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Chemical Review Committee
Eighth meeting
Geneva, 19–23 March 2012
Item 5 (b) (ii) of the provisional agenda**

Technical work: review of notifications of final regulatory actions: trichlorfon

Trichlorfon

Note by the Secretariat

Addendum

Supporting documentation provided by the European Community

The Secretariat has the honour to provide, in the annex to the present note, documentation received from the European Community[1] to support its notification of final regulatory action for trichlorfon as a pesticide. The documentation has not been formally edited.

* Reissued for technical reasons on 12 March 2012.

** UNEP/FAO/RC/CRC.8/1.

[1] As indicated by the Depositary of the Convention in a notification dated 31 March 2010 (C.N.182.2010.TREATIES-2), which was based on a communication from the Council of the European Union dated 8 March 2010 following the entry into force of the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, with effect from 1 December 2009 the European Union replaced the European Community (article 1, third paragraph, of the Treaty of Lisbon) and took over all rights and obligations of the European Community. The former European Community has accordingly been replaced by the European Union in respect of all conventions or agreements for which the Secretary-General of the United Nations is the depositary and to which the European Community is a signatory or a contracting party. Since the notification for trichlorfon was sent on 6 October 2009, before the entry into force of the Lisbon Treaty in December that same year, the notification was officially submitted by the European Community.

Annex

- **Commission decision of 21 May 2007 concerning the non-inclusion of trichlorfon in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance**

- **Review report for the active substance Trichlorfon Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 29 September 2006 in support of a decision concerning the non-inclusion of trichlorfon in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance**

- **Conclusion regarding the peer review of the pesticide risk assessment of the active substance trichlorfon**

COMMISSION DECISION

of 21 May 2007

concerning the non-inclusion of trichlorfon in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance

(notified under document number C(2007) 2096)

(Text with EEA relevance)

(2007/356/EC)

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 the fourth subparagraph of Article 8(2) thereof,

Whereas:

(1) Article 8(2) of Directive 91/414/EEC provides that a Member State may, during a period of 12 years following the notification of that Directive, authorise the placing on the market of plant protection products containing active substances not listed in Annex I of that Directive that are already on the market two years after the date of notification, while those substances are gradually being examined within the framework of a programme of work.

(2) Commission Regulations (EC) No 451/2000 [2] and (EC) No 703/2001 [3] lay down the detailed rules for the implementation of the second stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes trichlorfon.

(3) For trichlorfon the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 451/2000 and (EC) No 703/2001 for a range of uses proposed by the notifier. Moreover, those regulations designate the Rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 8(1) of Regulation (EC) No 451/2000. For trichlorfon the Rapporteur Member State was Spain and all relevant information was submitted on 23 August 2004.

(4) The assessment report has been peer reviewed by the Member States and the EFSA within its Working Group Evaluation and presented to the Commission on 12 May 2006 in the format of the EFSA Conclusion regarding the peer review of the pesticide risk assessment of the active substance trichlorfon [4]. This report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 29 September 2006 in the format of the Commission review report for trichlorfon.

(5) Due to significant lack of supporting studies, it has not been possible to demonstrate a safe use of the substance. Based on the available information it was not possible to perform the risk assessment of consumers, operators, workers and bystanders exposure. Moreover, the evaluation of fate and behaviour of the substance in the environment was limited and its eco-toxicological properties were not completely assessed.

(6) The Commission invited the notifier to submit its comments within four weeks on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments advanced, the above concerns remained unsolved, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing trichlorfon satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(7) Trichlorfon should therefore not be included in Annex I to Directive 91/414/EEC.

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/25/EC (OJ L 106, 24.4.2007, p. 34).
[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 98, 7.4.2001, p. 6.
[4] EFSA Scientific Report (2006) 76, 1-62, '*Conclusion on the peer review of trichlorfon*'.

(8) Measures should be taken to ensure that existing authorisations for plant protection products containing trichlorfon are withdrawn within a prescribed period and are not renewed and that no new authorisations for such products are granted.

(9) Any period of grace for disposal, storage, placing on the market and use of existing stocks of plant protection products containing trichlorfon allowed by Member States, should be limited to a period no longer than twelve months to allow existing stocks to be used in no more than one further growing season.

(10) This Decision does not prejudice the submission of an application for trichlorfon according to the provisions of Article 6(2) of Directive 91/414/EEC in view of a possible inclusion in its Annex I.

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

HAS ADOPTED THIS DECISION:

Article 1

Trichlorfon shall not be included as active substance in Annex I to Directive 91/414/EEC.

Article 2

Member States shall ensure that:

(a) authorisations for plant protection products containing trichlorfon are withdrawn by 21 November 2007;

(b) from 25 May 2007 no authorisations for plant protection products containing trichlorfon are granted or renewed under the derogation provided for in Article 8(2) of Directive 91/414/EEC.

Article 3

Any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC, shall be as short as possible and shall expire not later than 21 November 2008.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 21 May 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants, pesticides

Trichlorfon

SANCO/10049/06 rev.0

September 2006

EU Limited

COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

Review report for the active substance **Trichlorfon**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 29 September 2006
in support of a decision concerning the non-inclusion of trichlorfon in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of trichlorfon, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EC) No 451/2000([1]) laying down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1490/2002([2]), has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. trichlorfon is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EC) No 451/2000, Cequisa notified to the Commission of their wish to secure the inclusion of the active substance trichlorfon in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EC) No 451/2000, the Commission, designated Spain as rapporteur Member State to carry out the assessment of trichlorfon on the basis of the dossier submitted by the notifier. In Regulation (EC) No

[1] OJ No L 55, 29.02.2000, p.25.

[2] OJ No L 224, 21.8.2002, p.23.

703/2001[3] the Commission specified furthermore that the deadline for the notifier with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EC) No 451/2000, as well as for other parties with regard to further technical and scientific information was 30 April 2002.

Cequisa submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore Cequisa was considered to be the main data submitter.

In accordance with the provisions of Article 8(1) of Regulation (EC) No 451/2000, Spain submitted on 23 August 2004 to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of trichlorfon in Annex I to the Directive. Moreover, in accordance with the provisions of Article 8(2) of Regulation (EC) 451/2000, the Commission and the Member States received also the summary dossier on trichlorfon from Cequisa, on 7 October 2004.

In accordance with the provisions of Article 8 of Regulation (EC) No 451/2000, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Cequisa being the main data submitter, on 9 September 2004 by making it available.

The EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

In accordance with the provisions of Article 8 (7) of Regulation 451/2000 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance trichlorfon (finalised: 12 May 2006)] [4]. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 8 (7) of Regulation (EC) No 451/2000, the Commission referred on 29 September 2006 a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 29 September 2006.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report including the background documents has been developed and finalised in support of the Directive **2007/356/EC**[5] concerning the non-inclusion of trichlorfon in Annex I to Directive 91/414/EEC.

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[3] OJ No L 98, 7.4.2001, p. 6.

[4] *EFSA Scientific Report* (2006) 76, 1– 62

[5] OJ No L 133, 25.5.2007, p. 42 -43.

In accordance with the provisions of Article 8 of Regulation (EC) No 451/2000, as modified by Regulation (EC) No 1490/2002, the finalised review report, excluding any parts which refer to confidential information contained in the dossier and determined as such in accordance with Article 14 of the Directive shall be made available for public consultation.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion of this evaluation, based on the information available and the proposed conditions of use, is that:

- **the information available is insufficient** to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC in particular with regard to

    - the risk assessment for operator, workers, bystanders and consumer exposure which could not be finalised
    - the fate and behaviour of the substance in the environment and its eco-toxicological properties

- **concerns were identified with regard to**

    - level of relevant impurities in the technical material
    - risk for aquatic organisms

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general the requirements laid down in Article 5 (1) (a) and (b) of Council Directive 91/414/EEC.

Trichlorfon should therefore not be included in Annex I to Directive 91/414/EEC.

Conclusion regarding the peer review of the pesticide risk assessment of the active substance

trichlorfon

finalised: 12 May 2006

SUMMARY

Trichlorfon is one of the 52 substances of the second stage of the review programme covered by Commission Regulation (EC) No 451/2000[1], as amended by Commission Regulation (EC) No 1490/2002[2]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Spain being the designated rapporteur Member State submitted the DAR on trichlorfon in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 23 August 2004. Following a quality check on the DAR, the peer review was initiated on 09 September 2004 by dispatching the DAR for consultation of the Member States and the sole applicant Cequisa. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting on 18 May 2005. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in September 2005.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 5 April 2006 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative use as an insecticide as proposed by the applicant which comprises application via tractor mounted our handheld sprayer to control lepidopteron insects in protected tomatoes with a maximum total dose of 7.2 kg trichlorfon per hectare. It should be noted that trichlorfon also has acaricidal properties. The representative formulated product for the evaluation was Cekufon 80 SP a soluble powder formulation (SP), registered under different trade names in Europe. In the DAR two sources were originally proposed however one of these sources is no longer supported. It is not clear from the DAR what material was used in the supporting studies and this information has not been provided by the applicant. In addition

[1] OJ No L 53, 29.02.2000, p. 25
[2] OJ No L 224, 21.08.2002, p. 25

to this a justification is required that the material used in the studies is equivalent to the material currently being produced.

Adequate methods are not available to monitor all compounds given in the respective residue definitions. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues. There is no method available for soil or for the relevant impurity dichlorvos in the formulation. The air method has no validation for dichlorvos which is in the residue definition. No conclusion can be made on the methods for water, soil and plants as the residue definitions are not finalised.
Some analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

Trichlorfon is harmful during oral exposure and skin sensitizer. The proposed classification is Xn; R22 "Harmful if swallowed" and Xi; R43 "May cause sensitization by skin contact". The most sensitive effect observed during short term exposure is reduction in acetyl cholinesterase activity. No relevant short term NOAEL could be derived due to an inadequate database for short term toxicity (lack of subchronic studies in dog, which seems to be most sensitive, and inadequate dose-spacing in the 90-day rat study). Due to positive results for a genotoxic potential *in vitro*, a data requirement has been set for further *in vivo* data with mammalian somatic cells. Based on carcinogenicity studies in rats and mice, no carcinogenic potential has been shown for trichlorfon. Based on the poor quality of the reproductive studies, a data requirement has been set for a multigeneration study in rats. However, the available teratology studies show that trichlorfon has no developmental toxicity.
Due to the lack of data, the reference values were not confirmed in the expert meeting. Based on the provisional AOEL provided by the rapporteur Member State in the DAR, together with a dermal absorption of 100% instead of 10%, the operator, worker and bystander exposure estimates exceed the AOEL to a large extent.

The metabolism of trichlorfon has been investigated in tomatoes. It shows that trichlorfon undergoes dehydrochlorination and rearrangements to form different metabolites. The metabolites are either conjugated or further metabolised to form naturally occurring compounds. Only the parent trichlorfon and the metabolite trichlorethanol were determined as free compounds in tomatoes. The study presents a major deficiency. That is, the origin of the important loss of radioactivity encountered in the study, ascribed by the notifier to the volatility of the metabolite dimethyl O-(2, 2-dichlorovinyl phosphate), has not been proved.
As both the metabolism study and the information about the toxicological relevance of metabolites are considered incomplete, it is not possible to propose a residue definition for risk assessment. The number of the submitted supervised field trials in tomatoes, carried out according to the critical GAP, was not sufficient. As a result, the residue data provided are not considered sufficient to support the use of trichlorfon in tomatoes. The nature of trichlorfon residues in processed tomato commodities has not been investigated. Furthermore, due to the limited available data on the magnitude of

trichlorfon residue levels in processed commodities, the processing of raw commodities is not considered as sufficiently investigated.
A confined rotational crop study with radio labelled trichlorfon was carried out, but, on the base of the available data, it was not possible to conclude whether significant residue levels are expected in rotational crops following the application of trichlorfon according to the proposed GAP.
Studies on the metabolism, distribution and expression of trichlorfon residues in livestock are not required as trichlorfon is not intended for use in commodities used as animal feed.
Based on the currently available data, the investigation of the residue situation is incomplete and therefore the risk assessment for consumers cannot be performed, nor can an MRL be proposed.

The available data, from aerobic soil degradation studies that were not completely acceptable, suggested that trichlorfon breaks down rapidly in soil, being pH the most important factor for its degradation. The major metabolites (> 10% AR) identified in soil were desmethyl-dichlorvos and dichlorvinyl phosphate (tentatively identified). In a soil metabolism study with dichlorvos, the metabolites found were only short –lived, intermediate products of the degradation of dichlorvos, which rapidly underwent to complete mineralization. Nevertheless, due to the lack of information, a sound assessment of the route and rate of degradation of trichlorfon in soil cannot be concluded. Waiting for the new study, the available data indicated that trichlorfon and its metabolite are highly mobile in soil. Due to the difficulty to derive experimentally a reliable K_{oc} value for trichlorfon, a worst case K_{oc} value of 0 to be used in the risk assessment was suggested by the experts during the peer review process. Direct photodegradation cannot be expected to contribute to the dissipation of trichlorfon in the environment.
Trichlorfon appears to be stable under acid solutions, but unstable in neutral and basic solutions. Dichlorvos, desmethyl-dichlorvos and dichloroacetaldehyde were identified as degradates hydrolytically produced but they were not appropriately quantified.
Potential for contamination of surface and groundwater by trichlorfon and trichlorfon degradates cannot be adequately assessed because acceptable aerobic soil degradation study and water-sediment study are not available. Preliminary PEC_{sw} presented in the DAR by the rapporteur Member State can be considered as an unrealistic worst case. A water-sediment system performed with the metabolite dichlorvos indicated that dichlorvos degraded rapidly (DT_{50} < 1.5 d) in the water phase and shifted partly to the sediment. Dichloroacetic acid and dichloroacetaldehyde were identified as major short-lived metabolites in the water phase.
Trichlorfon would not be expected to be subject to long range transport, as in the upper atmosphere photochemical reaction with hydroxyl radicals is estimated to result in a half-life of 1.7 days.

The EPCO experts' meeting on ecotoxicology defined the glasshouse in the representative uses as a permanent structure to which entry by birds and mammals is limited. Due to the limited available data package in the section on ecotoxicology the following restriction/condition for use was recommended at the experts' meeting: 'Foliar application to tomatoes under protection in Southern Europe.
The risk to birds and mammals is regarded to be low based on a limited exposure situation in tomatoes under protection (see definition of a glasshouse above).

The study on *D. magna* needs to be repeated. Based on the existing study the risk to aquatic invertebrates can provisionally already be considered as high. The need for a study on *Chironomus riparius* and long term studies with aquatic organisms must be considered when the water/sediment study becomes available in the section on Fate and behaviour. The risk from metabolites potentially present in surface water as a result from emissions from glasshouses calculated according to the Dutch model still needs to be addressed. The risk from trichlorfon to aquatic organisms can only be concluded once the outstanding data becomes available.

Studies on the toxicity to bees are considered necessary as pollinators are present in tomato crops under glasshouse protection. The risk to bees can only be concluded once the outstanding data becomes available.

The risk to non-target arthropods, earthworms, other soil non-target macro-organisms, soil micro-organisms and non-target plants is considered to be low.

There is still an outstanding data gap for a study on the effects of trichlorfon on sewage treatment plants.

Key words: Trichlorfon, peer review, risk assessment, pesticide, insecticide

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BACKGROUND

Commission Regulation (EC) No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No 1490/2002, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Trichlorfon is one of the 52 substances of the second stage covered by the amended Regulation (EC) No 451/2000 designating Spain as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Spain submitted the report of its initial evaluation of the dossier on trichlorfon, hereafter referred to as the draft assessment report, to the EFSA on 23 August 2004. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 09 September 2004 to the Member States and the main applicant Cequisa as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed in an evaluation meeting on 18 May 2005 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier attended this meeting.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings organised on behalf of the EFSA by the EPCO-Team of the Pesticide Safety Directorate (PSD) in York, United Kingdom in September 2005. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 5 April 2006 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 8(7) of the amended Regulation (EC) No 451/2000, this conclusion summarises the results of the peer review on the active substance and the representative formulation

evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev. 1-1 of 7 June 2005)
- the consultation report

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 21 April 2006)

Given the importance of the draft assessment report including its addendum (compiled version of March 2006 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Trichlorfon is the ISO common name for Dimethyl (*RS*)-2,2,2-trichloro-1-hydroxyethylphosphonate. It is a racemic mixture of the *R* and *S* enantiomers.

Trichlorfon belongs to the class of phosphonate insecticides and acaracides the only other compound in this class is butonate. Trichlorfon is a non-systemic insecticide with contact and stomach action. It is acholinesterase inhibitor.
The representative formulated product for the evaluation was Cekufon 80 SP, a soluble powder (SP) formulation, registered under different trade names in Europe.

The evaluation of the representative use as an insecticide which comprises application via tractor mounted our handheld sprayer to control lepidopteron insects in protected tomatoes with a total maximum dose of 7.2 kg trichlorfon per hectare.

SPECIFIC CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of trichlorfon as manufactured should not be less than 980 g/kg, which is higher than the minimum purity given in the FAO specification 68/TC/S (1989) of 970 g/kg. The higher

value relates to the submitted results of current batch analysis and not to any toxicological concern to increase the minimum purity.

In the DAR two sources were originally proposed however one of these sources is no longer supported. It is not clear from the DAR what material was used in the supporting studies and this information has not been provided by the applicant. In addition to this a justification is required that the material used in the studies is equivalent to the material currently being produced.

As the above is the case, the specification for the technical material as a whole should be regarded as provisional.

The technical material contains dichlorvos, which has to be regarded as a relevant impurity. The FAO specification 68/TC/S (1989) does not have this compound listed as a relevant impurity. However, from its toxicology it is clear that it is a relevant impurity in trichlorfon.

The content of trichlorfon in the representative formulation is 800 g/kg (pure).

Beside the specification, the assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of dichlorvos or the respective formulation. However, the following data gaps were identified:
spectra for the relevant impurity dichlorvos,
shelf life study for the formulation to include analysis of the relevant impurity.

Also for the flammability and oxidizing properties the material used in the tests was purer than the minimum purity of the technical material and it is not clear if the data can be extrapolated.

In the FAO specification for the technical material 68/TC/S (1989) there are clauses for acidity and alkalinity of the technical material. It can not be confirmed that this technical material complies with this as it is not a data requirement for technical materials in accordance with Directive 94/37/EC.

In the FAO specification for the soluble powder formulation 68/SP/S (1989) the level of persistant foam at 6.4 mL after one minute exceeds the specification of 5 mL after 1 minute. However, this is not an issue as it is well within the test parameters which allow 60 mL after 1 minute. In addition to this there is also a wet sieve test clause in the FAO specification for the soluble powder but it can not be confirmed that this SP formulation will comply with it as it is not a data requirement under Directive 94/37/EC.

The main data regarding the identity of trichlorfon and its physical and chemical properties are given in appendix 1.

Adequate analytical methods are available for the determination of trichlorfon in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material. However, there is no method for the analysis of the relevant impurity in the formulation.

However, sufficient test methods and data relating to physical, chemical and technical properties and analytical methods are available to ensure that at least limited quality control measurements of the plant protection product are possible.

Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues. Residues in tomato crops are analysed for trichlorfon by GC-NPD with an LOQ of 0.01 mg/kg but no final conclusion can be reached as the residue definition is not finalised. There is no method available for soil and although the use is under protection it is not clear if this means under permanent structures or under protection that can be remove either during crop production or after the cropping cycle. Therefore as this may be the case a method of analysis for soil is required. A GC-ECD method is available for the analysis of trichlorfon in drinking water/groundwater with an LOQ of 0.05 µg/L and in surface water with an LOQ of 0.5 µg/L however, no conclusion can be drawn as the residue definition has not been finalised. The air method for trichlorfon was also by GC-ECD with an LOQ of 0.3 µg/m^3. No method is available for dichlorvos in air which is required as dichlorvos is included in the residue definition. An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed (see 3.2).

The discussion in the meeting of experts (EPCO 35, September 2005) on identity, physical and chemical properties and analytical methods was limited to the specification of the technical material, relevant impurity in the formulation and compliance with the FAO specification

2. Mammalian toxicology

Trichlorfon is an insecticide that acts by inhibiting the acetyl cholinesterase (AChE) activity. In September 2005 it was discussed at EPCO experts' meeting for mammalian toxicology (EPCO 33). The overall quality of the database is poor (absence of subchronic studies in dogs or mice, which are shown more sensitive in preliminary results of a 4-year study, non validity of the reproductive studies, lack of investigations of the genotoxic potential *in vivo*) and does not allow for a conclusive risk assessment for operators, workers and bystanders.

It should be noted that the material used in toxicological studies has not been shown to be representative of the current technical specification. Most of the toxicological studies were conducted with purities ≥98% but no information is available about the levels of impurities (see section 1).

2.1. ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

The absorption was rapid and complete (80-90% within 24 h). The highest levels in plasma were found at 0.5 h. and at 5 h, indicating an enterohepatic re-circulation. Is it widely distributed, with higher concentrations in the liver and kidney. The levels of radioactivity in the body ranged from 6 to 9% of the administered dose at 48h.

In the rat, the excretion was mainly via urine (50%), followed by feces (20%) and expired CO_2 (20%).

In the rabbit, the excretion was predominantly by urine (more than 95%).

The proposed main metabolic pathway is glucuronidation and further dehydrochlorination. Another pathway involves the conversion to dichlorvos. Based on the amounts of dichlorvos found in plasma or urine, this is considered to be a minor route in rats (less than 1% of the administered dose) but more important in rabbits and dogs (up to 5% of the administered dose). The third route of degradation implies reductive dechlorination and further glucuronidation.

2.2. ACUTE TOXICITY

The oral toxicity is higher than the dermal toxicity in rats (oral LD_{50} 212 mg/kg bw, dermal LD_{50} > 5000 mg/kg bw). According to these results, **the proposed classification is Xn, R22 "Harmful if swallowed"**.

The inhalatory LC_{50} in rats is greater than 0.533 mg/L. The study report does not specify that the highest tested concentration was the highest attainable. However, no further data requirement has been confirmed by the experts since the low vapour pressure of trichlorfon (below 0.01 Pa) doesn't imply the need of an inhalation study.

Trichlorfon is not a skin or an eye irritant, but a skin sensitizer (Magnusson and Kligman test). Therefore, **the proposed classification is Xi, R43 "May cause sensitization by skin contact"**.

EFSA notes: as regards the inhalation toxicity, a concern might be raised due to the fact that the formulation is a powder. However, a formulation (80% trichlorfon) has been tested for acute toxicity by inhalation and the LC_{50} was greater than 1.564 mg/L (~1.25 mg a.s./L), the maximum attainable concentration.

2.3. SHORT TERM TOXICITY

The short term effects of trichlorfon were studied in a 90-day oral gavage study in rats, a 3-week inhalation study in rats and a 3-week dermal study in rabbits. An 8-week pilot study with mice was performed but no NOAEL could be established since the study did not show the relation between the dietary concentration of trichlorfon and the effective dose level in mg/kg bw/day. In addition no 90-day or 1-year dog studies were presented. The most sensitive endpoint is the inhibition of acetylcholinesterase (AChE) activity. The target organs are the liver, kidneys and spleen (increased weights).

In the 90-day oral study in rats, the RBC and brain AChE activities were not determined. Based on the decrease in plasma AChE activity in females (more than 30%) and on the neurotoxicological signs in males (tremors, lower motor activity), the proposed LOAEL for female rats was 45 mg/kg bw/day (lowest dose tested) and the proposed NOAEL for male rats was 135 mg/kg bw/day.

Following the data requirement for the notifier to clarify RBC and brain AChE activities in this study, the results of a new 90-day neurotoxicity study in rats are presented in section 2.7.
In the 3-week inhalation study in rats, the proposed NOAEL is 3.43 mg/kg bw/day based on the inhibition of plasma/RBC/brain AChE activities in females and an increased spleen weight in males.
In a 3-week dermal study in rabbits, the proposed dermal NOAEL is 100 mg/kg bw/day based on the inhibition of RBC AChE activity.

The **data requirement** proposed in the DAR for an oral 90-day or 1-year dog study has been confirmed by the experts who concluded that a relevant short term NOAEL in relation to the setting of the AOEL could not be derived due to an inadequate database for short term toxicity.
EFSA notes: in a 4-year dog study, considered as non acceptable due to severe deviations from the guideline, mortality was very high at high dose levels (~20 and 80 mg/kg bw/day). The need for classification with R48 has been raised by the experts. Therefore, the lack of subchronic studies in dogs, which seem to be the most sensitive species, is an important data gap. In addition, the dose-spacing in the 90-day rat study did not allow the determination of an NOAEL.

2.4. GENOTOXICITY

The mutagenic potential of trichlorfon has been investigated in a comprehensive range of *in vitro* assays, including gene mutation, chromosomal aberration and DNA damage as endpoints. The purity of the toxicological batches was in accordance with the minimum purity of the technical specification (between 98.4 and 99.3%).
With respect to gene mutation *in vitro*, equivocal results were obtained in the cultured mammalian cells (Chinese hamster lung cells). Positive results were obtained for *in vitro* chromosome aberrations in human lymphocytes, with and without metabolic activation. However the clastogenicity could not be confirmed *in vivo* for somatic cells (micronucleus test) or germ cells (dominant lethal assay) since the studies were considered as non acceptable due to major deviations from the guidelines. Therefore, the genotoxic potential of trichlorfon *in vivo* cannot be concluded.

In conclusion, the experts confirmed the data requirement set by the rapporteur Member State in the DAR. Further *in vivo* data are needed in somatic cells using an *in vivo* test for clastogenicity (metaphase analysis in rodent bone marrow or micronucleus test in rodents) and an *in vivo* test to investigate unscheduled DNA synthesis.

2.5. LONG TERM TOXICITY

In relation with long term effects, two 2-year oncogenicity studies in rats and one 2-year oncogenicity study in mice are considered in the DAR.

In the rat carcinogenicity studies, the observed effects were hypercholesterolemia, depression of AChE activities (plasma, RBC and brain) and anaemia. The affected organs were the liver (increased weight, cytoplasmic vacuolation, nodular regeneration) and the kidneys (chronic nephropathy, increased kidney weights and renal calcifications). Thus, based on brain AChE depression (17-18%),

hypercholesterolemia and renal calcifications (in males), the proposed long term NOAEL is 4.5 mg/kg bw/day in rats.

The incidence of adrenal pheochromocytomas and mononuclear cell leukaemia were increased in male rats. However, they were neither increased in females to the same extent, neither increased in the second study at a higher dose. In addition, adrenal pheochromocytoma is common in this strain of rat. Thus, classification is not warranted.

In the mouse carcinogenicity study, all the treated animals presented inhibition of brain AChE greater than 20%. The target organ was the liver (increased liver weight). Based on the depression in AChE activities, the proposed long term LOAEL in mice is 49.21 mg/kg bw/day. There was no carcinogenic effect observed in this study.

Based on the available data in rats and mice, the rapporteur Member State concluded that trichlorfon is not a carcinogenic compound.

2.6. REPRODUCTIVE TOXICITY

The toxic potential of trichlorfon on mammalian reproduction was assessed in a three-generation study in the rat, as well as in teratology studies in the rat and rabbit.

Due to poor quality, both the multi-generation and the teratology studies with rats were considered as unacceptable in the DAR. The experts also concluded that the additional results, from a published multi-generation study in rats presented in the addendum, were inadequate due to shortcomings. Consequently the **data requirement** for a new multigeneration study was maintained.

However, the experts considered that the available rat teratology study, supported by the rabbit teratology study, were sufficient to demonstrate that trichlorfon has no developmental toxicity.

Therefore, the relevant maternal NOAEL is 15 mg/kg bw/day (rabbit study), and the relevant developmental NOAEL is 45 mg/kg bw/day (rabbit study).

2.7. NEUROTOXICITY

Acute and subchronic delayed neurotoxicity studies with hens are presented in the DAR, as well as an acute neurotoxicity study with rats. A new 90-day neurotoxicity study in rats has been provided during the peer review process.

The acute delayed neurotoxicity study in hens is considered acceptable as additional information due to poor quality. The proposed LD_{50} is 167 mg/kg bw. Typical clinical signs of cholinesterase activity inhibition are observed, but no delayed neurotoxicity and no inhibition of NTE.

In a 90-day delayed neurotoxicity study with hens, delayed neurotoxicity was observed at the highest dose level (18 mg/kg bw/day), with inhibition of whole blood AChE activity, associated clinical signs and slight axonal degeneration of the spinal cord. The proposed subacute NOAEL in hens is 9 mg/kg bw/day.

With regard to acute neurotoxicity in rats, the proposed NOAEL is 10 mg/kg bw based on clinical signs (oral stains, red nasal stains, and urine stains), alterations in FOB, decreased motor activity, and significant plasma/RBC/brain AChE inhibition.

A new 90-day neurotoxicity study in rats has been included in an addendum prior to the expert meeting. The agreed NOAEL is 6 mg/kg bw/day, based on a significant inhibition in RBC and plasma AChE and a statistically significant inhibition in brain AChE (9-17% at week 13).

2.8. FURTHER STUDIES

No supplementary studies have been submitted.

Metabolites of toxicological concern include dichlorvos, found in animal metabolism, and DCA, found in plant metabolism in high amounts. The genotoxic and carcinogenic potential of dichlorvos has been discussed by the PPR Panel (March 2006). As regards DCA, it has been identified as carcinogen category 2 by IARC in 2004.

Another metabolite, DCE, is found in high amounts in plants and not in rat metabolism. No toxicological information is available for DCE (see section 3.1.1).

2.9. MEDICAL DATA

Evaluation of historical surveillance data (1977-1982) from a production factory revealed decreased and reversible plasma cholinesterase activity and induced changes in EEG patterns. Several cases of acute poisoning from suicides or accidental exposure have occurred, with dose-related clinical signs of cholinesterase inhibition. Delayed polyneuropathy was also observed in cases where victims survived (with weakness of the lower limbs).

Trichlorfon is an insecticide that has also been used for treatment of intestinal parasites and in patients with possible Alzheimer Disease. As these patients frequently tolerate higher dose of cholinergic compounds than normal subjects, the results obtained cannot be considered valid for the general population.

2.10. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

EFSA notes: Due to the lack of subchronic studies in dogs, the requirement of a new multigeneration study in rats, and the lack of *in vivo* genotoxic studies, the reference values were not confirmed by the experts. Here are the *provisional values proposed in the DAR* :

Based on the NOAEL of 4.5 mg/kg bw/day from the 2-year rat study, the ***provisional ADI is 0.045 mg/kg bw/day****, with the use of a safety factor 100.*

Based on the 90-day oral study in rats, with a LOAEL of 45 mg/kg bw/day, the ***provisional AOEL is 0.09 mg/kg bw/day****, with the use of a higher safety factor of 500.*

Based on the NOAEL of 10 mg/kg bw/day from the acute oral neurotoxicity study in rats, the ***provisional ARfD is 0.1 mg/kg bw*** *with the use of a safety factor of 100.*

2.11. DERMAL ABSORPTION

In the absence of dermal absorption studies, the proposed default value in the DAR was 10%. However a default dermal absorption value of 100% was considered appropriate by the experts on the basis of the physical/chemical properties.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

EFSA notes:

a) As the AOEL could not be agreed on due to an inadequate database (short term, reproductive toxicity and genotoxicity), the risk assessment for operators, workers and bystanders is regarded as **inconclusive**. For transparency, *the provisional risk assessment provided by the rapporteur Member State is presented below.* This has not been discussed by the experts.

b) It is important to note that the dermal absorption value used with these estimates in the DAR was 10%. As the experts agreed for a dermal absorption value of 100%, this will result in exposure estimates much higher than the provisional AOEL for operators, workers and bystanders.

c) The models used for the exposure assessment are not appropriate for a greenhouse use.

d) Furthermore, in relation with worker exposure, the potential evaporation of the metabolite dichlorvos from the plant was discussed by the experts. Since this was shown to be more than 30% of the applied trichlorfon (see also 3.1.1), this could be relevant for worker exposure by inhalation.

It should be noted that neither the reference values nor the risk assessment was agreed for dichlorvos due to uncertainties related to the carcinogenic properties (see conclusion report for dichlorvos[3]).

The applicant has been requested to provide further information related to this potential inhalation of dichlorvos by workers. Nothing has been received until now (April 2006).

The representative plant protection product Cekufon 80 SP is a soluble powder containing 800 g trichlorfon/kg for use on tomatoes in greenhouses.

Operator exposure

According to the intended uses submitted by the notifier the maximum applied dose is 2.4 kg a.s./ha and the minimum volume 1000 L of water /ha. The applications were made using tractor-mounted sprayers, handsprayer (gun) and knapsack. For the tractor-mounted application, the work rate taken into account is 10 ha/day and 3 h of spraying/day. For the hand held application, the work rate taken into account is 0.4 to 4 ha/day and 2 h of spraying/day.

The UK POEM model gave estimated exposures below the AOEL for gun and knapsack application methods if gloves are worn. With the German BBA model, only the knapsack application gave estimated exposures below the AOEL (79% and lower) with the use of gloves. For all the uses and when standard PPE, plus mask and protection for the head are used, the estimated exposition is under the AOEL (74% and lower).

[3] Conclusion regarding the peer review of the pesticide risk assessment of the active substance dichlorvos, EFSA Scientific Report (2006) 77, 1-42.

Worker exposure

Workers re-entering fields treated beforehand with Cekufon 80 SP are exposed to 45.5% AOEL when PPE are used or >900% AOEL when PPE are not used.

Bystander exposure

The risk assessment for bystanders was based on the estimation of Ganzelmeier et al 1995, taking into account a default drift rate of 8% of application. According to this, the worst case applications (gun application use without PPE) led to possible bystander exposure of about 76% of the AOEL.

3. Residues

Trichlorfon was discussed at the EPCO experts' meeting for residues (EPCO 34) in September 2005.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

Plant metabolism was studied in tomatoes from plants grown in greenhouse following application of trichlorfon radio labelled in only one position (C-1). The application rate (1 x 2.0 kg a.s./ha) was lower than the rate of the critical GAP (3 x 2.4 kg a.s./ha). Only trichlorfon and the metabolite trichloroethanol (TCE) were determined as free compounds in tomatoes. An enzymatic hydrolysis of the extract released the radioactive metabolites dichloracetaldehyde, dichloroethanol (DCE), dichloracetic acid (DCA) and glucose. The metabolite dimethyl O-(2, 2-dichlorovinyl phosphate) (DDVP or dichlorvos) was detected only on the surface of the tomatoes and only in the first 2 days after treatment. Other metabolites were detected but not identified as they accounted for less then 5% of the radioactive residue.

The metabolic pathway of trichlorfon proceeds mainly through dehydrochlorination and rearrangements to form DDVP. Both parent trichlorfon and DDVP undergo hydrolysis. The dimethyl phosphate moiety from parent trichlorfon and DDVP degrades to monomethyl phosphate and phosphoric acid, respectively. Furthermore, parent trichlorfon gives raise to tricholrethanol (TCE), while dichlorvinylethanol is formed from DDVP. Dichlorvinylethanol is subsequently degraded to dichloracetaldheyde, dichlorethanol (DCE) and dichloracetic acid (DCA). These compounds are then either conjugated or further metabolised to form naturally occurring compounds such as glucose.

The metabolism study has been carried out for a period of 21 days. The total radioactive residue measured during the first 10 days of the study decreased by reaching a level of 64.2 % of the applied radioactivity at the 10th day after treatment. The notifier attributed the loss of radioactivity to the high volatility of metabolite DDVP formed on the surface of tomatoes. Different literature studies, which deal with the volatility and the analysis of DDVP in air, were provided by the notifier to support this hypothesis. Nevertheless, it is considered that the studies provided are not sufficient to demonstrate that the loss of radioactivity from the surface of tomatoes occurred by evaporation of DDVP. In conclusion, the metabolic pathway of trichlorfon in tomatoes cannot be considered as sufficiently investigated.

The metabolism study is considered to be incomplete. Nevertheless, on the base of the available data, it indicates that some metabolites are formed and that for some of these metabolites the measured amount in tomatoes increased over the time after application. After 21 days from the application, metabolites DCA and DCE largely exceeded the trigger value of 10% of the total radioactive residue, reaching the 41% and the 30% of the total radioactive residue, respectively. Metabolite TCE exceeded the trigger value of 10% of the total radioactive residue only at the sampling interval of 14 days after treatment. Furthermore, considering the data available it seems that the amount of TCE is not increasing over the time as for metabolites DCA and DCE. Concerning the toxicological relevance of metabolites DDVP, DCA and DCE, the notifier has provided some studies (see Addendum I, B-7 of July 2005). As it results that both DDVP and DCA are classified by IARC in the group 2B, i.e. as possibly carcinogenic to humans, the rapporteur Member State has proposed a residue definition for risk assessment purposes including the parent compounds, DDVP and DCA. It is noted that the metabolite DCE was not identified in the metabolism study of trichlorfon in rats and that no information are made available from the notifier on the toxicological relevance of DCE.
At the EPCO meeting 34 (September 2005) it was concluded that it was not possible to agree on the residue definition for risk assessment purposes as information on the toxicological relevance of metabolites was incomplete. In conclusion, as both the metabolism study provided by the notifier and the information about the toxicological relevance of metabolites are considered incomplete, it is not possible to propose a residue definition for risk assessment. For the same reasons mentioned above, it is not possible to draw a conclusion on the residue definition for enforcement purposes as well.
At the EPCO meeting held in September 2005 it was discussed the influence of the definition of the residue in plants. It was concluded that for Member States authorisations, Member States should be aware that the metabolite DDVP may be a significant component of the residue, particularly for GAPs with shorter pre-harvest intervals.

Only two residue trials have been conducted with trichlorfon in tomatoes under glasshouse conditions and in accordance with the proposed GAP. In these studies, only the residue level of parent trichlorfon was quantified. The residue levels determined in both studies were above the LOQ of 0.01 mg/kg (0.05 and 0.34 mg/kg). Furthermore, in the two studies provided the declining trends of the residue levels at different sampling times after the last treatment were significantly different. The notifier has submitted other studies on supervised field trials, but all of them have been carried out either in open field conditions or not in accordance to the proposed GAP. Therefore, the extrapolation from the results of these studies to the proposed GAP was not possible. As a result, the residue data provided are not considered sufficient to support the use of trichlorfon in tomatoes.

The storage stability study has shown that residue levels of trichlorfon in both tomatoes and ketchup are stable for a period up to 180 days. In the study, only parent trichlorfon was considered as residue.

The nature of trichlorfon residues in processed tomato commodities has not been investigated. For the assessment of the magnitude of trichlorfon residue in processed commodities only two data sets on

residue levels of parent trichlorfon were available. There, the residue levels in tomato juice, puree, ketchup, canned tomatoes and pomace from tomatoes treated according to the proposed GAP were analysed. Due to the limited available data in processed commodities the effect of the processing on the raw commodities are not considered as sufficiently investigated.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

A confined rotational crop study with radio labelled trichlorfon was carried out. Trichlorfon was applied to bare soil at a rate of 3.5 kg a.s./ha (ca 1.5 N) and aged in the soil for 30, 121 and 251 days before planting wheat, red beets and kale. The total radioactive residues were significantly higher in all three crops at the intermediate planting interval of 121 days (up to 0.624 mg trichlorfon equivalents/kg in wheat straw) than in the first planting interval of 30 days (up to 0.024 mg trichlorfon equivalents/kg in wheat straw).

After 30 days aging, no residues of parent trichlorfon were detected in soil, but only traces of trichloroacetic acid. In the crops none of the peaks detected were attributed to known metabolites. The only analytical peaks that accounted for more than 0.05 mg trichlorfon equivalents/kg were found in wheat straw samples from the intermediate interval planting. As an explanation why the residues found in the intermediate rotational crops were higher than the residues in the first rotational crops has not been provided, the rotational crop study has been considered incomplete. Therefore, based on the available data, it is not possible to conclude whether significant residue levels of trichlorfon are expected in rotational crops following the application of trichlorfon according to the proposed GAP.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Studies on the metabolism, distribution and expression of trichlorfon residues in livestock have not been provided. Based on the representative uses for Annex I inclusion these studies are not required as trichlorfon is not intended for use in commodities used as animal feed.

3.3. CONSUMER RISK ASSESSMENT

As the investigation of the residue situation is incomplete and the residue definition has not been agreed the risk assessment for consumers cannot be performed.

3.4. PROPOSED MRLS

As the investigation of the residue situation is incomplete, it is not possible to propose an MRL for the representative use in tomatoes.

4. Environmental fate and behaviour

Trichlorfon was discussed at the EPCO experts' meeting for Fate and Behaviour in the environment (EPCO 31) in September 2005.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

In a laboratory study on 4 soils maintained under aerobic conditions (26 ± 4ºC at field capacity) dosed with 1-^{14}C-(2,2,2-trichloro hydroxyethyl) dimethyl phosphonate, the pH of the soil was the most important factor in trichlorfon degradation. No clear information regarding the formation fractions of metabolites was given in the original report with respect to the experiments carried out with distilled water (pH 5) and tap water (pH 7). However, accumulation of **desmethyl dichlorvos** (desmethyl DDVP; methyl O-(2,2-dichlorovinyl phosphate) and an unknown metabolite, proposed to be **dichlorvinyl phosphate**, seemed to occur. Indicative information on the maximum amounts reached during the study were 37.5% AR (67d, study end) for desmethyl DDVP, and 40.7% AR (67d, study end) for dichlorvinyl phosphate (67d, study end), no reaching a plateau at the end of the study. The applicant proposed that trichlorfon degrades to desmethyl dichlorvos by two routes by the desmethylation of the parent and also by dichlorvos (DDVP) via at pH 7, acting dichlorvos as an intermediate in the degradation of trichlorfon. Nevertheless, due to different uncertainties in the experimental methodology, the study was considered not valid and a data requirement for the applicant for a new aerobic soil degradation study was identified by the rapporteur Member State in the DAR and confirmed by the experts' meeting (EPCO 31). In a second study, the degradation and the metabolic behaviour of 1-^{14}C-dichlorvos (2,2 dichloroethyl dimethyl phosphate) was investigated in a natural soil under aerobic conditions. No information regarding the pH conditions of the study was given; therefore it was not possible to compare the results with the ones from the previous study. Dichlorvos degraded rapidly in soil with the formation of very short-lived intermediate products: desmethyl-dichlorvos (max. 14.2% AR, 0 d), 2,2-dichloroacetaldehyde (max. 11.6% AR, 0 d), and 2,2-dichloroethanol (max. 4% AR, 1d). However, in contrast with the results of the degradation study with trichlorfon, no accumulation of desmethyl dichlorvos was seen. Therefore, a sound assessment of the route of degradation of trichlorfon in soil cannot be concluded.

No information on the degradation of trichlorfon under anaerobic conditions was submitted. Nevertheless, as anaerobic conditions are not likely to occur under intended uses, an anaerobic degradation study is not required.

In soil photolysis studies the degradation rate of trichlorfon on irradiated and non-irradiated samples was similar. No novel extractable breakdown products were identified in addition to those found in dark experiments. However, the degradation pathway followed maybe influenced by the presence or the absence of light.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The data package submitted on the degradation rate in soil was not sufficient to derive a reliable DT_{50} for trichlorfon to be used in the assessment (the data requirement was already identified by rapporteur Member State and confirmed by the meeting of experts). The degradation rate of dichlorvos was investigated in a separate study under aerobic conditions in two biologically active soils and one

sterile soil (22ºC, 40% MWHC). Dichlorvos degraded very rapidly in soil, with 59-61% AR recovered as $^{14}CO_2$ after only 2 days of incubation. The unextracted fraction of radioactivity was approximately the same in all soils (< 22%). The rapporteur Member State estimated the first order DT_{50} to be < 1 day.

Field dissipation studies were not submitted as not required.

PECsoil were recalculated by the rapporteur Member State using a $DT_{50lab,\ pH\ 6.5}$ value of 13.184 days as a realistic worst case for tomatoes, a crop with the optimal yield in the pH range 6.5-6.9. However, this DT_{50} value was derived from a degradation study considered not reliable during the peer review. Therefore, PECsoil values for trichlorfon and its metabolites need to be recalculated once the data requirement for new soil degradation studies is fulfilled. It is the opinion of EFSA that as the use is in glasshouses, exposure to soil organisms that are part of an agricultural soil ecosystem is expected to be negligible, but can not be excluded.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

One batch adsorption/desorption study is available for trichlorfon with four soils. Due to the instability of the active ingredient (a fast degradation was observed during the study) reliable adsorption coefficient values were not determined, even if results suggested that trichlorfon does not adsorb strongly to soil. At the experts' meeting it was agreed that, due to the difficulty to derive experimentally a reliable Koc value for trichlorfon, a worse-case Koc value of 0 in lieu of actual experimental data should be used for the FOCUS modelling.

No studies on the mobility of the soil metabolites DDVP, desmethyl-DDVP, dichloroacetaldehyde and dichlorvinyl phosphate were submitted. The experts' decided that the data requirement for an aged leaching column study proposed by rapporteur Member State was not necessary in this case. As it was done for the parent compound, no adsorption to soil particles (Koc= 0) for DDVP, desmethyl-DDVP and dichloroacetaldehyde was assumed in the FOCUS modelling. In the case of dichlorvinyl phosphate, Koc value was estimated with the PCKOCWIN (v. 1.66) software being of 10.2 mL/g.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

In sterile buffer solutions at 25ºC trichlorfon degradation is pH dependent. In acid medium (pH 5), at the study end (34 days) the 80% AR was identified as parent compound, desmethyl-DDVP seemed to reach a plateau of 10% AR, and 7.7% AR was identified as dichloroacetaldehyde (DCAA), no reaching a plateau. At pH 7, 40% AR was identified as trichlorfon at the end of the study (45 min.), 25.5% AR was identified as DDVP, 22.7% AR as DCAA, and 12% AR as desmethyl-DDVP, no reaching a plateau in any case. Finally, at the end of the study (45 min) at pH 9, 10.5% AR was identified as trichlorfon, 52.3% AR as DDVP (no reaching a plateau), and 10.5% AR as desmethyl-DDVP (no reaching a plateau). No desmethyl trichlorfon was detected in any sample of the buffered solutions and no other hydrolysis products accounting for more than 10% AR were formed.

Because the metabolites did not degraded or reached a plateau at the end of the studies, the maximum percent of the TAR identified as each metabolite should be carefully taken into account. A data requirement for an accurate identification of the metabolites hydrolytically produced was set by the rapporteur Member State and confirmed by the experts' meeting. The DT_{50} values for trichlorfon were calculated to be 117 days, 38 hours and 31 minutes (extrapolated value) at pH 5, 7, and 9 respectively.

A study with the UV-absorption properties of trichlorfon in water was submitted. Trichlorfon absorbed light at short wavelengths up to 200 nm. At wavelengths of 239 nm and more (up to 300 nm) the molar extinction coefficient ε was < 10 L mol^{-1} cm^{-1}. Another aqueous photolysis study evaluated in the physical/chemical section confirmed that the contribution of the direct photodegradation to the environmental degradation of trichlorfon can be excluded.

Trichlorfon is not ready biodegradable according to the available study.

A water/sediment study conducted with the parent substance trichlorfon is required to complete the risk assessment. A rapid degradation of the metabolite dichlorvos was observed in a water/sediment study carried out in two systems (pH 7.1 and 7.4) with [1-^{14}C] dichlorvos. Dichlorvos degraded in the water phase and shifted partly to the sediment phase where it reached a peak concentration after 16 days (17% AR) and 7 days (32% AR). The first order DT_{50} for the water phase was calculated by the rapporteur Member State varying between 8.5 and 33 hours. DCAA (max. 21.7% AR after 1 hour) and **dichloroacetic acid** (max. 49.6% AR after 3 days) were identified as major metabolites in the water phase. Desmethyl-DDVP reached a maximum of 9.8% AR after 1 hour in the surface water. In the sediment phase no metabolites were measured at levels > 10% AR. All metabolites declined rapidly to very low levels until the end of the study.

It was argued by the applicant that for the representative use, the predicted environmental concentration in surface water (PEC_{sw}) is 0.0 µg/L. Nevertheless, the meeting of experts agreed that exposure of the natural surface water environmental compartment arising from glasshouse use can not be excluded. Since there is not at the moment an European guidance document for assessing the risk under glasshouse/greenhouse conditions, preliminary $PEC_{sw/sed}$ calculations were provided by the rapporteur Member State using the Dutch approach (a loading of 0.1% of the applied dose is considered to cover the possible ways of entrance in a standard water body of 1ha and 30 cm depth) as an illustrative exposure assessment. The meeting of experts agreed that the method used was appropriate for use in the ecotoxicology risk assessment. Due to the lack of information regarding partitioning to the sediment it was assumed that the whole amount of the parent entering into the pond is adsorbed to the sediment. Because of the data requirement for a water sediment study, it was also assumed in the available PEC_{sw} calculations that the degradation rate in water was the worst DT_{50} value obtained in the hydrolysis study. PEC_{sw} were also calculated for the metabolites dichlorvos (actual and time weighted average) DCCA and dichloroacetic acid.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The leaching potential of trichlorfon and its metabolites to groundwater was estimated by the applicant with FOCUS PELMO model. However, some of the input parameters (mainly DT_{50} values)

were not considered valid and a data requirement was set for new PECgw calculations for all the scenarios taking into account the results of the new aerobic soil degradation study. Regarding the Koc values to be used in the modelling, it was agreed by the experts that a worse-case Koc value of 0 in lieu of actual experimental data can be used (see section 4.1.3).

4.3. FATE AND BEHAVIOUR IN AIR

The available data on volatilisation studies indicated a low volatility of trichlorfon from soil surface.
Trichlorfon would not be expected to be subject to long range transport in the upper atmosphere, as using the method of Atkinson and the Atmospheric Oxidation Program (v. 1.89) to estimate photochemical reaction with hydroxyl radicals, atmospheric DT_{50} was calculated to be 1.73 days.
On the basis of the peer reviewed studies presented for the of the risk assessment of dichlorvos for Annex I inclusion, wet and dry re-deposition of dichlorvos to land and surface waters would be expected to be negligible. Dichlorvos would not be expected to be subject to long range transport in the upper atmosphere, as rate constants of 6.381×10^{-12} to 9.4×10^{-12} cm^3 $molecule^{-1}sec^{-1}$ were estimated with the Atkinson method. Assuming an atmospheric concentration of 1.5×10^6 hydroxyl radicals cm^{-3} an atmospheric half life of 13-20 hours was calculated. It should be noted that this information on the fate of dichlorvos in air were not part of the trichlorfon dossier submitted by the applicant.

5. Ecotoxicology

Trichlorfon was discussed at the EPCO experts' meeting for ecotoxicology (EPCO 32) in September 2005 in York (UK).
Due to the limited available data package in general in the section on ecotoxicology the following restriction/condition for use was recommended at the experts' meeting: 'Foliar application to tomatoes under protection in Southern Europe.

5.1. RISK TO TERRESTRIAL VERTEBRATES

No studies on the toxicity to birds with trichlorfon are available and none are considered necessary as the representative use is in glasshouses to which birds and mammals have limited access and this will hence limit exposure.

Acute and long term toxicity studies on mammals are available in the section on toxicology. For the same reasons as for birds no risk assessment was performed.

The experts' meeting agreed that exposure of birds and mammals would be low and defined the glasshouse of the representative use as a permanent structure to which entry of birds and mammals is limited. Therefore the risk to birds and mammals from the representative use evaluated is regarded as low.

5.2. RISK TO AQUATIC ORGANISMS

In the section on Fate and behaviour it is concluded that surface water contamination from glasshouse uses cannot be excluded. An aquatic risk assessment is therefore required.

The test concentrations were not analytically verified during the available studies with trichlorfon on fish, *Daphnia magna* and algae. Therefore the experts' meeting considered that these studies can only be used as additional information. Nevertheless, based on the available studies, a high risk to aquatic invertebrates was identified. The meeting felt that the existing study on the most sensitive species, *D. magna*, was of poor quality. It was proposed that only this study needs to be repeated as *D. magna* was the most sensitive species by more than one order of magnitude.

The experts' meeting concluded that no study with the lead formulation on *D. magna* is necessary as any exposure will be primarily to the active substance and the lead formulation contains 80% trichlorfon.

The experts' meeting pointed out that the need for a study on *Chironomus riparius* must be considered when the water/sediment study becomes available in the section on fate and behaviour. The EFSA would like to add to this, that also the need for long term studies with aquatic organisms needs to be revised once the water/sediment study becomes available.

No studies with the major metabolites in surface water are available. Therefore the following data gap was set during the experts' meeting: applicant to address the risk from metabolites potentially present in surface water as a result from emissions from glasshouses calculated according to the Dutch model.

As trichlorfon is an insecticide no studies with *Lemna gibba* are considered necessary.

As the logPow is below 3 the risk for bioconcentration in fish is considered to be low.

5.3. RISK TO BEES

No toxicity studies on bees are available. The need for studies with bees was discussed in the experts' meeting. The meeting concluded that, due to the proposed use in glasshouses on tomatoes where pollinators will be present, the applicant must address the risk to bees. The risk to bees can only be concluded once these data become available.

5.4. RISK TO OTHER ARTHROPOD SPECIES

A standard laboratory toxicity study on *Aphidius rhopalosiphi* with the lead formulation CEKUFON 80 SP and on *Typhlodromus pyri* with the formulation DIPTEREX (50% trichlorfon) are available. Both these studies indicate a very high toxicity to non-target arthropods.

The need for further studies was discussed at the experts' meeting. The meeting concluded that a high toxicity to the indicator species has been demonstrated, however, as the use is in-doors, the risk to non-target arthropods was considered to be low.

The EFSA would like to point out that at MS-level in case of integrated pest management, a further risk assessment will be necessary.

5.5. RISK TO EARTHWORMS

A study on the acute toxicity of trichlorfon to earthworms is available. As the LogPow is below 2, no correction factor for the organic content of the test soil is required. Based on a provisional PEC_{soil} of 2.733 mg a.s./kg soil the resulting acute TER value is above the appropriate Annex VI trigger value indicating a low risk to earthworms from the representative uses of trichlorfon evaluated. PEC_{soil} needs to be revised after receipt of the new soil aerobic degradation study. In line with the conclusion on 1,3-dichloropropene, no studies on soil-organisms for indoor uses and hence no risk assessment are considered necessary. The EFSA would like to point out that soil-organisms could come into contact with trichlorfon if the tomato plants are grown in full soil. MS may wish to recalculate the acute risk to earthworms in such cases once the new soil aerobic degradation study becomes available.

No studies with the lead formulation are available. According to the Directive 91/414 no acute study with the lead formulation is necessary if the formulation contains only one active substance, which is the case for the lead formulation Cekufon 80SP, and the toxicity can be reliably predicted from the study with the active substance. It is difficult to say if toxicity can be reliably predicted from the study with the active substance as the toxicity of the co-formulants is not known but in this case the lead formulation contains 80% active substance. The Guidance Document on Terrestrial Ecotoxicology states additionally that no study is necessary if the TER for the active substance is well above the trigger. The decision should always be based on a case-by-case analysis. The provisional acute TER for trichlorfon equals 51 which is only 5 times higher than the trigger. But furthermore there will be only limited exposure due to the use in glasshouses. Therefore no acute toxicity study with the formulation is considered necessary by the EFSA.

Trichlorfon is intended to be applied three times a year. The DT_{90} in soil is not known as there is still an outstanding data requirement for a new aerobic soil degradation study in the section on fate and behaviour. Based on the fact that the provisional acute TER for the active substance exceeds 10 and the limited exposure due to the use in glasshouses, no long term toxicity studies on earthworms are considered necessary.

At the moment 3 major soil metabolites are identified in the section on Fate and behaviour but confirmation is still needed by the requested new aerobic degradation study. The identified metabolites are dichlorvos, desmethyl-dichlorvos and dichlorvinyl phosphate. In line with the conclusion on 1,3-dichloropropene, no studies on soil-organisms for indoor uses are considered

necessary. The EFSA would like to point out that soil-organisms could come into contact with these metabolites if the tomato plants are grown in full soil. MS may wish to reconsider the need for studies with the metabolites on soil organisms in such cases. The metabolites were not discussed during the experts' meeting.

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

Based on the fact that the provisional acute TER for earthworms for the active substance exceeds 10, effects of the active substance on soil micro-organisms were below 25% and the limited exposure due to the use in glasshouses, no studies on other soil non-target macro-organisms are considered necessary and the risk is considered to be low.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects of trichlorfon were tested on soil microbial respiration and nitrogen transformation. Effects were less than 25 % at day 28 at 9.6 mg a.s./kg d.w. soil (7200 g a.s/ha). This tested concentration exceeds the application rate of the representative use evaluated and therefore the risk to soil non-target micro-organisms from trichlorfon is considered to be low.

The need for a study with the lead formulation was discussed at the experts' meeting. The meeting considered that the study on the active substance was sufficient and a study with the formulation is not needed as there will be limited exposure, no effects were seen in the study with the active substance and the formulation contains 80% active substance.

At the moment 3 major soil metabolites are identified in the section on Fate and behaviour but confirmation is still needed by the requested new aerobic degradation study. The identified metabolites are dichlorvos, desmethyl-dichlorvos and dichlorvinyl phosphate. In line with the conclusion on 1,3-dichloropropene, no studies on soil-organisms for indoor uses are considered necessary. The EFSA would like to point out that soil-organisms could come into contact with these metabolites if the tomato plants are grown in full soil. MS may whish to reconsider the need for studies with the metabolites on soil organisms in such cases. The metabolites were not discussed during the experts' meeting.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

No studies on the effects of trichlorfon on non-target plants are available and none are considered necessary. Due to the indoor use of trichlorfon the exposure of non-target plants will be limited and hence the risk can be regarded as low.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

No study on the effects of trichlorfon on biological methods of sewage treatment is available. The expert's meeting concluded that such a study is necessary and therefore a data gap for the applicant was set.

6. Residue definitions

Soil

Definitions for risk assessment: trichlorfon, dichlorvos, desmethyl-dichlorvos, dichlorvinyl phosphate (these may require revision after evaluation of the new soil aerobic degradation study).

Definitions for monitoring: trichlorfon, dichlorvos (desmethyl-dichlorvos and dichlorvinyl phosphate can not be excluded since no ecotoxicological assessment is available)

Water

Ground water

Definitions for exposure assessment: trichlorfon, dichlorvos, desmethyl-dichlorvos, dichlorvinyl phosphate (these may require revision after evaluation of the new PECgw modelling).

Definitions for monitoring: no definitions can be currently set due to outstanding data gap in ecotoxicology and toxicology sections.

Surface water

Definitions for risk assessment: trichlorfon, dichlorvos, desmethyl-dichlorvos, dichloroacetaldheyde, dichloroacetic acid (definitions based on the hydrolysis study and water/sediment study with dichlorvos; these may required revision on evaluation of the outstanding sediment/water study with parent substance trichlorfon).

Definitions for monitoring: no definitions can be currently set due to outstanding data gap in ecotoxicology.

Air

Definitions for risk assessment: trichlorfon, dichlorvos.

Definitions for monitoring: trichlorfon, dichlorvos

Food of plant origin

Definitions for risk assessment: as both the metabolism study provided by the notifier and the information about the toxicological relevance of metabolites are considered incomplete, it is not possible to propose a residue definition for risk assessment.

Definitions for monitoring: as both the metabolism study provided by the notifier and the information about the toxicological relevance of metabolites are considered incomplete, it is not possible to propose a residue definition for risk assessment.

Food of animal origin: not applicable

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil[4]

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
Trichlorfon	Data not reliable. Data required	See 5.5, 5.6 and 5.7
Dichlorvos (O,O-dimethyl, -2,2-dichlorovinyl phosphate)	Very low persistent 1st order DT_{50lab} (22ºC, 40% MWHC) = < 1 d	No data available. Not required.
Desmethyl-dichlorvos (methyl O-(2,2-dichlorovinyl phosphate))	Data not reliable. Data required	No data available. Not required.
Dichlorvinyl phosphate	Data not reliable. Data required	No data available. Not required.

[4] Residue definitions in soil may require revision after evaluation of the new soil aerobic degradation study

Ground water[5]

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
Trichlorfon	Due to the difficulty to derive experimentally a reliable K_{oc} value, a worst case K_{oc} value of 0 should be used	New calculations required taking into account the results of the new aerobic degradation study required.	Yes	Yes	See 5.2.
Dichlorvos (2,2 dichloroethyl dimethyl phosphate)	No data. As a worst case, a K_{oc} value of 0 should be used	New calculations required taking into account the results of the new aerobic degradation study required.	Yes	Yes	No conclusion possible due to outstanding data gap.
Desmethyl-dichlorvos	No data. As a worst case, a K_{oc} value of 0 should be used	New calculations required taking into account the results of the new aerobic degradation study required.	No data available.	No data available.	No conclusion possible due to outstanding data gap.

[5] Residue definitions in soil may require revision after evaluation of the new PECgw modelling

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
Dichlorvinyl phosphate	Very high mobile. K_{oc} = 10.2 mL/g (estimated with PCKOCWIN model)	New calculations required taking into account the results of the new aerobic degradation study required.	No data available.	No data available.	No conclusion possible due to outstanding data gap.

Surface water and sediment[6]

Compound (name and/or code)	Ecotoxicology
Trichlorfon	See 5.2.
Dichlorvos	No conclusion possible due to outstanding data gap.
Desmethyl-dichlorvos	No conclusion possible due to outstanding data gap.
Dichloroacetaldheyde	No conclusion possible due to outstanding data gap.
Dichloroacetic acid	No conclusion possible due to outstanding data gap.

[6] From hydrolysis study and therefore for sediment they should be considered with precaution. Acceptable water/sediment study with trichlorfon is required to confirm these definitions.

Air

Compound (name and/or code)	**Toxicology**
Trichlorfon	Not acutely toxic by inhalation
Dichlorvos	Very toxic during acute exposure by inhalation

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- For studies conducted with technical material across all areas of the risk assessment the applicant must justify the material used is equivalent to the currently manufactured technical (date of submission unknown, data gap identified by EPCO 35 in September 2005; refer to chapter 1 and to the evaluation table.).
- The spectra for the relevant impurity dichlorvos is required (date of submission unknown, data gap identified in the DAR and confirmed by EPCO 35 in September 2005, refer to chapter 1).
- A shelf life study is required for the formulation which must include analysis of the relevant impurity dichlorvos (date of submission unknown, data gap identified in the DAR and confirmed by EPCO 35 in September 2005, refer to chapter 1).
- Accurate chromatograms must be provided for the relevant impurity dichlorvos for the analytical method used to analyse dichlorvos in the technical material (date of submission unknown, data gap identified in the DAR and confirmed by EPCO 35 in September 2005, refer to chapter 1).
- Methods of analysis are required for food of plant origin, water, soil and air for the relevant residue definitions for monitoring (date of submission unknown, data gap identified in the DAR and confirmed by EPCO 35 in September 2005, refer to chapter 1).
- A method of analysis is required for the relevant impurity in the formulation (date of submission unknown, data gap identified by EFSA and confirmed by the Evaluation meeting and EPCO 35 in September 2005, refer to chapter 1).
- Due to the inadequacy of the database for short term toxicity, 90-day or 1-year toxicity studies in dogs are required (date of submission unknown, data requirement identified in the DAR and confirmed by EPCO 33 in September 2005, refer to section 2.3).
- Further *in vivo* genotoxicity studies are needed in somatic cells in order to address the potential clastogenic properties of the compound (date of submission unknown, data requirement identified in the DAR and confirmed by EPCO 33 in September 2005, refer to section 2.4).
- A new multi-generation study in rats has to be submitted (date of submission unknown, data requirement identified in the DAR and confirmed by EPCO 33 in September 2005, refer to section 2.6).
- Depending on the outcome of the outstanding study demonstrating that the loss of radioactivity from plant metabolism occurred by evaporation of dichlorvos, an estimation of the potential inhalation of dichlorvos by re-entry workers might be necessary (date of submission unknown, data gap identified by EPCO 33 in September 2005, refer to section 2.12).
- Data demonstrating that the loss of radioactivity in the plant metabolism study occurred by evaporation of the metabolite dimethyl O-(2, 2-dichlorovinyl phosphate) (date of submission unknown, data requirement identified in the DAR and confirmed by EPCO 34 in September 2005, refer to section 3.1.1).

- A study to justify the non-relevance of metabolite dichlorethanol (DCE) (date of submission unknown, data requirement identified in the DAR and confirmed by EPCO 34 in September 2005, refer to section 3.1.1).
- Six residue trials under greenhouse conditions and according to the critical GAP. If the residue definition will include also some metabolites, then residue level data from 8 residue trials will be needed, as the new definition will be not applicable to the two trials available any longer (date of submission unknown, data requirement identified in the DAR and confirmed by EPCO 34 in September 2005, refer to section 3.1.1).
- Data on the nature of trichlorfon residues in processed tomato commodities (date of submission unknown, data requirement identified in the DAR and confirmed by EPCO 34 in September 2005, refer to section 3.1.1).
- Data to calculate the transfer factor for processed tomato commodities (date of submission unknown, data requirement identified in the DAR and confirmed by EPCO 34 in September 2005, refer to section 3.1.1).
- An explanation of the higher residue levels in rotational crops planted after a soil aging period of 120 days (intermediate period) compared to levels in rotational crops planted after the shorter ageing period of 30 days (intermediate period) (date of submission unknown, data requirement identified in the DAR and confirmed by EPCO 34 in September 2005, refer to section 3.1.2).
- A new aerobic soil degradation study with trichlorfon in 4 different soils (at different pH values) is needed to finalise the EU risk assessment (date of submission unknown; refer to point 4.1).
- Pending on the results of the new soil degradation study, new PECsoil calculations and soil risk assessment are necessary (data gap identified after experts' meeting, date of submission unknown; refer to point 4.1).
- Applicant to submit an accurate identification of the metabolites hydrolytically produced (date of submission unknown; refer to point 4.2).
- A new water/sediment study with trichlorfon is needed to finalise the EU risk assessment (date of submission unknown; refer to point 4.2).
- Pending on the results of the new soil degradation study, new PECgw calculations and potential groundwater contamination assessment for trichlorfon and its soil major metabolites are necessary (date of submission unknown; refer to point 4.2).
- Applicant to submit an acute toxicity study with *Daphnia magna* (including analytical verification of the test concentrations) (relevant for all representative uses evaluated; no submission date proposed by the notifier; refer to point 5.2).
- Applicant to address the risk from metabolites present in surface water as a result from emissions from glasshouses calculated according to the Dutch model (relevant for all representative uses evaluated; date of submission unknown; refer to point 5.2).
- Pending on the outcome of the water/sediment study, a study on the toxicity to *Chironomus riparius* and studies on the long term risk to aquatic organisms might become necessary. (relevant for all representative uses evaluated; date of submission unknown; refer to point 5.2).

- Applicant to address the risk to bees (relevant for all representative uses evaluated; date of submission unknown; refer to point 5.3).
- Applicant to submit a study on the effects of trichlorfon on biological methods of sewage treatment (relevant for all representative uses evaluated; date of submission unknown; refer to point 5.9).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative use as an insecticide as proposed by the applicant which comprises application via tractor mounted our handheld sprayer to control lepidopteron insects in protected tomatoes with a maximum total dose of 7.2 kg trichlorfon per hectare. It should be noted that trichlorfon also has acaricidal properties. The representative formulated product for the evaluation was Cekufon 80 SP a soluble powder formulation (SP), registered under different trade names in Europe. In the DAR two sources were originally proposed however one of these sources is no longer supported. It is not clear from the DAR what material was used in the supporting studies and this information has not been provided by the applicant. In addition to this a justification is required that the material used in the studies is equivalent to the material currently being produced.

Adequate methods are not available to monitor all compounds given in the respective residue definitions. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues. There is no method available for soil or for the relevant impurity dichlorvos in the formulation. The air method has no validation for dichlorvos which is in the residue definition. No conclusion can be made on the methods for water, soil and plants as the residue definitions are not finalised.
Some analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

Trichlorfon is harmful during oral exposure and skin sensitizer. The proposed classification is Xn; R22 “Harmful if swallowed” and Xi; R43 “May cause sensitization by skin contact”. The most sensitive effect observed during short term exposure is reduction in acetyl cholinesterase activity. No relevant short term NOAEL could be derived due to an inadequate database for short term toxicity (lack of subchronic studies in dog, which seem to be most sensitive, and inadequate dose-spacing in the 90-day rat study). Due to positive results for a genotoxic potential *in vitro*, a data requirement has been set for further *in vivo* data with mammalian somatic cells. Based on carcinogenicity studies in rats and mice, no carcinogenic potential has been shown for trichlorfon. Based on the poor quality of the reproductive studies, a data requirement has been set for a multigeneration study in rats. However, the available teratology studies show that trichlorfon has no developmental toxicity.

Due to the lack of data, the reference values were not confirmed in the expert meeting. Based on the provisional AOEL provided by the rapporteur Member State in the DAR, together with a dermal absorption of 100% instead of 10%, the operator, worker and bystander exposure estimates exceed the AOEL to a large extent.

The metabolism of trichlorfon has been investigated in tomatoes. It shows that trichlorfon undergoes dehydrochlorination and rearrangements to form different metabolites. The metabolites are either conjugated or further metabolised to form naturally occurring compounds. Only the parent trichlorfon and the metabolite trichlorethanol were determined as free compounds in tomatoes. The study presents a major deficiency. That is, the origin of the important loss of radioactivity encountered in the study, ascribed by the notifier to the volatility of the metabolite dimethyl O-(2, 2-dichlorovinyl phosphate), has not been proved.
As both the metabolism study and the information about the toxicological relevance of metabolites are considered incomplete, it is not possible to propose a residue definition for risk assessment. The number of the submitted supervised field trials in tomatoes, carried out according to the critical GAP, was not sufficient. As a result, the residue data provided are not considered sufficient to support the use of trichlorfon in tomatoes. The nature of trichlorfon residues in processed tomato commodities has not been investigated. Furthermore, due to the limited available data on the magnitude of trichlorfon residue levels in processed commodities, the processing of raw commodities is not considered as sufficiently investigated.
A confined rotational crop study with radio labelled trichlorfon was carried out, but, on the base of the available data, it was not possible to conclude whether significant residue levels are expected in rotational crops following the application of trichlorfon according to the proposed GAP.
Studies on the metabolism, distribution and expression of trichlorfon residues in livestock are not required as trichlorfon is not intended for use in commodities used as animal feed.
Based on the currently available data, the investigation of the residue situation is incomplete and therefore the risk assessment for consumers cannot be performed, nor can an MRL be proposed.

Studies submitted on the environmental fate and behaviour of trichlorfon were reviewed and found to be either acceptable, non acceptable or supplemental. The studies determining laboratory persistence (degradation and metabolism process) suggested that trichlorfon degraded primarily trough biotic process, forming two major metabolites: desmethyl dichlorvos and dichlorovinyl phosphate. Nevertheless, due to lack of information, a sound assessment of the route and rate of degradation of trichlorfon in soil can not be concluded. Based on marginally acceptable information, trichlorfon and its metabolite can be considered as highly mobile in soil. Pending on the results of the new soil degradation study, new PECsoil and PEC_{gw} calculations for trichlorfon and its metabolites may be necessary.
Dichlorvos, desmethyl-dichlorvos and dichloroacetaldehyde were identified as degradates hydrolytically produced, but they were not appropriately quantified. Reliable data on degradation in natural water systems are available only for the metabolite dichlorvos, indicating a fast degradation of the active ingredient and the formation of the major metabolites dichloroacetaldehyde and

dichloroacetic acid. Studies submitted provided sufficient information for an unrealistic worst case aquatic exposure assessment, considering the Dutch approach for the glasshouse use.

The EPCO experts' meeting on ecotoxicology defined the glasshouse in the representative uses as a permanent structure to which entry by birds and mammals is limited. Due to the limited available data package in the section on ecotoxicology the following restriction/condition for use was recommended at the experts' meeting: 'Foliar application to tomatoes under protection in Southern Europe.
The risk to birds and mammals is regarded to be low based on a limited exposure situation in tomatoes under protection (see definition of a glasshouse above).
The available studies on aquatic organisms are of poor quality. It was proposed that only the study on *D. magna* needs to be repeated as this was the most sensitive species by more than one order of magnitude. Based on the existing study the risk to aquatic invertebrates can provisionally already be considered as high. The need for a study on *Chironomus riparius* and long term studies with aquatic organisms must be considered when the water/sediment study becomes available in the section on Fate and behaviour. The risk from metabolites potentially present in surface water as a result from emissions from glasshouses calculated according to the Dutch model still needs to be addressed. The risk from trichlorfon to aquatic organisms can only be concluded once the outstanding data becomes available.
Studies on the toxicity to bees are considered necessary as pollinators are present in tomato crops under glasshouse protection. The risk to bees can only be concluded once the outstanding data becomes available.
The risk to non-target arthropods, earthworms, other soil non-target macro-organisms, soil micro-organisms and non-target plants is considered to be low.
There is still an outstanding data gap for a study on the effects of trichlorfon on sewage treatment plants.

Particular conditions proposed to be taken into account to manage the risk(s) identified

- The EPCO experts' meeting on ecotoxicology defined the glasshouse in the representative uses as a permanent structure to which entry by birds and mammals is limited. Due to the limited available data package in general in the section on ecotoxicology the following restriction/condition for use was recommended at the experts' meeting: 'Foliar application to tomatoes under protection in Southern Europe.

Critical areas of concern

- It is not clear what technical material was used to conduct studies across all areas of the risk assessment and therefore no conclusion can be drawn on these studies or on the technical specification.
- Enforcement methods are not available that cover the residue definition for food, water, soil and air.

- No confirmation that the toxicological batches have the same composition as the currently manufactured technical material.
- Major data gap: no acceptable dog study has been submitted, and no relevant short term NOAEL in relation to the setting of the AOEL could be derived.
- The genotoxic potential of trichlorfon *in vivo* has not been investigated adequately.
- Dichlorvos is a metabolite and an impurity of toxicological concern.
- The reference values could not be determined due to the lack of data, and consequently the operator/worker/bystander risk assessment is considered inconclusive (if the AOEL proposed by the rapporteur Member State is considered, together with the dermal absorption of 100%, the operator exposure estimates exceed the AOEL to a large extent).
- As the investigation of the residue situation is incomplete and the residue definition has not been agreed, the risk assessment for consumers cannot be performed, nor can an MRL be proposed.
- Due to lack of information, a sound assessment of the route and rate of degradation of trichlorfon in soil can not be concluded.
- Pending on the results of the new soil degradation study, new PEC_{gw} calculations for trichlorfon and its metabolites are necessary.
- The EPCO experts' meeting on ecotoxicology defined the glasshouse in the representative uses as a permanent structure to which entry by birds and mammals is limited. Due to the limited available data package in general in the section on ecotoxicology the following restriction/condition for use was recommended at the experts' meeting: 'Foliar application to tomatoes under protection in Southern Europe.
- The available studies on aquatic organisms are of poor quality. It was proposed that only the study on *D. magna* needs to be repeated as this was the most sensitive species by more than one order of magnitude. Based on the existing study the risk to aquatic invertebrates can provisionally already be considered as high. The risk from trichlorfon to aquatic organisms can only be concluded once a new study on *D. magna* becomes available. The need for a study on *Chironomus riparius* and long term studies with aquatic organisms must be considered when the water/sediment study becomes available in the section on Fate and behaviour. The risk from trichlorfon to aquatic organisms can only be concluded once the outstanding data becomes available.
- The risk to bees can only be concluded once the outstanding data becomes available.

APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

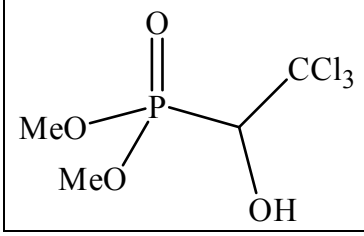
(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Trichlorfon
Function (e.g. fungicide)	Insecticide

Rapporteur Member State	Spain
Co-rapporteur Member State	--

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Dimethyl (*RS*)-2,2,2-trichloro-1-hydroxyethylphosphonate
Chemical name (CA) ‡	Dimethyl-(2,2,2-trichlor-1-hydroxyethyl)phosphonate
CIPAC No ‡	68
CAS No ‡	52-68-6
EEC No (EINECS or ELINCS) ‡	200-149-3
FAO Specification ‡ (including year of publication)	AGP: CP/237 (1988) Minimum purity 970 g/Kg (980 ± 10 g/Kg) Water: 3 g/kg max. Acetone insolubles: 5 g/kg max.
Minimum purity of the active substance as manufactured ‡ (g/kg)	980 g/Kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Dichlorvos 0.02 g/kg.
Molecular formula ‡	$C_4H_8Cl_3O_4P$
Molecular mass ‡	257.44
Structural formula ‡	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Anomalous melting behaviour between 77-83ºC (99.4%)
Boiling point (state purity) ‡	Decomposition before boiling (99.4%)
Temperature of decomposition	>100ºC (99.4%)
Appearance (state purity) ‡	Between white and pink waxy solid (90.1-94.1%)
Relative density (state purity) ‡	Density: 1.68 g/mL at 20 ºC (99.4%)
Surface tension	71.8 mN / m (20ºC; 99.3%, 1 g/L)
Vapour pressure (in Pa, state temperature) ‡	2.1 x 10^{-4} Pa (20 ºC); 5.0 x 10^{-4} Pa (25 ºC) (99.5%)
Henry's law constant (Pa m^3 mol^{-1}) ‡	4.5 10^{-7} Pa m^3 / mol (20ºC)
Solubility in water ‡ (g/L or mg/L, state temperature)	pH not stated: 120 g / L at 20 ºC; (99.5%)
Solubility in organic solvents ‡ (in g/L or mg/L, state temperature)	Xylene: 21.5 g/L (23ºC) (99.3%) Ethyl Acetate: 363 g/L (23ºC) (99.3%) Acetone: 707 g/L (23ºC) (99.3%) 1,2-Dichloroethane: 498 g/L (23ºC) (99.3%) Methanol: 1346 g/L (23ºC) (99.3%) n-Heptane: 0.66 g/L (23ºC) (99.3%)
Partition co-efficient (log POW) ‡ (state pH and temperature)	pH not stated: 0.43 at 20 ºC (99.5%)
Hydrolytic stability (DT_{50}) ‡ (state pH and temperature)	(>98% radiochemical purity) pH 5: 5.4 days (25ºC) pH 7: 34 hours (25ºC)
	pH 9: 31 minutes (25ºC)
Dissociation constant ‡	Trichlorfon exhibits no basic properties in aqueous solution. Acidic properties cannot be determined, since deprotonation followed by formation of DDVP occurs in the presence of bases. It is not possible to specify a pKa value for trichlorfon in water.
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	Absorption observed only < 225 nm
Photostability (DT_{50}) ‡ (aqueous, sunlight, state pH)	Not photodegradation is observed
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡	Not applicable (λ < 290 nm)
Flammability ‡	Trichlorfon is not highly flammable
Explosive properties ‡	Not explosive

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

List of representative uses evaluated*

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hl min max	water l/ha min max	kg a.s./ha min max		
Tomato	Spain	Cekufon 80 SP	G	*L*epidopteran species	SP	800	Tractor mounted, knapsack - and hand sprayer	Throughout the season	3 applications per growing season	14 days	0.240	1000	2.4	7	[1]

[1] The risk assessment has revealed data gaps in sections 3, 4 and 5.

Remarks:	*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.2: Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	HPLC-UV
Impurities in technical as (principle of method)	a) HPLC-UV b) GC-NPD Confirmatory method : HPLC/MS and GC/MS
Plant protection product (principle of method)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Open point, no residue definition.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not relevant
Soil (principle of method and LOQ)	Open point, no final residue definition.
Water (principle of method and LOQ)	Open point, no residue definition.
Air (principle of method and LOQ)	GC-ECD, LOQ: 0.3 µg/m^3, trichlorfon. *Data Gap* no method for the dichlorvos.
Body fluids and tissues (principle of method and LOQ)	Not relevant

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	None

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption ‡	Rapid and almost complete (Rat: ~ 90% at 24 hr; in urine, faeces and expired CO_2) (Rabbit: 97% at 24hr, mainly in urine)
Distribution ‡	Widely distributed to all organs, crossing the blood-brain barrier. Liver, kidney and bone marrow had the highest levels of radioactivity.
Potential for accumulation ‡	No potential for accumulation. Repeated dose resulted in longer plasma half-life ($T_{1/2}$ = 28.4 hr)
Rate and extent of excretion ‡	Rat: Rapid, by urine (45-50%), faeces (21%) and expired CO2 (21%) at 24 h. Rabbit: Very rapid by urine (96%) at 24 h
Metabolism in animals ‡	Extensively metabolised with extensive conjugation. (rat and rabbit)
Toxicologically significant compounds ‡ (animals, plants and environment)	Trichlorfon, dichlorvos

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	212 mg/kg bw **Xn; R22**
Rat LD_{50} dermal ‡	> 5000 mg/kg bw
Rat LC_{50} inhalation ‡	Highest concentration tested 0.53 mg/l.
Skin irritation ‡	Not irritant
Eye irritation ‡	Not irritant
Skin sensitization ‡ (test method used and result)	Sensitiser (Magnusson and Kligman´s test) **R43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Depression of plasma, RBC and brain CHE activities and neurotoxicological signs. Target organs: kidneys and spleen (increased weight)
Lowest relevant oral NOAEL / NOEL ‡	No adequate data for brain AChE in rats. Lack of subchronic studies in dogs (most sensitive).
Lowest relevant dermal NOAEL / NOEL ‡	100 mg/kg bw/day (rabbits, 3 weeks)
Lowest relevant inhalation NOAEL / NOEL ‡	0.013 mg/L (3.43 mg/kg bw/day) (rats, 3 weeks)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Genotoxicity ‡ (Annex IIA, point 5.4)

.....	Positive *in vitro*, inadequate data *in vivo*

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Cholinesterase inhibition in rats and mice. Hypercholesterolemia and chronic nephropathy in rats
Lowest relevant NOAEL / NOEL ‡	4.5 mg/kg bw/day (2-year dietary study in rats)
Carcinogenicity ‡	No evidence of a carcinogenic effect

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	Inadequate information
Lowest relevant reproductive NOAEL / NOEL ‡	Inadequate information (parental and offspring)
Developmental target / critical effect ‡	No evidence of fetotoxicity in rats and rabbits
Lowest relevant developmental NOAEL / NOEL ‡	Maternal: 15 mg/kg bw/day (rabbits) Offspring: 45 mg/kg bw/day (rabbits)

Neurotoxicity / Delayed neurotoxicity ‡ (Annex IIA, point 5.7)

Acute neurotoxicity	Clinical signs, alterations in FOB, decreased motor activity, and inhibition of AChE activity. NOAEL = 10 mg/kg bw (gavage; rat).
Subchronic neurotoxicity	Clinical signs, decreased bodyweight, decreased motor and locomotor activity, inhibition of all types of cholinesterase, myelin degeneration NOAEL = 6.08 mg/kg bw/day (90-d; diet; rat)
Delayed neurotoxicity	Indications of potential to induce delayed neurotoxicity (axonal degeneration) NOAEL = 9 mg/kg bw/day (90-day, gavage, hens)

Other toxicological studies ‡ (Annex IIA, point 5.8)

.....	None submitted.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Medical data ‡ (Annex IIA, point 5.9)

.....	Occupational exposure where air concentration exceeded 0.5mg/m^3, resulted in a reversible decrease in plasma AChE activity. Trichlorfon has been used for the treatment of intestinal parasites and Alzheimer Disease. Acute poisonings have shown dose-related clinical signs of AChE inhibition (and delayed neuropathy in some cases)

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	No value derived*		
AOEL ‡	No value derived*		
ARfD ‡ (acute reference dose)	No value derived*		

* Inadequate data package.

Dermal absorption (Annex IIIA, point 7.3)

CEKUFON 80SP	No data available. Default value of 100%.

Acceptable exposure scenarios (including method of calculation)

Operator **Scenario 1**: Tomatoes, Greenhouse Tractor mounted-sprayers **Scenario 2**: Tomatoes, Greenhouse Gun application **Scenario 3**: Tomatoes, Greenhouse Knapsack application	Cannot be performed
Workers	Cannot be performed
Bystanders	Cannot be performed

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	DAR proposal (July 2005) R 22; Harmful if swallowed R 43; May cause sensitisation by skin contact
	ECB (29th ATP) R 22; Harmful if swallowed R 43; May cause sensitisation by skin contact

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.4: Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Fruit vegetables (tomatoes - foliar treatment). Study incomplete.
Rotational crops	Two studies in rotational crops (Red beets, wheat and kale). Studies incomplete.
Plant residue definition for monitoring	Not agreed, pending outstanding data on the metabolism study and on toxicological relevance of metabolites.
Plant residue definition for risk assessment	Not agreed, pending outstanding data on the metabolism study and on toxicological relevance of metabolites
Conversion factor (monitoring to risk assessment)	To be calculated, pending outstanding data

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Not applicable
Animal residue definition for monitoring	Not applicable
Animal residue definition for risk assessment	Not applicable
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Not applicable
Fat soluble residue: (yes/no)	Not applicable

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

.....	No data submitted. *Data required pending outstanding data on the rotational crop studies.*

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

.....	Good stability of Trichlorfon residues in tomatoes and ketchup for up to 180 days of frozen storage (less than 30% of degradation)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: no	Poultry: no	Pig: no
Muscle	Not applicable		
Liver	Not applicable		
Kidney	Not applicable		
Fat	Not applicable		
Milk	Not applicable		
Eggs	Not applicable		

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Tomato	S	0.05, 0.34	Additional data required		

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	Not derived
TMDI (% ADI)	To be calculated when outstanding data on residue trials and ADI available.
IEDI (European Diet) (% ADI)	To be calculated when outstanding data on residue trials and ADI available.
Factors included in IEDI	Not applicable
ARfD	Not derived.
Acute exposure (% ARfD)	To be calculated when outstanding data on ARfD and residue trials available.

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Further studies required		To be calculated when outstanding data available	

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

.....	To be proposed when outstanding data on residue trials available

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	*A new aerobic degradation study required*
Non-extractable residues after 100 days ‡	Indicative available information, pending on results of a new aerobic degradation study 30% after 67 d, [1-^{14}C-(2,2,2-trichloro hydroxymethyl) dimethyl phosphonate]-label (n= 1; pH 5) 9-21% after 33 d, [1-^{14}C-(2,2,2-trichloro hydroxymethyl) dimethyl phosphonate]-label (n= 3; pH 7) Sterile conditions: 25 % after 47 d (n= 1; pH 5)
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	Indicative available information, pending on results of a new aerobic degradation study desmethyl-dichlorvos –37.55% at 67 d, study end (n= 1; pH 5) potential accumulation dichlorivinylphosphate – 40.68% at 67 d, study end (n= 1; pH 5) potential accumulation

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	No data submitted. Anaerobic conditions are not likely to occur under intended uses.
Soil photolysis ‡	Mineralisation 1.2-10.9 % after 20-14 d (n=2) Non-extractable residues 6.3-5.1 % after 20-14 d (n=2) Metabolites desmethyl dichlorvos 34.9-48 % at 20-14 d (n=2) potential accumulation in light and dark control dichlorvos (DDVP) 24.5-3.1% 20-14d (n=2) potential accumulation in light and dark control

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	Data available considered not valid *A new aerobic degradation study with trichlorfon is required*

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Laboratory studies ‡ (range or median, with n value, with r^2 value)	*A new aerobic degradation study with trichlorfon is required* **Metabolites** Study 1 of the parent: desmethyl dichlorvos: no degradation was observed in the route of degradation study for the parent dichlorivinylphosphate no degradation was observed in the route of degradation study for the parent Study carried out with dichlorvos (DDVP) as test substance: DT_{50lab} (22°C, aerobic; pH soil 5.8): <1 d (n= 1, r^2 = not determined). For FOCUSgw modelling: trichlorfon: reliable DT_{50} data not available. Data required. DDVP: DT_{50} <1 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.2) based on the data from the degradation study with dichlorvos. desmethyl dichlorvos: DT_{50} <1 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.2) based on the data from the degradation study with dichlorvos. No considered valid since potential accumulation was observed in the parent study dichloroacetaldehyde: DT_{50} <1 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.2) based on the data from the degradation study with dichlorvos. dichlorivinyl phosphate: potential accumulation.
	Degradation in the saturated zone ‡: no data submitted
Field studies ‡ (state location, range or median with n value)	No data submitted, not required
Soil accumulation and plateau concentration ‡	No data

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ K_d ‡ pH dependence ‡ (yes / no) (if yes type of dependence)	Due to the instability of trichlorfon (very fast degradation), actual experimental Koc values can not be derived. Metabolites: no data For FOCUS gw modelling – worst case in place of actual experimental data: K_{foc}: parent, Koc = 0 mL/g $^1/_n$= 0.9 K_{foc}: DDVP, 0 mL/g, $^1/_n$= 0.9 K_{foc}: desmethyl-DDVP, 0 mL/g, $^1/_n$= 0.9. K_{foc}: dichloroacetaldehide, 0 mL/g, $^1/_n$=0.9. K_{foc}: dichlorovinylphosphate 10.2 mL/g (estimated with PCKOCWIN 1.66) $^1/_n$=0.9

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	No data. (worst-case Koc = 0 instead of actual experimental data for trichlorfon)
Aged residues leaching ‡	No data. Aged column leaching study is not required in this case.
Lysimeter/ field leaching studies ‡	No data

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	DT_{50} (d): no data *Data gap* Assessment is necessary once the data requirement for new soil degradation studies is fulfilled
Application rate	Crop: tomatoes % plant interception: 50% Number of applications: 3 Interval (d): 14 Application rate(s): 2.4 Kg a.s./ha

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Metabolite

Desmethyl dichlorvos Method of calculation	DT_{50} (d): no data *Data gap* Reassessment is necessary once the data requirement for new soil degradation study with the parent is fulfilled
Application rate	Crop: tomatoes % plant interception: 50% Number of applications: 3 Interval (d): 14 Application rate(s): 2.4 Kg a.s./ha (assumed desmethyl-DDVP is formed at a maximum of 37.55% of the applied dose)

Dichlorovinylphosphate Method of calculation	DT_{50} (d): no data *Data gap* Reassessment is necessary once the data requirement for new soil degradation study with the parent is fulfilled.
Application rate	Crop: tomatoes % plant interception: 50% Number of applications: 3 Interval (d): 14 Application rate(s): 2.4 Kg a.s./ha (assumed dichlorovinyl phosphate is formed at a maximum of 41% of the applied dose)

Dichlorvos (DDVP) [7] Method of calculation	DT_{50} (d): no data *Data gap* Reassessment is necessary once the data requirement for new soil degradation study with the parent is fulfilled
Application rate	Crop: tomatoes % plant interception: 50% Number of applications: 3 Interval (d): 14 Application rate(s): 2.4 Kg a.s./ha (assumed DDVP is formed at a maximum of 100% of the applied dose)

[7] Not detected in the degradation study soil with the parent. Supposed intermediate

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Dichloroacetaldehide (DCAA) [8] Method of calculation	DT_{50} (d): no data *Data gap* Reassessment is necessary once the data requirement for new soil degradation study with the parent is fulfilled
Application rate	Crop: tomatoes % plant interception: 50% Number of applications: 3 Interval (d): 14 Application rate(s): 2.4 Kg a.s./ha (assumed DDVP is formed at a maximum of 11.6% of the applied dose)

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}) ‡ (state pH and temperature)	*Accurate information of the metabolites hydrolytically produced should be submitted* pH5: 25°C DT_{50} 116.7 days (1^{st} order, r^2=0.97).extrapolated desmethyl-DDVP: 10.5 %AR (28d) DCAA: 7.7% AR (34 d) pH 7: 25°C DT_{50} 37.967 h (1^{st} order, r^2=0.97) DDVP: 25.5% (48 h). DT_{50} (22ºC)= 2.9 d desmethyl-DDVP: 11.9 %AR (48 h) DCAA: 22.7 % AR (48 h) DT_{50} (22ºC)= 2 d pH9: 25°C DT_{50} 31.11 min (1^{st} order, r^2=98.5) DDVP: 52.3% (45 min). desmethyl-DDVP: 10.5 %AR (45 min)
Photolytic degradation of active substance and relevant metabolites ‡	UV light does not affect degradation of trichlorfon At wavelengths of 239 nm and more (up to 300 nm) the molar extinction coefficient ε is < 10 L mol^{-1} cm^{-1}. Metabolites: no data
Readily biodegradable (yes/no)	No

[8] Based on the results found in the degradation study with DDVP

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Degradation in water/sediment	No data for trichlorfon. *Data required* Degradation of DDVP in water/sediment (2 systems)
- DT_{50} water ‡	First order DT_{50} water: System A: 33 h (r^2= 99.8%, pH 7.4) System B: 8.5 h (r^2= 98.7%, pH 7.1)
- DT_{90} water ‡	System A: 109.6 h System B: 28.43 h
- DT_{50} whole system ‡	Not available
- DT_{90} whole system ‡	Not available
Mineralization	System A: maximum 57.6% AR (7d) System B: maximum 40.8% AR (3d)
Non-extractable residues	System A: max. 17.1% AR (16d) System B: max. 32% AR (7d)
Distribution in water / sediment systems (active substance) ‡	Dichlorvos accounted for (only 2 samples in 24 hours): System A: max. 2.6% AR after 1 h System B: max. 1.9% AR after 1 h
Distribution in water / sediment systems (metabolites) ‡	Water: DCCA max of 9.4-21.7% AR (1h, n= 2) Dichloroacetic acid: max of 48.3-49.6% AR (24h-72h, n= 2) Sediment: radioactivity detected <10% AR

PEC (surface water) (Annex IIIA, point 9.2.3)

Parent

Method of calculation	DT_{50} (d): 116.7 days Kinetics: 1st order Lab: from hydrolysis studies
Application rate	Crop: tomatoes Number of applications: 3 Interval (d): 14 Application rate(s): 2.4 Kg a.s./ha Depth of water body: 30 cm
Main routes of entry	0.1% of loading (drainage, runoff, condensation and rainwater)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PEC$_{(sw)}$ (µg / L)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			2.40	2.40
Short term 24h			2.39	2.39
2d			2.37	2.39
4d			2.34	2.37
Long term 7d			2.30	2.35
14d			2.21	2.30
21d			2.12	2.26
28d			2.03	2.21
42d			1.87	2.12

Metabolites

Method of calculation	DT_{50} (d): 1.4 days Kinetics: fist order kinetic Lab: from sediment water studies carried out at pH>7 not considered as a worst case
Application rate	Crop: tomatoes Number of applications: 3 Interval (d): 14 Application rate(s): 2.4 kg a.s./ha (assumed dichlorovos is formed at a maximum of 100% of the applied dose in water) Depth of water body: 30 cm
Main routes of entry	0.1% of loading (drainage, runoff, condensation and rainwater)

Dichlorvos

PEC$_{(sw)}$ (µg / L)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			2.06	2.06
Short term 24h			1.3	1.63
2d			0.77	1.31
4d			0.28	0.89

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

$PEC_{(sw)}$ (µg / L)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Long term 7d			0.064	0.58
14d			0.002	0.29
21d			0.00006	0.2
28d			0.000	0.15
42d			0.000	0.099

DCCA

$PEC_{(sw)}$ (µg / L)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.23	0.23

Dichloroacetic acid

$PEC_{(sw)}$ (µg / L)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.6	0.6

PEC (sediment) - Parent

Method of calculation	100 % partitioning to top 5 cm layer of sediment
Application rate	Crop: tomatoes Number of applications: 3 Interval (d): 14 Application rate(s): 2.4 kg a.s./ha

$PEC_{(sed)}$ (mg / kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.010	-
Short term				-
Long term				-

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Metabolite

Dichlorvos	Radioactivity detected <10%
Method of calculation	Not relevant
Application rate	Not relevant

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	*Pending on the results of the new soil degradation study, new PECgw calculations and potential groundwater contamination assessment for trichlorfon and its soil major metabolites are necessary*
Application rate	-

$PEC_{(gw)}$

Maximum concentration	*Data required*
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	Not considered valid *A new simulation is required*

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Not studied
Quantum yield of direct phototransformation	Not determined
Photochemical oxidative degradation in air ‡	Half life of trichlorfon in the troposphere due to reaction with hydroxyl radicals is calculated to be DT_{50} = 1.73 days (Atkinson model).
Volatilization ‡	From plant surfaces no data from soil:< $6x10^{-4}$ µg/cm^2/h

PEC (air)

Method of calculation	No data

$PEC_{(a)}$

Maximum concentration	No data

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	**Soil and groundwater:** trichlorfon, and the metabolites dichlorvos (DDVP), desmethyl-dichlorvos and dichlorvinyl phosphate (these may require revision on evaluation of the outstanding aerobic soil degradation study) **For surface water and sediment:** Trichlorfon and the metabolites dichlorvos, desmethyl-dichlorvos, dichloroacetaldehyde and dichloroacetic acid (these may require revision on evaluation of the outstanding sediment/water study). **Air:** trichlorfon and dichlorvos (DDVP)

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data provided
Surface water (indicate location and type of study)	No data provided
Ground water (indicate location and type of study)	No data provided
Air (indicate location and type of study)	No data provided

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	N; Harmful to the environment Candidate for R53 May cause long-term adverse effects in the aquatic environment

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.6: Effects on non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals ‡	Oral: LD_{50}: 212 mg/kg_{bw}/d (rat female)
Long term toxicity to mammals	Oral: NOAEL : 13.2 mg/kg_{bw}/d (rat male) Reproduction: NOEL: 300 ppm* (rat)
Acute toxicity to birds ‡	Technical: No data and not required Metabolites No data and not required
Dietary toxicity to birds ‡	Technical: No data and not required Metabolites: No data and not required
Reproductive toxicity to birds ‡	Technical: No data and not required Metabolites: No data and not required

* Daily dose calculations not available

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

The experts' meeting agreed that exposure of birds and mammals would be low and defined the glasshouse of the representative use as a permanent structure to which entry to birds and mammals is limited. Therefore the risk to birds and mammals from the representative use evaluated is regarded as low.

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Laboratory tests ‡				
Fish Rainbow trout *Oncorynchus mykiss*	Technical Trichlorfon (98.1 % a.s.)	Acute static	96h LC_{50}	0.70*
	Trichlorfon	Chronic dynamic	NOEC	No data
	Metabolites	Acute	LC_{50}	No data
	Metabolites	Chronic	NOEC	No data
Invertebrates *Daphnia x*	Technical	Acute	48h EC_{50}	*Required*
	Technical	Chronic	NOEC	No data
	Metabolites	Acute	EC_{50}	*Required*
Algae *Scenedesmus subspicatus*	Technical (98.1%)	Acute	120 h EC_{50}	10*

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Plant *Lemna gibba*	Technica1			Not required

* Additional information as test concentrations were not analytically identified.

Microcosm or mesocosm tests
No data. Need for these data pending on outstanding first tier laboratory data.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Application rate (kg a.s./ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
2.4	Tomato (indoor)	*Daphnia*	Acute	Not applicable	Study required	100

Bioconcentration

Bioconcentration factor (BCF) ‡	Not required log Pow < 3
Annex VI Trigger:for the bioconcentration factor	Not required
Clearance time (CT_{50}) (CT_{90})	Not required
Level of residues (%) in organisms after the 14 day depuration phase	Not required

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity ‡	Technical *Data required*
Acute contact toxicity ‡	Technical *Data required*

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg a.s./ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
2.4	Tomato	Oral	Data required	50
2.4	Tomato	Contact	Data required	50

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Field or semi-field tests No data. Need for these data pending on outstanding first tier laboratory data.

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Stage	Test Substance	Dose (kg a.s./ha)	Endpoint	LR_{50} (g a.s./ha)	HQ	Escort II Trigger
Laboratory tests							
Aphidius rhopalosiphi	adult	Trichlorfon	2.4	Mortality	0.519	Low risk is assumed for indoor uses	2
Typhlodromus pyri	adult	Trichlorfon	2.4	Mortality	90% mortality was observed at 1.2 kg a.s./ha	Low risk is assumed as result of indoor uses	2

Field or semi-field tests No data and not required.

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity ‡	Technical: *E. foetida* 14 days-LC_{50} = 140 mg a.s./kg soil Metabolites: *No data*
Reproductive toxicity ‡	NOEC *No data*

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg a.s./ha)	Crop	Time-scale	TER	Annex VI Trigger
2.4	Tomato	14 days	51*	10

*Based on a provisional PEC_{soil} of 2.733 mg a.s./kg soil. PEC_{soil} needs to be revised after receipt of the new soil aerobic degradation study.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡	Technical: Effects < 25% at 28 days at 9.6 mg a.s./kg d.w. soil (7200 g a.s/ha).
Carbon mineralization ‡	Technical: Effects < 25% at 28 days at 9.6 mg a.s./kg d.w. soil (7200 g a.s/ha).

Effects on non-target plants

No data.

Effects on biological methods for sewage treatment

Specific study on biological methods for sewage treatment is required.

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	R50 Toxic to aquatic organisms

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median

LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year