COMMISSION REGULATION (EC) No 1095/2007

of 20 September 2007

amending Regulation (EC) No 1490/2002 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 Regulation (EC) No 2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], and in particular Article 8(2) thereof,

Whereas:

(1) Article 8(2) of Directive 91/414/EEC provides that the Commission undertakes a programme of work for the gradual examination of active substances on the market two years after the date of notification of this Directive. This programme is still ongoing.

(2) The second and third stage of work are 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 [2] and Commission Regulation 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 [3]. The fourth stage of work is laid down by Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC [4].

(3) Several substances in the third and fourth stages are still in the assessment phase. It appears necessary to speed up the examination process. Depending on whether a substance is already under peer review or not, for certain aspects of the procedure, different provisions should apply.

(4) To speed up the examination process the workflow of the peer review and relationship between notifiers, Member States, the European Food Safety Authority (EFSA) and the Commission and the obligations of each of the parties for the implementation of the programme should be adapted without harming the level of safety for health and the environment.

(5) The resources of the EFSA should be used efficiently. Where there are clear indications that the active substance concerned meets the criteria referred to in Article 5(1) of Directive 91/414/EEC, and in particular does not have any harmful effects on humans or animal health or on groundwater or any unacceptable influence on the environment, that substance should be included in Annex I to that Directive. Such clear cases would not require detailed scientific advice from the EFSA before the substance is included in Annex I. The EFSA should, however, deliver its view on those substances later, in particular to ensure a harmonised approach when Member States apply the uniform principles at the evaluation of authorisations. Where, on the contrary, there are clear indications that an active substance has harmful affects; the Commission is not required to have this clear situation confirmed, so it should have the possibility to decide on non-inclusion without consulting the EFSA.

(6) The EFSA should focus on cases where the remaining doubts need to be resolved before a decision on the inclusion of the active substance concerned can be taken.

(7) To further speed up procedures, it should be possible to grant a longer withdrawal period in cases where there are such remaining doubts and notifiers agree to withdraw their support of the inclusion of the active substance. This procedure should only apply to cases where there are no clear indications that the substance has harmful effects on humans or animal health or on groundwater or any unacceptable influence on the environment.

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/52/EC (OJ L 214, 17.8.2007, p. 3).
[2] OJ L 55, 29.2.2000, p. 25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p. 32).
[3] OJ L 224, 21.8.2002, p. 23. Regulation as last amended by Regulation (EC) No 1744/2004 (OJ L 311, 8.10.2004, p. 23).
[4] OJ L 379, 24.12.2004, p. 13. Regulation as amended by Regulation (EC) No 647/2007 (OJ L 151, 13.6.2007, p. 26).

(8) To identify cases where there are clear indications of either a substance having no harmful effects or, on the contrary, a substance having such effects, criteria should be set out.

(9) In order to ensure that the deadlines for evaluation are met, and to ensure equal treatment of all notifiers, the current legislation provides that notifiers may not submit new studies after a certain stage of the assessment, subject to limited exceptions. This general principle should be retained, but it is appropriate to clarify when notifiers may submit new information other than studies.

(10) Regulations (EC) No 1490/2002 and (EC) No 2229/2004 should therefore be amended accordingly.

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

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1490/2002

Regulation (EC) No 1490/2002 is amended as follows:

1. Articles 11 and 12 are replaced by the following:

'*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).

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.

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.

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.

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.'

2. The Annexes to Regulation (EC) No 1490/2002 are amended in accordance with Annex I to this Regulation.

Article 2

Amendments to Regulation (EC) No 2229/2004

Regulation (EC) No 2229/2004 is amended as follows:

1. Articles 24 and 25 are replaced by the following:

'*Article 24*

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 21(1) or Article 22(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, the 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 24a

Evaluation 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 24(2).

Article 24b

Active substances 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 VI, Article 25(1)(a) and (2)(a) shall apply.

Article 24c

Consultation of the EFSA

1. Where Article 24b 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 VII. 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 VII, the EFSA shall inform the Commission.

The Commission may take a Decision as referred to in Article 24f.

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 24d

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 24c, 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.

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 24e

Withdrawal by notifier

Where Article 24b 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 24(2).

Article 24f

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 VII 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 25(1)(a) and (2)(b) of this Regulation.

Article 25

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 24b or Article 24f applies;

(b) receipt of the conclusion by the EFSA where Article 24c applies;

(c) receipt of a written withdrawal of the notifier's support where Article 24e 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.

3. By way of derogation from point (b) of paragraph 2, the latest date for Member States to withdraw authorisations shall be 31 December 2010 in the case referred to in point (c) of paragraph 1 unless the Commission concluded that the substance meets the criteria of Annex VII, if appropriate after having consulted the EFSA.

Article 25a

View by the EFSA

Where an active substance is included in Annex I to Directive 91/414/EEC pursuant to Article 24b 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.'

2. The Annexes to Regulation (EC) No 2229/2004 are amended in accordance with Annex II to this Regulation.

Article 3

Transitional provisions for Regulation (EC) No 1490/2002

1. As regards active substances for which at the date of entry into force of this Regulation the EFSA had submitted its conclusions to the Commission, Regulation (EC) No 1490/2002, as it stood before its amendment by this Regulation, shall continue to apply.

2. As regards active substances for which, at the date of entry into force of this Regulation, the draft assessment report by the rapporteur Member State had been sent to the EFSA but for which the EFSA had not submitted its conclusions to the Commission, by way of derogation from Article 11e of Regulation (EC) No 1490/2002, Article 12(3) of that Regulation shall apply if both of the following conditions are satisfied:

(a) Article 11b does not apply and one of the following cases is present:

(i) the active substance is not expected to meet the criteria of Annex VI of that Regulation;

(ii) upon being consulted by the Commission, the EFSA has concluded that the active substance does not meet the criteria to Annex VI of that Regulation; and

(b) the notifier informs the Commission of the withdrawal of his support of the inclusion of the active substance in Annex I to Directive 91/414/EEC within two months from the entry into force of this Regulation.

Article 4

Transitional provisions for Regulation (EC) No 2229/2004

As regards active substances for which, at the date of entry into force of this Regulation, the draft assessment report by the rapporteur Member State had been sent to the EFSA but for which the EFSA had not submitted its conclusions to the Commission, by way of derogation from Article 24e of Regulation (EC) No 2229/2004, Article 25(3) of that Regulation shall apply if both of the following conditions are satisfied:

(a) Article 24b does not apply and one of the following cases is present:

(i) the active substance is not expected to meet the criteria of Annex VII of that Regulation;

(ii) upon being consulted by the Commission, the EFSA has concluded that the active substance does not meet the criteria to Annex VII of that Regulation; and

(b) the notifier informs the Commission of the withdrawal of his support of the inclusion of the active substance in Annex I to Directive 91/414/EEC within two months from the entry into force of this Regulation.

Article 5

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

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

Done at Brussels, 20 September 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

Amendments to the Annexes to Regulation (EC) No 1490/2002

After Annex IV to Regulation (EC) No 1490/2002 the following Annexes are added as Annexes V and VI:

'*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 (*);

   (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. 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.

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

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.'

ANNEX II

Amendments to the Annexes to Regulation (EC) No 2229/2004

After Annex V to Regulation (EC) No 2229/2004 the following Annexes are added as Annexes VI and VII:

'ANNEX VI

Criteria for clear indications of no harmful effects

An active substance shall be considered as fulfilling the requirement, as referred to in Article 24b, 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 (*);

(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. 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.

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

ANNEX VII

Criteria for clear indications of harmful effects

An active substance shall be considered as fulfilling the requirement, as referred to in Article 24f, of there being clear indications that on the basis on the available data, and which have been evaluated in accordance with the provisions of Article 24d, 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.'