumulation in fish	
Acute toxicity to invertebrates	
Chronic toxicity to invertebrates	
Acute toxicity to algae	
Acute toxicity to aquatic plants	
Chronic toxicity to sediment dwelling organisms	
Micro/mesocosm study	

Honeybees

Acute oral toxicity	
Acute contact toxicity	
Semi-field/field study	

Other arthropod species (1)

Test species	% effect

Earthworms

Acute toxicity	
Reproductive toxicity	
Field study	

Soil micro-organisms

Nitrogen mineralisation	
Carbon mineralisation	

(1) Specify type of study: laboratory/extended laboratory/semi-field/field study.

▼B

ANNEX V

PART 1

Criteria for the admissibility of notifications referred to in Article 4

A notification will only be considered admissible if the following conditions are satisfied:

1. it is presented within the time limit referred to in Article 4(1);
2. it is introduced by a notifier who is a producer as defined in Article 2(2)(a) for an active substance as defined by the Directive;
3. it is presented in the format as provided for in Annex IV, Part 1;
4. a fee as referred to in Article 12(2)(d) has been paid.

PART 2

Criteria for the admissibility of notifications referred to in Article 10

A notification will only be considered admissible if the following conditions are satisfied:

1. it is presented within the time limit referred to in Article 10(2);
2. it is introduced by a notifier who is a producer as defined in Article 2(2)(a) for an active substance as defined by the Directive;
3. it is presented in the format as provided for in Annex IV, 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 13 has been paid.

▼B

ANNEX VI

Organisations in the Member States to be contacted concerning further details on the payment of the fees referred to in Article 12 and to which such fees have to be paid

AUSTRIA

Bundesamt und Forschungszentrum für Landwirtschaft
Spargelfeldstraße 191
A-1226 Wien

BELGIUM

Fonds budgétaire des matières premières
Ministère des classes moyennes et de l'agriculture
Inspection générale des matières premières et produits transformés, WTC 3
Boulevard Simon Bolivar 30
B-1000 Bruxelles

Account number 679-2005985-25 (Banque de la Poste)

Begrotingsfonds voor de grondstoffen
Ministerie van Middenstand en Landbouw
Inspectie-generaal Grondstoffen en verwerkte producten, WTC 3
Simon Bolivarlaan 30
B-1000 Brussel

Account number 679-2005985-25 (Bank van De Post)

DENMARK

Ministry of Environment and Energy
Danish Environmental Protection Agency
Strandgade 29
DK-1401 Copenhagen K

GERMANY

Biologische Bundesanstalt für Land- und Forstwirtschaft
Abteilung für Pflanzenschutzmittel und Anwendungstechnik
Messeweg 11-12
D-38104 Braunschweig

GREECE

Hellenic Republic
Ministry of Agriculture
General Directorate of Plant Produce
Directorate of Plant Produce Protection
Department of Pesticides
3-4 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
ES-28007 Madrid

FINLAND

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

Bank and account:
Leonia Bank plc
PSP BFIHH
800015-18982

▼B

FRANCE

Ministère de l'agriculture et de la pêche
Bureau de la réglementation des produits antiparasitaires
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

Tesoreria Provinciale dello Stato di Viterbo
post current account n. 11281011

LUXEMBOURG

Administration des services techniques de l'agriculture
Boîte postale 1904
L-1019 Luxembourg

NETHERLANDS

College voor de Toelating van Bestrijdingsmiddelen
Postbus 217
6700 AE Wageningen
Nederland

PORTUGAL

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

Account number: 003505840003800793097

Bank: Caixa Geral de Depósitos

SWEDEN

Kemikalieinspektionen
Box 1384
S-171 27 Solna

National Giro Account: 4465054-7

UNITED KINGDOM

Pesticides Safety Directorate
Ministry of Agriculture, Fisheries and Food
Mallard House
Kings Pool
3 Peasholme Green,
York YO1 7PX
United Kingdom

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ANNEX VII

Designated body referred to in Article 10

The following body is designated to perform on behalf of the Commission the tasks referred to in Article 11: Biologische Bundesanstalt für Land und Forstwirtschaft (RENDER PROJECT), Messeweg 11-12 D-38104 Braunschweig (Internet: http://www.bba.de/english/render.htm or e-mail: render@bba.de). The fee referred to in Article 13 has to be paid to account No 250 010 00, BLZ 250 000 00, Landeszentralbank Hannover (reference 'BBA-RENDER' mentioning the reference number of the notification).

This body will:

1. examine the notifications referred to in Article 10;
2. make available to the notifiers the format of the notification referred to in Article 10(2);
3. examine the notifications and consult with experts from other Member States in the light of the acceptability criteria referred to in Annex V, Part 2;
4. report to the Commission within six months from the time limit referred to in Article 10(2)(b) 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.