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COMMISSION REGULATION (EC) No 1490/2002

of 14 August 2002

laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000

(Text with EEA relevance)

(OJ L 224, 21.8.2002, p. 23)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EC) No 1044/2003 of 18 June 2003	L 151	32	19.6.2003
►M2	Commission Regulation (EC) No 1744/2004 of 7 October 2004	L 311	23	8.10.2004
►M3	Commission Regulation (EC) No 1095/2007 of 20 September 2007	L 246	19	21.9.2007
►M4	Commission Regulation (EU) No 741/2010 of 17 August 2010	L 217	2	18.8.2010

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COMMISSION REGULATION (EC) No 1490/2002

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laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant-protection products on the market [1], as last amended by Commission Directive 2002/48/EC [2], and in particular the second subparagraph of Article 8(2) thereof,

Whereas:

(1) The Commission is to undertake a programme of work 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 this programme was laid down by Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant-protection products on the market [3], as last amended by Regulation (EC) No 2266/2000 [4]. This first stage is ongoing.

(2) The second stage of work was laid down by Commission Regulation (EC) No 451/2000 of 28 February 2000 laying down the detailed rules for the implementation of the second and third stages of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC [5], and is also ongoing.

(3) A third stage of work was provided for in Regulation (EC) No 451/2000 for an additional number of active substances not covered by the first and second stages of the programme. Producers wishing to secure the inclusion of these active substances in Annex I to Directive 91/414/EEC have provided detailed information relating to the current stage of completeness of their dossiers and on the endpoints and have undertaken to provide a full data package.

(4) For the third stage of the work programme, Article 10(3) of Regulation (EC) No 451/2000 specifies that detailed provisions concerning the submission of complete dossiers, the time limit(s) for their submission and the fee regime for the active substances concerned have to be established by the Commission in a Regulation to be adopted in accordance with the second subparagraph of Article 8(2) of Directive 91/414/EEC.

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[1] OJ L 230, 9.8.1991, p. 1.
[2] OJ L 148, 6.6.2002, p. 19.
[3] OJ L 366, 15.12.1992, p. 10.
[4] OJ L 259, 13.10.2000, p. 27.
[5] OJ L 55, 29.2.2000, p. 25.

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(5) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 ([1]) created the European Food Safety Authority (EFSA) to ensure that the Community has access to high-quality, independent and efficient scientific and technical support in order to achieve a high level of health protection in relation to legislation concerning safety of food and feed. It is therefore appropriate to provide that the EFSA should have a role in the programme of work on active substances, and the scope of this involvement should be defined as soon as possible.

(6) In order to ensure that dossiers are received by the Member States in a manageable way, the active substances to be evaluated should be divided into two groups with separate time limits for the submission of dossiers.

(7) Further, at an initial stage it should be sufficient that notifiers provide only a list of the available tests and studies to the rapporteur Member States, in order to permit the Member States to establish whether a full data package is available to be submitted by the specified time limit. Where such data will not be available by the time limit, it will not be possible to complete re-evaluation of the active substance within the timetable provided for in Directive 91/414/EEC and a decision should therefore be taken immediately not to include the substance concerned in Annex I to the Directive. Authorisation of products containing such active substance should be withdrawn by Member States.

(8) The relationships between producers, Member States, the Commission and the EFSA and the obligations on each of them for the implementation of the programme should be laid down, taking into account experience gained during the first and second stages of the programme. Close cooperation between all parties involved and a scrupulous respect of time limits laid down is necessary to ensure the efficiency of the programme. Strict time limits for all elements of the third stage of the work programme should be set in order to ensure its finalisation within an acceptable time period. Where cooperation with notifiers ceases it is impossible to continue further evaluation efficiently and therefore the evaluation should be terminated.

(9) In order to ensure that all relevant information on the potentially dangerous effects of an active substance or its residues are considered, technical or scientific information submitted within the relevant time limits by any person should also be taken into consideration in the evaluations.

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

([1]) OJ L 31, 1.2.2002, p. 1.

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(11) 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. The rapporteur Member State should assess the completeness check provided by the notifier, and examine and evaluate the information submitted. It should present to the EFSA the results of the evaluation and make a recommendation to the Commission concerning the decision to be taken with regard to the active substance concerned.

(12) Member States should send draft reports of their evaluations to the EFSA. The draft reports prepared by the rapporteur Member States should be peer reviewed by the EFSA before they are submitted to the Standing Committee on the Food Chain and Animal Health.

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

(14) 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 that Directive. Therefore, operators which have not submitted notifications should be able to be informed at all stages of the evaluation process of the possible further requirements for continued marketing of plant-protection products containing an active substance under evaluation.

(15) The procedures established in this Regulation should not prejudice procedures and actions to be undertaken in the framework of other Community legislation, in particular, under Council Directive 79/117/EEC prohibiting the placing on the market and use of plant-protection products containing certain active substances [1], as last amended by the Act of Accession of Austria, Finland and Sweden, where information becomes available to the Commission showing that its requirements may be satisfied.

(16) The use of anti-microbials from classes, which are or may be used in human or veterinary medicine for the purpose of plant protection should be discouraged. Two of the substances concerned by this Regulation — kasugamycin and streptomycine — fall into this category [2]. Pending eventual decisions on their inclusion in Annex I, their uses should continue to be restricted and only be permitted where essential. For the purpose of their evaluation, information on anti-microbial resistance will be required.

(17) This Regulation shall be without prejudice to Community obligations regarding methyl bromide under the Montreal Protocol.

[1] OJ L 33, 8.2.1979, p. 36.
[2] Opinion of the Scientific Steering Committee of 28 May 1999 on anti-microbial resistance.

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(18) In the case of an apparent imbalance in the responsibilities borne by the Member States as rapporteur in the assessment and evaluation, it should be possible to replace the Member State originally designated as rapporteur for a particular active substance by another Member State.

(19) To ensure the proper resourcing of this stage of the programme of work, a fee should be paid to the Member States for the handling and evaluation of dossiers in addition to the fee already paid for the evaluation of the notifications pursuant to Article 13 of Regulation (EC) No 451/2000.

(20) Regulation (EC) No 451/2000 provided that for the active substances covered by the third stage of the work programme, the time limit for the submission of a full data package was 25 May 2003 at the latest. That Regulation also provided that detailed provisions concerning the submission of complete dossiers would be established at a later stage. In order to organise the work programme efficiently, it is not necessary to submit full data packages shortly before full dossiers have to be submitted. However, to ensure that active substances without full data packages do not remain on the market, a list of available data should be submitted, while the full data packages should be submitted only in exceptional cases and on request.

(21) Regulation (EC) No 451/2000 should be amended accordingly.

(22) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation lays down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC with respect to the continued evaluation of the active substances notified under Regulation (EC) No 451/2000.

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

3. This Regulation shall apply without prejudice to:

(a) reviews by Member States of active substances in Annex I in particular pursuant to renewals of authorisations in accordance with Article 4(4) of Directive 91/414/EEC;

(b) reviews by the Commission pursuant to Article 5(5) of Directive 91/414/EEC;

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

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Article 2

Definitions

For the purpose of this Regulation, the definitions in Directive 91/414/EEC shall apply.

The following definitions shall also apply:

(a) 'notifier' means the natural or legal person who submitted a notification in accordance with the terms specified in Regulation (EC) No 451/2000 as listed in Annex II;

(b) 'Committee' means the Standing Committee on the Food Chain and Animal Health, referred to in Article 19 of Directive 91/414/EEC;

(c) 'data list' means a list of all the data which is available to be submitted in the full data package;

(d) 'full data package' means information and results of studies sufficient to satisfy the requirements of Annexes II and III to Directive 91/414/EEC in relation to a limited range of representative uses of the active substance concerned.

Article 3

Member State authority

1. Member States shall allocate responsibility for the implementation of their obligations under the programme of work referred to in Article 8(2) of Directive 91/414/EEC to an authority or authorities.

2. Each Member State shall designate one national authority, referred to in Annex III, to coordinate and ensure all necessary contacts with notifiers, other Member States, the Commission and the European Food Safety Authority (EFSA) pursuant to this Regulation. Each Member State shall inform the details concerning the designated coordinating national authority to the Commission, the EFSA and the designated coordinating national authority of each other Member State and of any modifications thereof.

Article 4

Measures in case of imbalances

If, during the assessment and evaluation referred to in Articles 9 and 10, it becomes apparent that there is an imbalance in the responsibilities borne and the work to be done or actually done by the Member States as rapporteurs, it may be decided, in accordance with the procedure provided for in Article 19 of Directive 91/414/EEC, 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 to the notifier the fee referred to in Article 17 except for the part referred to in paragraph 2(d) thereof. The newly designated rapporteur Member State shall then require the notifiers to pay the fee referred to in Article 17 except the part referred to in paragraph 2(d) thereof.

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Article 5

Withdrawal or replacement of notifier

1. If a notifier decides to end its participation in the programme of work for an active substance, it shall immediately inform the rapporteur Member State, the Commission, the EFSA and all other notifiers of the substance concerned of its decision, giving the reasons. Where a notifier ends its participation or fails to fulfil its obligations under this Regulation, the procedures provided for in Article 9 or 10 shall be terminated as regards its dossier.

2. If a notifier agrees with another producer that the notifier shall be replaced for the purposes of further participation in the programme of work under this Regulation, the notifier and such other producer shall inform the rapporteur Member State, the Commission and the EFSA by a common declaration agreeing that such other producer shall replace the original notifier in carrying out the notifier's duties pursuant to Articles 6, 7, 9, 10 or 11. They shall ensure that the other notifiers for the substance concerned are informed at the same time. The other producer in this case shall be jointly liable with the original notifier for any fees remaining payable in relation to the notifier's application under the regime established by Member States pursuant to Article 17.

3. All information submitted shall remain available to the rapporteur Member States, the Commission or the EFSA.

Article 6

Submission and checking of data lists

1. By 23 May 2003 at the latest, the notifier(s) shall submit to the relevant rapporteur Member State the data lists for active substances listed in Annex I, and submit a copy to the EFSA.

Where, for any active substance listed in Annex I, there are several notifications, the notifiers concerned shall take all reasonable steps to submit these data lists collectively.

Where a data list is not submitted by all notifiers concerned, it shall mention the efforts made and the reasons why certain notifiers have not participated.

For active substances notified by more than one notifier those notifiers shall for each study involving vertebrate animals, detail the attempts made to avoid duplication of testing and give, if applicable, the reasons for conducting a duplicate study.

2. The data lists shall be prepared in the format specified in accordance with the procedure provided for in Article 19 of Directive 91/414/EEC. The full data package, as defined in Article 10(4) of Regulation (EC) No 451/2000, shall be kept available by the notifiers. On written request from the rapporteur Member State or the Commission, the notifier shall provide without delay, the part of the data package or the full data package requested.

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3. The rapporteur Member State shall examine the data lists submitted to establish whether they indicate that a full data package is available to be submitted. For those active substances for which a rapporteur Member State considers that no full data package is available to be submitted, the rapporteur Member State shall request the notifier to submit without delay a full data package and check whether it is complete. The rapporteur Member State shall report the results of these checks to the Commission at the latest within three months of receipt of the data lists.

4. For those active substances for which the rapporteur Member State considers that no full data package is available it shall inform the Commission without delay. In accordance with the procedure provided for in Article 19 of Directive 91/414/EEC, it shall be decided whether a full data package is available.

5. Where it is considered that no full data package is available for a particular active substance, the Commission shall decide, as provided for in the fourth subparagraph of Article 8(2) of Directive 91/414/EEC, not to include the active substance concerned in Annex I to Directive 91/414/EEC.

6. Unless the Commission informs the notifier that no full data package is available for a particular active substance, the notifier shall submit the dossiers referred to in Article 7(2) and (3) by the time limits specified in Article 7(1).

Article 7

Submission of dossiers

1. The notifier(s) shall submit to the relevant rapporteur Member State the summary dossier referred to in paragraph 2 and the complete dossier referred to in paragraph 3, by 30 November 2003 at the latest for active substances listed in Annex I, part A, and by 30 November 2004 at the latest for active substances listed in Annex I, part B.

Where for any active substance listed in Annex I there are several notifications, the notifiers concerned shall take all reasonable steps to submit these dossiers collectively.

Where a dossier is not submitted by all notifiers concerned, it shall mention the efforts made and the reasons why certain notifiers have not participated.

For active substances notified by more than one notifier, those notifiers shall for each study involving vertebrate animals, detail the attempts made to avoid duplication of testing and give, if applicable, the reasons for conducting a duplicate study.

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 10 of Regulation (EC) No 451/2000 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;

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(b) a limited range of representative uses of the active substance, in respect of which the data submitted by the notifier in the dossier shall demonstrate that for one or more preparations, the requirements set out in Article 5 of Directive 91/414/EEC for inclusion of the active substance in Annex I to Directive 91/414/EEC, can be met;

(c) (i) for each point of Annex II to Directive 91/414/EEC, the summaries and results of studies and trials, the name of the person or institute that has carried out the trials;

(ii) for each point of Annex III to Directive 91/414/EEC the summaries and results of studies and trials, the name of the person or institute that has carried out the trials, relevant to the assessment of the criteria referred to in Article 5 of Directive 91/414/EEC for one or more preparations which are representative for the uses referred to in subparagraph (b) taking into account 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 into Annex I to Directive 91/414/EEC;

(iii) and for active substances listed in Annex I, part B, for studies not yet fully completed the evidence that these studies have been commissioned as required by Article 10(4) of Regulation (EC) No 451/2000 with an undertaking that they will be submitted at the latest by 31 May 2005;

(d) a checklist to be filled in by the notifier, demonstrating that the dossier is complete.

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

4. Each Member State shall define the number of copies and the format of the summary and the complete dossiers to be submitted by the notifiers. In defining the format of the dossier Member States shall take account of the recommendations made in accordance with the procedure provided for in Article 19 of Directive 91/414/EEC.

5. Where the dossiers or any part of them are not sent within the relevant time limit, the rapporteur Member State shall inform the Commission and the EFSA within two months, giving any justification for the delay provided by the notifiers.

6. On the basis of the information transmitted by the rapporteur Member State in accordance with paragraph 5, the Commission shall determine whether the notifier has demonstrated that the delay in submission of the dossier was caused by *force majeure*. In this case, it shall establish a new time limit for the submission of a dossier fulfilling the requirements of paragraphs 2 and 3 in accordance with the procedure provided for in Article 19 of Directive 91/414/EEC.

7. The Commission shall decide, as provided for in the fourth subparagraph of Article 8(2) of Directive 91/414/EEC, not to include in Annex I to Directive 91/414/EEC an active substance for which no dossier has been submitted within the established time limit.

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Article 8

Submission of information by third parties

Any person wishing to submit information which might 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 to the rapporteur Member States shall do so by 30 November 2003 at the latest for substances listed in Annex I, part A, and by 30 November 2004 at the latest for substances listed in Annex I, part B. The rapporteur Member State shall submit any information received to the EFSA.

Article 9

Completeness check of dossiers

1. For each active substance for which it has been designated rapporteur, the Member State shall examine the dossiers referred to in Article 7(2) and (3) and assess the checklists provided by the notifiers. The rapporteur Member State shall at the latest six months after the receipt of all dossiers for an active substance report to the EFSA and the Commission on the completeness of the dossiers.

The EFSA shall assess the reports submitted to it by the rapporteur Member States and 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, the rapporteur Member State shall perform the evaluation as referred to in Article 10, unless the EFSA informs the rapporteur Member State and the Commission, within two months of receipt of the Member State report on completeness, that it does not consider the dossier to be complete.

For those active substances for which the dossier is to be completed, as provided for under Article 7(2)(c)(iii), the report must confirm the date by which the dossier will be completed and by which date the evaluation as referred to in Article 10 will begin.

2. For those active substances for which a rapporteur Member State or the EFSA consider that the dossier is not complete within the meaning of Article 7(2) and (3), the Commission shall, within three months after the receipt of the report of the rapporteur Member State or the EFSA, refer such report to the Committee. In accordance with the procedure provided for in Article 19 of Directive 91/414/EEC, it shall be decided whether a dossier is considered complete within the meaning of Article 7(2) and (3).

3. The Commission shall decide, as provided for in the fourth subparagraph of Article 8(2) of Directive 91/414/EEC, not to include in Annex I to Directive 91/414/EEC an active substance for which no complete dossier has been submitted within the prescribed time limit.

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Article 10

Evaluation by the rapporteur Member State

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 9. 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 8. It shall send a draft report of its assessment of the dossier to the 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 accordance with the procedure provided for in Article 19 of Directive 91/414/EEC.

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 Directive 91/414/EEC, stating the conditions for inclusion, or

— not to include the active substance in Annex I to Directive 91/414/EEC, 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 Directive 91/414/EEC, 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 Directive 91/414/EEC.

2. Without prejudice to Article 7 of Directive 91/414/EEC, submission of new studies shall not be accepted except for the studies as specified in Article 10(4) of Regulation (EC) No 451/2000. The rapporteur Member State may however 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 its examination of the dossier, 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.

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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 Commission or the EFSA may request through the rapporteur Member State that notifiers also send them an updated complete dossier 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. Where necessary, certain active substances may be reassigned to another Member State in accordance with the procedure provided for in Article 19 of Directive 91/414/EEC.

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Article 11

Receipt of and access to the draft assessment report

1. After receiving the updated summary dossier and the draft assessment report referred to in Article 10(1) the EFSA shall, within 30 days, acknowledge to the rapporteur Member State receipt of that report.

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 two months.

2. The EFSA shall without delay communicate the draft assessment report to the Commission, the other Member States and the notifiers setting a time period of no more than two months for the submission of comments by those Member States and the notifiers.

It shall collate the comments it receives, including available comments from the EFSA, and forward them to the Commission, Member States and the notifiers.

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

(a) the draft assessment report except the elements thereof which have been accepted as confidential in accordance with Article 14 of Directive 91/414/EEC;

(b) the list of any data required for the evaluation in view of the possible inclusion of the active substance in Annex I to that Directive as finalised by the EFSA where it has finalised such a list.

Article 11a

Examination of the draft assessment report

The Commission shall, without delay, examine the draft assessment report and the recommendation by the rapporteur Member State and the comments received from other Member States, the EFSA and from the notifiers in accordance with Article 11(2).

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Article 11b

Active substance with clear indications that they do not have any harmful effects

If there are clear indications that it may be expected that the active substance does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, as set out in Annex V, Article 12(1)(a) and (2)(a) shall apply.

Article 11c

Consultation of the EFSA

1. Where Article 11b does not apply, the Commission may, at any time during the evaluation, ask the EFSA to carry out a peer review of the full draft assessment report or to focus on specific points including points related to criteria set out in Annex VI. The EFSA shall organise a consultation of Member States experts including the rapporteur Member State.

Where the Commission requests the EFSA to carry out a full peer review, the EFSA shall deliver its conclusion at the latest six months after the request. Where the Commission does not request a full peer review, but only a conclusion on specific points, the period shall be reduced to three months. The submission of the conclusions shall in any event be no later than 30 September 2008.

2. If during the peer review there are clear indications that an active substance is expected to have harmful effects on human or animal health or on groundwater as set out in Annex VI, the EFSA shall inform the Commission.

The Commission may take a Decision as referred to in Article 11f.

3. The Commission and the EFSA shall agree on a schedule for the delivery of the conclusions in order to facilitate the planning of the work. The Commission and the EFSA shall agree on the format in which the conclusions of the EFSA are submitted.

Article 11d

Submission of additional information after the draft assessment report has been submitted to the EFSA

1. Without prejudice to Article 7 of Directive 91/414/EEC, submission of new studies shall not be accepted.

2. Where the EFSA considers that additional information from the notifier is necessary to comply with a request made by the Commission under Article 11c, the rapporteur Member State shall request that information. Such requests shall be made explicitly and in writing, setting a time period for submission of one month. They shall not concern the submission of new studies. The rapporteur Member State shall inform the Commission and the EFSA of such requests in writing.

The rapporteur Member State shall, within one month after the receipt of such information, evaluate the information received and send its evaluation to the EFSA.

3. Information submitted by the notifier but which has not been requested, or which has not been submitted before the end of the time period referred to in paragraph 2, shall not be taken into account unless this information has been submitted in accordance with Article 7 of Directive 91/414/EEC.

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Where the rapporteur Member State, pursuant to paragraph 1 or to the first subparagraph of this paragraph, refuses to take into account studies or information received from the notifier, it shall inform the Commission and the EFSA and indicate the reasons for such refusal.

Article 11e

Withdrawal by notifier

Where Article 11b does not apply, the notifier may withdraw his support of the inclusion of the active substance in Annex I to Directive 91/414/EEC within two months from receipt of the draft assessment report referred to in Article 11(2).

Article 11f

Active substance for which there are clear indications of harmful effects

If there are clear indications that it may be expected that the active substance has harmful effects on human or animal health or on groundwater as set out in Annex VI, the Commission shall take a Decision on the non-inclusion of the active substance in Annex I to Directive 91/414/EEC, in accordance with Article 12(1)(a) and (2)(b) of this Regulation.

Article 12

Presentation of a draft directive or draft decision

1. The Commission shall submit to the Committee a draft review report at the latest six months after:

(a) receipt of the draft assessment report where Article 11b or Article 11f applies;

(b) receipt of the conclusion established by the EFSA where Article 11c applies;

(c) receipt of a written withdrawal of the notifier's support where Article 11e applies.

2. Together with the draft review report the Commission shall submit to the Committee:

(a) a draft directive including the active substance in Annex I to Directive 91/414/EEC, setting out where appropriate the conditions, including the time limit, for such inclusion; or

(b) a draft decision addressed to the Member States requiring them to withdraw, within six months, the authorisations of plant protection products containing the active substance, pursuant to the fourth subparagraph of Article 8(2) of Directive 91/414/EEC, whereby that active substance is not included in Annex I to that Directive, mentioning the reasons for the non-inclusion.

The Directive or Decision shall be adopted in accordance with the procedure referred to in Article 19(2) of Directive 91/414/EEC.

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3. By way of derogation from paragraph 2(b), the latest date for Member States to withdraw authorisations shall be 31 December 2010 in the case referred to in paragraph 1(c) unless the Commission has concluded that the substance meets the criteria of Annex VI, if appropriate after having consulted the EFSA. ►M4 However, the latest date for Member States to withdraw authorisations shall be 31 December 2011 where an application has been submitted in accordance with the accelerated procedure provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 ([1]). ◄

Article 12a

View by the EFSA

Where an active substance is included in Annex I to Directive 91/414/EEC pursuant to Article 11b of this Regulation, the Commission shall request the EFSA to deliver its view on the draft review report by 31 December 2010 at the latest. Member States and notifiers shall cooperate with the EFSA and the Commission.

In order to facilitate the planning of the work, the Commission and the EFSA shall agree on a schedule for the delivery of the view of the EFSA on the draft review report and on the format in which that view is submitted.

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Article 13

Finalised review report

Where the Commission submits a draft directive or a draft decision in accordance with Article 12, 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 Directive 91/414/EEC, shall be made available for public consultation.

Article 14

Suspension of time limits

Where, in respect of a substance listed in Annex I, the Commission submits a proposal for a total prohibition under Directive 79/117/EEC, the time limits provided for in this Regulation shall be suspended until a decision on that 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 shall be terminated.

([1]) OJ L 15, 18.1.2008, p. 5.

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Article 15

Measures taken by Member States

Any Member State which, on the basis of information contained in the dossiers referred to in Article 7 or in the report concerning an active substance referred to in Article 10, envisages taking action to withdraw from the market or to restrict severely the use of a plant-protection product containing that substance, shall, as soon as possible, inform the Commission, the EFSA, the other Members States and the notifiers giving the reasons for its intended action.

Article 16

Interim progress report

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 shall be made by 30 November 2004 for the active substances mentioned in Annex I, part A, and by 30 November 2005 for those of Annex I, part B.

Article 17

Fees

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

2. For this purpose, the Member States shall:

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

(b) ensure that the amount of the fee or charge shall be established in a transparent manner with the view to correspond to the real cost of the examination and administrative treatment of a dossier; however this does not exclude that Member States provide for a scale of fixed charges based on average costs for the calculation of the total fee;

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(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 IV 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 dossiers for which that Member State is rapporteur or to finance general activities of the Member States resulting from Articles 9, 10 or 11;

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(d) require that a first part of the fee or charge, covering the costs of the rapporteur Member State's obligations resulting from Article 6 and Article 9 is paid at the time of the submission of the data lists referred to in Article 6; this part will not be refundable under any circumstance.

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Article 18

Other charges, taxes, levies or fees

Article 17 is without prejudice to Member States' rights to maintain or introduce, to the extent permitted under the Treaty, charges, taxes, levies or fees with regard to authorisation, placing on the market, use and control of active substances and plant-protection products other than the fee provided for in Article 17.

Article 19

Temporary measures

If necessary and on a case-by-case basis, the Commission may take appropriate temporary measures as provided for by the third subparagraph of Article 8(2) of Directive 91/414/EEC 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 20

Amendment to Regulation (EC) No 451/2000

Regulation (EC) No 451/2000 is amended as follows:

1. Article 8 is replaced by the following:

'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 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.

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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.

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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.

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

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(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.'

2. In Article 10(4), the first sentence is replaced by the following:

'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.'

3. In Article 11(2), the second sentence is replaced by the following:

'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.'

4. In Annex I, part A, in relation to the active substance Tolclofos-methyl 'The Netherlands' is replaced by 'Sweden'.

Article 21

Entry into force

This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Communities*.

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

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ANNEX I

List of active substances (column A), rapporteur Member States (column B) and notifying producers (code identification) (column C)

PART A

A	B	C
Name	Rapporteur Member State	Notifiers
Abamectin	Netherlands	IBE-ES
		PRO-ES
		SNO-FR
		SYN-GB
Acetochlor	Spain	DAS-GB
		MON-BE
		RIV-IE
Amidosulfuron	Austria	AVS-DE
Benfluralin	Belgium	DAS-GB
		MAK-BE
Bifenox	Belgium	FSG-DE
Bifenthrin	France	FMC-BE
Bitertanol	United Kingdom	BAY-DE
Bromuconazole	Belgium	AVS-FR
Buprofezin	Finland	NIH-GB
Butralin	France	CFP-FR
Carbetamide	France	FSG-DE
Chlorflurenol	Germany	SCC-DE
Chloridazon	Germany	BAS-DE
Chloropicrin	Italy	EBR-NL
		RIV-IE
Chlorthal-dimethyl	Greece	AMV-GB
Cinosulfuron	Italy	SYN-GB
Clethodim	Netherlands	TOM-FR
Clofentezine	United Kingdom	MAK-BE
Clomazone	Denmark	FMC-BE
Coppercompounds	France	EUC-GB
Cresylic acid	Netherlands	ASP-NL

▼B

A	B	C
Name	Rapporteur Member State	Notifiers
Cyanamide	Germany	DUS-DE
Cycloxydim	Austria	BAS-DE
Dichlorophen	Ireland	CCD-GB
Diclofop	France	AVS-DE
		PPC-ES
Dicloran	Spain	MAI-PT
Diflubenzuron	Sweden	UNI-NL
Diflufenican	United Kingdom	AVS-DE
		HRM-BE
		MAK-BE
Dimethipin	Greece	CRO-GB
Dithianon	Greece	BAS-BE
		HRM-BE
Epoxiconazole	Germany	BAS-DE
		MAK-BE
Etofenprox	Italy	LKC-UK
Fenazaquin	Greece	DAS-GB
Fenbuconazole	United Kingdom	DAS-GB
Fenoxaprop-P	Austria	AVS-DE
Fenpropidin	Sweden	SYN-GB
Fenpropimorph	Germany	BAS-DE
Fenpyroximate	Germany	NIH-GB
Fluazifop-P	France	SYN-GB
Fluazinam	Austria	ISK-BE
Fludioxonyl	Denmark	SYN-GB
Fluometuron	Greece	MAK-BE
		NLI-AT
Fluquinconazole	Ireland	AVS-FR
Flurenol	Germany	SCC-DE
Flutolanil	Finland	NIH-GB
Fuberidazole	United Kingdom	BAY-DE
Hexaflumuron	Portugal	DAS-GB

▼B

A	B	C
Name	Rapporteur Member State	Notifiers
Hexythiazox	Finland	NPS-DE
Imidacloprid	Germany	BAY-DE
Kasugamycin	Netherlands	LAI-ES
Mefluidide	Ireland	MKC-BE
Mepiquat	United Kingdom	BAS-DE
Metaldehyde	Austria	LON-DE
Metazachlor	United Kingdom	BAS-DE
		FSG-DE
		MAK-BE
Methyl bromide	United Kingdom	EBR-NL
Myclobutanil	Belgium	DAS-GB
Napropamide	Denmark	UPL-GB
Nicosulfuron	United Kingdom	ISK-BE
Nuarimol	Portugal	DAS-GB
Pencycuron	Netherlands	BAY-DE
Polyoxin	Spain	LAI-ES
Pretilachlor	Italy	SYN-GB
Propaquizafop	Italy	MAK-BE
Prosulfocarb	Sweden	SYN-GB
Pyriproxyfen	Netherlands	SUM-FR
Quinoclamine	Sweden	AKA-DE
Streptomycine	Netherlands	DSM-NL
Tebufenozide	Germany	DAS-GB

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Tetraconazole	Italy	ISA-IT
Thiobencarb	Spain	KCI-GB
Tralkoxydim	United Kingdom	SYN-GB

▼B

A	B	C
Name	Rapporteur Member State	Notifiers
Triadimefon	United Kingdom	BAY-DE
Triadimenol	United Kingdom	BAY-DE
		MAK-BE
Tridemorph	Germany	BAS-DE
Triflumizole	Netherlands	CRE-NL
Triflumuron	Italy	BAY-DE
Triflusulfuron	France	DPD-FR
Zeta-Cypermethrin	Belgium	FMC-BE

PART B

A	B	C
Name	Rapporteur Member State	Notifiers
8-Hydroxyquinoline	Spain	ASU-DE
		PRO-ES
Aclonifen	Germany	AVS-DE
Acrinathrin	France	AVS-DE
Aluminium phosphide	Germany	DET-DE
Ammonium sulphamate	Ireland	DAP-GB
Asulam	United Kingdom	AVS-DE
Azocyclotin	Italy	CRX-FR
Bensulfuron	Italy	DPD-FR
Bupirimate	Netherlands	MAK-BE
Calcium phosphide	Germany	CFW-DE
Carboxin	United Kingdom	CRO-GB
Chlorate	France	ATO-FR
Chlormequat	United Kingdom	BCL-IE
		CTF-AT
		FSG-DE
		PUS-FR

▼B

A	B	C
Name	Rapporteur Member State	Notifiers
Chlorsulfuron	Greece	DPD-FR
Cyhexatin	Italy	CRX-FR
		OXO-IT
Cymoxanil	Austria	CAL-FR
		DPD-FR
		OXO-IT
		PUS-FR
Cyproconazole	Ireland	SYN-GB
Cyromazine	Greece	SYN-GB
Dazomet	Belgium	BAS-DE
Dicamba	Denmark	GHA-GB
		SYN-GB
Dichlobenil	Netherlands	UNI-NL
Dichlorobenzoic acid methylester	Germany	ASU-DE
Dicofol	Spain	DAS-GB
		MAK-BE
Diethofencarb	France	SUM-FR
Difenoconazole	Sweden	SYN-GB
Dimethachlor	Germany	SYN-GB
Diniconazole	France	SUM-FR
Diphenylamine	Ireland	CRX-FR
		CSI-UK
Dodemorph	Netherlands	BAS-DE
Dodine	Portugal	CAG-BE
		OXO-IT
Ethalfluralin	Greece	DAS-GB
Etridiazole	Netherlands	UNI-NL

▼B

A	B	C
Name	Rapporteur Member State	Notifiers
Fenbutatin oxide	Belgium	BAS-BE
		CRX-FR
Fenoxycarb	Netherlands	SYN-GB
Flamprop-M	Sweden	BAS-BE
Flufenoxuron	France	BAS-BE
Flurochloridone	Spain	MAK-BE
Flurprimidole	Finland	DAS-GB
Flutriafol	United Kingdom	CHE-DK
Guazatine	United Kingdom	MAK-BE
Hexaconazole	Italy	IQV-ES
		SYN-GB
Hymexazol	Finland	TSG-GB
Imazamethabenz	United Kingdom	BAS-BE
Imazaquin	Belgium	BAS-BE
Imazethapyr	Italy	BAS-BE
Isoxaben	Sweden	DAS-GB
Lenacil	Belgium	HRM-BE
		SCH-DE
Lufenuron	Portugal	SYN-GB
Magnesium phosphide	Germany	DET-DE
Metam	Belgium	FMF-ES
		LAI-ES
		MAK-BE
		UCB-BE

▼B

A	B	C
Name	Rapporteur Member State	Notifiers
Metamitron	United Kingdom	BAY-DE
		BCL-IE
		EXC-BE
		FSG-DE
		HRM-BE
		MAK-BE
		PUS-FR
		UPL-GB
Methabenzthiazuron	Sweden	PUS-FR
Metosulam	France	BAY-DE
Monocarbamide-dihydrogensulphate	Spain	AGX-GB
Oryzalin	France	DAS-GB
Oxadiazon	Italy	AVS-DE
Oxyfluorfen	Spain	DAS-GB
		MAK-BE
		PPC-ES
Paclobutrazol	United Kingdom	SYN-GB
Penconazole	Germany	SYN-GB
Picloram	United Kingdom	DAS-GB
Primisulfuron	Austria	SYN-GB
Prochloraz	Ireland	AVS-FR
		BCL-IE
		MAK-BE
		PUS-FR
		SPC-FR

▼B

A	B	C
Name	Rapporteur Member State	Notifiers
Propachlor	Netherlands	MAK-BE
		MON-BE
Propanil	Italy	DAS-GB
		MAK-BE
		RCO-PT
Propargite	France	CRO-GB
		PPC-ES
Pyridaben	Netherlands	NCI-DE
Quinclorac	Portugal	BAS-DE
Quinmerac	United Kingdom	BAS-DE
Quizalofop-P	Finland	CRO-GB
		MAK-BE
		NCI-DE
Sintofen	France	DPD-FR
Sodium 5-nitroguaiacolate	Greece	CAL-FR
Sodium o-nitrophenolate	Greece	CAL-FR
Sodium p-nitrophenolate	Greece	CAL-FR
Sodium tetrathiocarbonate	Spain	AGX-GB
Sulcotrione	Germany	BAY-DE
Tau-fluvalinate	Denmark	MAK-BE
Tebuconazole	Denmark	BAY-DE
		MAK-BE
Tebufenpyrad	Germany	BAS-BE
▼M2		
Teflubenzuron	United Kingdom	BAS-BE
▼B		
Tefluthrin	Germany	SYN-GB

▼B

A	B	C
Name	Rapporteur Member State	Notifiers
Terbuthylazine	United Kingdom	MAK-BE
		OXO-IT
		SYN-GB
Thidiazuron	Spain	AVS-FR
Tri-allate	United Kingdom	MON-BE
Triazoxide	United Kingdom	BAY-DE
Tricyclazole	France	DAS-GB

▼B

ANNEX II

List of notifiers' code identification, names and addresses

Code identification	Name	Address
AGX-GB	Agrilex UK Ltd	PO Box 31 Robertsbridge TN32 5ZL United Kingdom Tel. (44-1580) 88 20 59 Fax (44-1580) 88 20 57
AKA-DE	Agro-Kanesho Co., Ltd, European Branch	Stader Elbstraße D-21683 Stade Tel. (49-41) 41 40 83 88 Fax (49-41) 41 40 83 90
AMV-GB	Amvac Chemical UK Ltd	Surrey Technology Centre, 40 Occam Rd The Surrey Research Park Guildford, Surrey GU2 5YG United Kingdom Tel. (44-1483) 29 57 80 Fax (44-1483) 29 57 81
ASP-NL	Asepta BV	Cyclotronweg 1 / P.O. Box 33 2600 AA Delft Nederland Tel. (31-15) 256 92 10 Fax (31-15) 257 19 01
ASU-DE	Stähler Agrochemie GmbH & Co. KG	Postfach 2047 D-21680 Stade Tel. (49-41) 41 92 04-0 Fax (49-41) 41 92 04-10
ATO-FR	Atofina	4-8, cours Michelet F-92800 Puteaux Tel. (33-1) 49 00 80 80 Fax (33-1) 49 00 88 80
AVS-DE	Aventis CropScience GmbH	Industriepark Höchst Gebäude K 607 D-65926 Frankfurt am Main Tel. (49-69) 305 66 99 Fax (49-69) 305 176 69
AVS-FR	Aventis CropScience SA	14-20, rue Pierre Baizet BP 9163 F-69263 Lyon Cedex 09 Tel. (33-4) 72 85 25 25 Fax (33-4) 72 85 30 81
BAS-BE	BASF (Belgium)	Global Regulatory Affairs — APD/RF Avenue Hamoir, 14 B-1180 Bruxelles Tel. (32-2) 373 27 11 Fax (32-2) 373 27 00
BAS-DE	BASF AG (Deutschland)	Agricultural Center PO Box 120 D-67114 Limburgerhof Tel. (49-621) 60-0 Fax (49-621) 60-27701

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Code identification	Name	Address
BAY-DE	Bayer AG	Business Group Crop Protection Agricultural Centre Monheim D-51368 Leverkusen Tel. (49-2173) 38 49 28 Fax (49-2173) 38 37 35
BCL-IE	Barclay Chemicals Ltd	Tyrellstown Way Damastown Industrial Park Mulhuddart Dublin 15 Ireland Tel. (353-18) 42 57 55 Fax (353-18) 42 53 81
CAG-BE	Chimac-Agriphar SA	26, rue de Renory B-4102 Ougrée Tel. (32-4) 385 97 46 Fax (32-4) 385 97 49
CAL-FR	Calliope SAS	Route d'Artix BP 80 F-64150 Noguères Tel. (33-5) 59 60 92 92 Fax (33-5) 59 60 92 19
CCD-GB	Coalite Chemicals Division	PO Box 152 Buttermilk Lane Bolsover Chesterfield Derbyshire S44 6AZ United Kingdom Tel. (44-1246) 82 68 16 Fax (44-1246) 24 03 09
CFP-FR	CFPI Nufarm	Regulatory Affairs Dept. 28, boulevard Camélinat F-92230 Gennevilliers Tel. (33-1) 40 85 50 20 Fax (33-1) 40 85 51 56
CFW-DE	Chemische Fabrik Wülfel GmbH & Co. KG	Hildesheimer Straße 305 D-30519 Hannover Tel. (49-511) 98 49 60 Fax (49-511) 984 96 40
CHE-DK	Cheminova A/S	Thyborønvej 76-78 DK-7673 Harboøre Tel. (45) 96 90 96 90 Fax (45) 96 90 96 91
CRE-NL	Certis Europe BV	Straatweg 30B PO Box 1180 3600 BD Maarssen Nederland Tel. (31-346) 55 24 00 Fax (31-346) 55 42 74
CRO-GB	Crompton Europe Ltd	Registration Department Kennet House 4 Langley Quay Slough Berkshire SL3 6EH United Kingdom Tel. (44-17) 53 60 30 00 Fax (44-17) 53 60 30 77

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Code identification	Name	Address
CRX-FR	Cerexagri	Registration Department 1, rue des Frères Lumière F-78370 Plaisir Tel. (33-1) 30 81 73 00 Fax (33-1) 30 81 72 51
CSI-UK	CSI-Europe	Pentlands Science Park Penicuik Edinburgh EH26 0PZ United Kingdom Tel. (44-131) 445 60 82 Fax (44-131) 445 60 85
CTF-AT	CCC Task Force	c/o Nufarm GmbH & Co KG St.-Peter-Straße 25 A-4021 Linz Tel. (43-732) 69 18 23 13 Fax (43-732) 69 18 20 04
DAP-GB	Dax Products Ltd	76 Cyprus Road Nottingham NG3 5ED United Kingdom Tel. (44-11) 59 26 9996 Fax (44-11) 59 66 1173
DAS-GB	Dow AgroSciences	Letcombe Laboratory Letcombe Regis Wantage Oxon OX12 9JT United Kingdom Tel. (49-69) 78 99 60 Fax (49-69) 97 84 24 77
DET-DE	Detia Freyberg GmbH	Dr.-Werner-Freyberg-Straße 11 D-69514 Laudenbach Tel. (49-6201) 70 80 Fax (49-6201) 70 84 27
DPD-FR	DuPont de Nemours (France) SAS	Crop Protection Products 137, rue de l'Université F-75334 Paris Cedex 07 Tel. (33-1) 45 50 65 50 Fax (33-1) 45 50 60 05
DSM-NL	DSM Food Specialties, Agri Ingredients	Alexander Fleminglaan 1 PO Box 1 2600 MA Delft Nederland Tel. (31-15) 279 91 11 Fax (31-15) 279 34 82
DUS-DE	Degussa AG	Dr.-Albert-Frank-Straße 32 D-83308 Trostberg Tel. (49-8621) 86-0 Fax (49-8621) 86 22 52
EBR-NL	Eurobrom BV	Regulatory Affairs Department Verrijn Stuartlaan 1c 2288 EK Rijswijk Nederland Tel. (31-70) 3 408 408 Fax (31-70) 3 999 035

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Code identification	Name	Address
EUC-GB	European Union Copper Task Force	c/o TSGE Conyngham Hall Knaresborough North Yorkshire HG5 9AY United Kingdom Tel. (44-1423) 79 91 51 Fax (44-1423) 79 91 55
EXC-BE	Excel Industries Ltd	Luithagen Haven 9 B-2030 Antwerpen Tel. (32-3) 239 82 24 Fax (32-3) 239 82 69
FMC-BE	FMC Chemical SPRL	Agricultural Products Group Boulevard de la Plaine 9/3 B-1050 Bruxelles Tel. (32-2) 645 95 84 Fax (32-2) 645 96 55
FMF-ES	FMC Foret SA	Córcega 293 E-08008 Barcelona Tel. (34) 934 16 75 17 Fax (34) 934 16 74 13
FSG-DE	Feinchemie Schwebda GmbH	Straßburger Straße 5 D-37269 Eschwege Tel. (49-221) 94 98 14-0 Fax (49-221) 94 98 14 15
GHA-GB	Gharda Chemicals Ltd Europe	Holbrook House 72 Lower Addiscombe Road Croydon CR9 6AD United Kingdom Tel. (44-2086) 55 41 03 Fax (44-2086) 55 41 02
HRM-BE	Hermoo Belgium NV	Zepperenweg 257 B-3800 Sint-Truiden Tel. (32-11) 68 68 66 Fax (32-11) 70 74 84
IBE-ES	Iberotam SA	Muntaner, 322, 12a E-08021 Barcelona Tel. (34) 934 54 34 64 Fax (34) 934 54 89 21
IQV-ES	Industrias Químicas del Vallés SA	Av. Rafael Casanova 81 E-08100 Mollet del Vallès (Barcelona) Tel. (34) 935 79 66 77 Fax (34) 935 93 80 11
ISA-IT	Isagro SPA	Registration Department Centro Uffici San Siro Fabbricato D ala 3 Via Caldera, 21 I-20153 Milano Tel. (39-02) 40 90 11 Fax (39-02) 40 90 12 87
ISK-BE	ISK Biosciences Europe SA	Tour ITT Avenue Louise 480 bte 12 B-1050 Bruxelles Tel. (32-2) 627 86 11 Fax (32-2) 627 86 00

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Code identification	Name	Address
KCI-GB	Kumiai Chemical Industry Co., Ltd	London Liaison Office 35 Piccadilly London W1J 0DW United Kingdom Tel. (44-2077) 34 72 82 Fax (44-2077) 34 45 61
LAI-ES	Lainco, SA	Polígono Can Jardí Av. Bizet 8-12 E-08191 Rubí (Barcelona) Tel. (34) 935 86 20 15 Fax (34) 935 86 20 16
LKC-UK	Landis Kane Consulting	PO Box 383 Cheltenham Gloucestershire GL52 6WD United Kingdom Tel. (44-4161) 906 85 04 Fax (44-4161) 906 85 09
LON-DE	Lonza GmbH	Morianstraße 32 Postfach 13 14 53 D-42041 Wuppertal Tel. (49-202) 245 38-0 Fax (49-202) 245 38 10
MAI-PT	Margarita Internacional	Comércio e Serviços, Limitada Rua do Bom Jesus, 18-3.º Esq.º P-9050-028 Funchal Tel. (351-291) 23 24 84
MAK-BE	Makhteshim Agan	International Coordination Center (MAICC) Avenue Louise 283 B-1050 Bruxelles Tel. (32-2) 646 86 06 Fax (32-2) 646 91 52
MKC-BE	McKenna & Cuneo, L. L.P.	56, rue des Colonies, Box 14 B-1000 Bruxelles Tel. (32-2) 278 12 11 Fax (32-2) 278 12 00
MON-BE	Monsanto Europe SA	Regulatory Department Avenue de Tervuren 270-272 B-1150 Bruxelles Tel. (32-10) 49 42 11 Fax (32-10) 49 42 42
NCI-DE	Nissan Chemical Europe GmbH	Deutsch-Japanisches Center Immermannstraße 45 D-40210 Düsseldorf Tel. (49-211) 17 22 70 Fax (49-211) 16 22 43
NIH-GB	Nihon Nohyaku Co., Ltd	8 Cork Street Mayfair London W1S 3LJ United Kingdom Tel. (44-2074) 34 00 33 Fax (44-2072) 87 13 35

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Code identification	Name	Address
NLI-AT	Nufarm GmbH & Co KG	St.-Peter-Straße 25 A-4021 Linz Tel. (43-73) 26 91 80 Fax (43-73) 26 91 82 004
NPS-DE	Nisso Chemical Europe GmbH	Berliner Allee 29/Ecke Steinstraße D-40212 Düsseldorf Tel. (49-211) 323 01 35 Fax (49-211) 32 82 31
OXO-IT	Oxon Italia SpA	Via Sempione, 195 I-20016 Pero(MI) Tel. (39-02) 35 37 81 Fax (39-02) 339 02 75
PPC-ES	Proplan-Plant Protection Company, SL	Vía de las dos Castillas 11. Bloque 3, 1º C. E-28224 Pozuelo de Alarcón (Madrid) Tel. (34) 913 52 29 60 Fax (34) 913 52 72 82
PRO-ES	Probelte, SA	Ctra. Madrid Km. 384.6 Polígono Industrial El Tiro E-30100 Espinardo (Murcia) Tel. (34) 968 30 72 50 Fax (34) 968 30 54 32
PUS-FR	Phytorus SA	Parc d'Ariane, Bât B 11, boulevard de la grande Thumine F-13090 Aix-en-Provence Tel. (33-1) 60 27 26 26 Fax (33-4) 42 52 68 52
RCO-PT	Rice Madeira Company Europe	Comércio Internacional e Serviços, Sociedade Unipessoal Lda. Rua 31 de Janeiro n.º 81-A, 5.º E PT-9050-011 Funchal (Madeira) Tel. (351-291) 22 77 44 Fax (351-291) 22 66 31
RIV-IE	Rivendell Consulting Ltd	Rivendell House Stamullen County Meath Ireland Tel. (353-18) 41 52 95 Fax (353-18) 41 47 68
SCC-DE	SCC Scientific Consulting Company GmbH	Mikroforum Ring 1 D-55234 Wendelsheim Tel. (49-67) 34 91 90 Fax (49-67) 34 91 91 91
SCH-DE	Dr. Schirm AG	Kipper Straße 9-11 D-44147 Dortmund Tel. (49-392) 845 63 02 Fax (49-392) 845 63 00
SNO-FR	SINON EU Corporation	170, boulevard Haussmann F-75008 Paris Tel. (33-5) 59 60 92 92 Fax (33-5) 59 60 92 19

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Code identification	Name	Address
SPC-FR	Sipcam-Phyteurop	Courcellor 2 35, rue d'Alsace F-92531 Levallois-Perret Cedex Tel. (33-1) 47 59 77 00 Fax (33-1) 47 37 54 52
SUM-FR	Sumitomo Chemical Agro Europe SA	2, rue Claude Chappe F-69370 Saint-Didier-au-Mont-d'Or Tel. (33-4) 78 64 32 60 Fax (33-4) 78 47 70 05
SYN-DE	Syngenta Agro GmbH	Am Technologiepark 1-5 Postfach 110353 D-63477 Maintal Tel. (49-6971) 55-0 Fax (49-6971) 55-319
SYN-GB	Syngenta Europe Ltd	European Regional Centre Priestley Road Surrey Research Park Guildford Surrey GU2 7YH United Kingdom Tel. (44-1483) 26 00 00 Fax (44-1483) 26 00 19
TOM-FR	Tomen France	18, avenue de l'Opéra F-75001 Paris Tel. (33-1) 42 96 14 56 Fax (33-1) 42 97 52 91
TSG-GB	Sankyo Company Ltd	C/o TSGE Conyngham Hall Knaresborough North Yorkshire HG5 9AY United Kingdom Tel. (44-1423) 79 91 51 Fax (44-1423) 79 91 55
UCB-BE	UCB Chemicals NV	Allée de la Recherche 60 B-1070 Bruxelles Tel. (32-2) 559 99 99 Fax (32-2) 559 99 00
UNI-NL	Uniroyal Chemical Europe BV	Registration Department Ankerweg 18 1041 AT Amsterdam Nederland Tel. (31-20) 587 18 60 Fax (31-20) 587 18 68
UPL-GB	United Phosphorus Ltd	Chadwick House Birchwood Park Warrington Cheshire WA3 6AE United Kingdom Tel. (44-1925) 81 99 99 Fax (44-1925) 81 74 25

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ANNEX III

Coordinating authority in the Member States (more details are available at the following website: http://www.europa.eu.int/comm/food/fs/ph_ps/pro/index_en.htm)

AUSTRIA

Bundesamt für Ernährungssicherheit
Landwirtschaftliche Untersuchungen und Forschung Wein
Spargelfeldstraße 191
A-1220 Wien

BELGIUM

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

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
Ciudad de Barcelona, 118-120
E-28007 Madrid

FINLAND

Kasvintuotannon tarkastuskeskus
Torjunta-aineet
PL 42
FIN-00501 Helsinki

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FRANCE

Ministère de l'agriculture, de l'alimentation, de la pêche et des affaires rurales
Sous-direction de la qualité et de la protection des végétaux
Bureau de la réglementation et de la mise sur le marché des intrants
251, rue de Vaugirard
F-75732 Paris Cedex 15

IRELAND

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

ITALY

Ministero della Salute
Direzione generale della Sanità pubblica veterinaria degli alimenti e della nutrizione
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 Oeiras

SWEDEN

Kemikalieinspektionen
Box 1384
S-17127 Solna

UNITED KINGDOM

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

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ANNEX IV

Organisations in the Member States to be contacted concerning further details on the payment of the fees referred to in Article 17 and to which such fees have to be paid

AUSTRIA

Bundesamt für Ernährungssicherheit

Landwirtschaftliche Untersuchungen und Forschung Wein

Spargelfeldstraße 191

A-1220 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 S. Bolivar 30

B-1000 Bruxelles

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

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

Ciudad de Barcelona, 118-120

E-28007 Madrid

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FINLAND

Kasvintuotannon tarkastuskeskus
Torjunta-aineet
PL 42
FIN-00501 Helsinki
Bank and account:
LEONIA BANK PLC
PSP BFIHH
800015-18982

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 number: 11281011

LUXEMBOURG

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

THE 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 Oeiras
Account number: 003505840003800793097
Bank: Caixa Geral de Depósitos

SWEDEN

Kemikalieinspektionen
Box 1384
S-17127 Solna
National Giro Account: 4465054-7

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UNITED KINGDOM

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

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ANNEX V

Criteria for clear indications of no harmful effects

An active substance shall be considered as fulfilling the requirement, as referred to in Article 11b, of there being clear indications that it may be expected that it does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment if all the criteria set out in points 1 and 2 are met.

1. The active substance satisfies the following criteria:

   (a) it is not classified or proposed for classification as C (carcinogenic effects) M (mutagenic effects) R (toxic to reproduction) in categories 1, 2 or 3 in accordance with Directive 67/548/EEC;

   (b) either not requested or, if required, an ADI (Acceptable Daily Intake), AOEL (Acceptable Operator Exposure Level) and ARfD (Acute Reference Dose) can be established on the basis of the standard assessment factor of 100;

   (c) it is not considered to have the potential to meet the criteria of a persistent organic pollutant set out in Regulation (EC) No 850/2004 of the European Parliament and of the Council ([1]);

   (d) it is not considered to have the potential to meet the criteria set out in Annex XIII to the Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([2]).

2. At least one supported representative use of the active substance satisfies all of the following criteria:

   (a) operator exposure is less than or equal to 75 % of the AOEL in modelled scenarios, considered relevant for the intended use and where the use of such modelling is appropriate to the supported use and at maximum using gloves as personal protective equipment (PPE);

   (b) bystander exposure and worker exposure is less than or equal to 75 % AOEL in modelled scenarios, considered relevant for the intended use and where the use of such modelling is appropriate to the supported use and without the use of PPE;

   (c) consumer exposure is less than or equal to 75 % of the ADI or ARfD (where such a value is necessarily established) in all available EU consumer diets on the basis of the MRLs (Maximum Residues Level) proposed for the active substance (without special refinements);

   (d) leaching to groundwater is below 0,1 μg/l in at least half of the scenarios considered relevant for the intended use, or in relevant lysimeter/field studies, for both the parent substance and relevant metabolites;

   (e) buffer zones for the protection of the environment do not exceed 30m without any further risk mitigation measures (e.g. drift reducing nozzles);

   (f) the risk to non-target organisms is acceptable based on standard refinements.

([1]) OJ L 158, 30.4.2004, p. 7; corrected by OJ L 229, 29.6.2004, p. 5.
([2]) OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3.

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ANNEX VI

Criteria for clear indications of harmful effects

An active substance shall be considered as fulfilling the requirement, as referred to in Article 11f, of there being clear indications that on the basis on the available data, and which are evaluated in accordance with the provisions of Article 11d, it may be expected that it has harmful effects on human or animal health or on groundwater if either the criterion in point 1 or one of the criteria in point 2 is met.

1. As regards the active substance, the existing evidence is not sufficient to allow the establishment of an ADI, ARfD or an AOEL and such values are necessary to conduct a consumer and operator risk assessment.

2. As regards each supported representative use, at least one of the following criteria is met:

   (a) operator exposure is greater than 100 % AOEL in all modelled scenarios with the use of PPE/RPE (Personal Protective Equipment/Respiratory Protective Equipment), where the use of such modelling is appropriate to the supported use, and where actual exposure data, if available, also indicate that the AOEL will be exceeded under normal conditions of use;

   (b) bystander exposure and worker exposure is greater than 100 % AOEL in modelled scenarios, where the use of such modelling is appropriate to the supported use, and where actual exposure data, if available, indicate that the AOEL will be exceeded for these groups under normal conditions of use;

   (c) consumer exposure is greater than 100 % of the ADI or ARfD (where such a value is required) in at least one of the available EU consumer diets on the basis of the MRLs (Maximum Residues Level) proposed for the active substance;

   (d) leaching to groundwater is equal to or above 0,1 μg/l in all modelled scenarios either for the parent substance or for relevant metabolites.