CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance *(EZ)*-1,3-dichloropropene[1]

European Food Safety Authority[2]

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SUMMARY

(EZ)-1,3-dichloropropene[3] is one of the 52 substances of the second stage of the review programme covered by Commission Regulation (EC) No 451/2000[4], as amended by Commission Regulation (EC) No 1490/2002[5]. This Regulation required 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 *(EZ)*-1,3-dichloropropene in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 16 January 2004. Following a quality check on the DAR, the peer review was initiated on 10 May 2004 by dispatching the DAR for consultation of the Member States and the applicant Task Force, which originally consisted of Dow AgroScience B.V. and BASF Agro B.V. BASF sold the business of *(EZ)*-1,3-dichloropropene to Kanesho Soil Treatment BVBA on 17 December 2003 and therefore was replaced in the Task Force. 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 8 November 2004. 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 April and May 2005.

A discussion of the outcome of the consultation of experts following the procedure set out in Commission Regulation (EC) 451/2000 took place with representatives from the Member States on 8 February 2006 leading to the conclusions set out in the EFSA Conclusion finalised on 12 May 2006 (EFSA Scientific Report (2006) 72).

Following the Commission Decision of 20 September 2007 (2007/619/EC)[6] concerning the non-inclusion of *(EZ)*-1,3-dichloropropene in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicants, Dow AgroScience B.V. and Kanesho Soil Treatment BVBA made a resubmission application for the

1 On request from the European Commission, Question No EFSA-Q-2009-00713, issued on 30 September 2009.
2 Correspondence: praper@efsa.europa.eu
3 A common abbreviation is 1,3-D
4 OJ No L 53, 29.02.2000, p. 25
5 OJ No L 224, 21.08.2002, p. 25
6 OJ No L249, 25.09.2007, p. 11

For citation purposes: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance (*EZ*)-1,3-dichloropropene on request from the European Commission. EFSA Journal 2009; 7(10):1341. [102 pp.]. doi:10.2903/j.efsa.2009.1341. Available online: www.efsa.europa.eu

inclusion of *(EZ)*-1,3-dichloropropene in Annex I, in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[7]. The resubmission dossier included further data in response to the areas of concern identified in the review report (European Commission, 2007) as follows:

- A finalised assessment of consumer exposure
- The environmental fate and ecotoxicology of the substance
- Lack of data on the persistency, toxicological behaviour, uptake from crops, accumulation, metabolic fate and residue level of certain polychlorinated impurities

and concerns were identified with regard to:

- The potential contamination of groundwater
- The consumer exposure
- The risk to birds, mammals and aquatic organisms
- Its possible impact on non-target organisms

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Spain, being the designated rapporteur Member State, submitted an evaluation of the additional data on (*EZ*)-1,3-dichloropropene in the format of an Additional Report (Spain, 2009a). The Additional Report was received by the EFSA on 15 April 2009. In accordance with Article 19, the EFSA distributed the Additional Report to the Member States and the applicant for comments on 20 April 2009. The EFSA collated and forwarded all comments received to the Commission on 25 May 2009. At the same time the collated comments were forwarded to the rapporteur Member State for compilation in the format of a Reporting Table.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 2 July 2009, the Commission requested the EFSA to arrange a peer review of the Additional Report provided by the rapporteur Member State, and to deliver its conclusion on the risk assessment within 90 days.

The peer review commenced with EFSA's consideration of the Reporting Table containing the applicant's response to the comments and the RMS' evaluation of the comments and response. All points that were identified as unresolved at the end of the comment evaluation phase were further considered in a series of scientific telephone conferences with Member State experts in September 2009.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in September 2009. The EFSA conclusion has therefore been re-issued to update the risk assessment in all areas.

The original conclusion was reached on the basis of the evaluation of the representative uses as a nematicide as proposed by the applicants. The application to bare soil comprises either introduction of the formulated product into the drip irrigation system ("EF-1478") or soil injection at 15-20 cm depth ("XRM-5048") to control nematodes in soil where tomatoes or peppers will be grown. The application rates are up to 283 kg *(EZ)*-1,3-dichloropropene per hectare ("EF-1478") and up to 224 kg per hectare ("XRM-5048"), respectively. *(EZ)*-1,3-dichloropropene can be used as nematicide, insecticide,

[7] OJ No L 15, 18.01.2008, p. 5

fungicide and herbicide, depending on the dose rate used. In general, an application of *(EZ)*-1,3-dichloropropene by soil injection and/or drip irrigation is followed by partial sterilisation of the soil. It should be noted that the applicants stated that only the use as a nematicide would be supported in the EU review programme. The conclusion of the peer review of the resubmission was reached on the basis of the evaluation of the same representative use as a nematicide.

The representative formulated products for the evaluation under the resubmission were the same as for the original submission, 'Telone EC Drip (EF-1478)', an emulsifiable concentrate (EC), registered under different trade names in Southern European countries, and 'Telone Injected (XRM-5048)' a liquid formulation (AL), registered under different trade names in the EU.

Adequate methods are 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.

Sufficient 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 products are possible.

(EZ)-1,3-dichloropopene is rapidly absorbed and extensively metabolised in the rat. The acute oral and dermal toxicity is high and the inhalatory toxicity is moderate, proposed classification and risk phrases are T; R24/25 "Toxic in contact with and if swallowed" and R20 "Harmful by inhalation". It is a skin irritant and sensitizer, proposed classification and risk phrases are R38 "Irritant to skin" and R43 "May cause sensitization by skin contact". According to medical data 1,3-dichloropopene should also be classified as irritant to eyes and to the respiratory system, proposed classification and risk phrases are R36/R37 "Irritating to eyes and respiratory system" and R65 "May cause lung damage if swallowed". The Technical Committee for Classification and Labelling in 2005 agreed not to classify 1,3-D as mutagenic or carcinogenic, unless epichlorhydrin (a known carcinogen) had been used as a stabiliser. The applicants confirmed that the current product is not stabilised with epichlorhydrin. No reproduction toxicity or neurotoxicity was observed. The metabolites (EZ)-3-chloroallyl alcohol[8] and (EZ)-3-chloroacrylic acid[9] are both toxic. Dependent on the identity on the polychlorinated impurities, it might be necessary to require new toxicological studies. The Acceptable Daily Intake (ADI) is 0.025 mg/kg bw/day, with the use of the safety factor of 100. The systemic Acceptable Operator Exposure Level (AOEL) is 0.1 mg/kg bw/day, safety factor 100. As inhalation exposure is the main route of exposure and all data from operator exposure are expressed as atmospheric concentration (mg/m3), an additional inhalatory human AOEC was assigned which is 0.45 mg/m3. The ARfD is 0.2 mg/kg bw, with the safety factor of 100 added. The operator and worker exposure during drip irrigation activities is below the AOEL with the use of PPE and RPE; the estimated exposure levels for a bystander at >7 m from the site of application are below the AOEC, however at closer distances estimated exposure levels exceed the AOEC. During soil injection activities the operator, worker and bystander exposure estimates show levels below the AOEC (operator and worker wearing PPE and RPE).

The degradation and metabolism of 1,3-D has been studied comparatively in fruit (tomatoes and citrus), root vegetables (sugar beet), pulses and oilseeds (soybeans) following application of radio-labelled material to the soil surrounding the tree, or to the soil in which seeds were planted. Additional information from succeeding crop studies is given on leafy crops (lettuce) and cereals (wheat).

Even though a high amount of applied 1,3-D is expected to volatilise from soil, the results of the available studies indicate that 1,3-D is also absorbed into plants, translocated and degraded. Naturally occurring plant constituents contained the majority of radioactivity recovered in edible plant parts, indicating complete metabolism of 1,3-D. Consequently, no 1,3-D residues above the limit of

[8] (*EZ*)-3-chloroacrylic acid: (2*EZ*)-3-chloroprop-2-enoic acid
[9] (*EZ*)-3-chloroallyl alcohol: (2*EZ*)-3-chloroprop-2-en-1-ol

quantification (LOQ) are expected to be present in primary or succeeding crops. This was confirmed by supervised residue trials data.

In the resubmission dossier of 2009 a number of additional residue trials were provided to allow some further clarification with regard to manufacturing process impurities that are applied to the soil in high amounts when 1,3-D is used at the notified application rate.

1,3-D and six impurities (1, 2, 3, 5b, 5c and 8a) were analysed. 1,3-D and its six studied impurities did not leave detectable residues in the crop.

However, even though potential chronic and acute dietary exposure to residues of 1,3-D per se from tomatoes and peppers is well below the ADI (<10%) and ARfD (<2%), respectively the consumer risk assessment cannot be considered as finalised in relation to 11 manufacturing process impurities. The consumer risk assessment is pending a conclusion on the fate and behaviour of these 11 identified impurities in the environment, and/or with regard to toxicological data on manufacturing process impurities in the updated specification in the section on mammalian toxicology.

(EZ)-1,3-dichloropropene is a volatile liquid, so even though it is injected below the soil surface or applied via drip irrigation systems, the major route of dissipation from soil is volatilisation to the air. In aerobic laboratory soil studies it exhibited low to moderate persistence and formed the major (>10% applied radioactivity, AR) degradation product *(EZ)*-3-chloroacrylic acid which exhibited very low to moderate persistence and the minor (<10%AR) degradation product *(EZ)*-3-chloroallyl alcohol which exhibited very low persistence. Mineralisation to CO_2 accounted for 11-37%AR at 49-77 days. At these times unextracted soil residue accounted for 9-28%AR.

In laboratory soil batch adsorption studies *(EZ)*-1,3-dichloropropene exhibited very high to high mobility. *(EZ)*-3-chloroallyl alcohol and *(EZ)*-3-chloroacrylic acid exhibited very high soil mobility.

In a laboratory study on a natural sediment water system (25°C) with dosing under the water surface, volatilisation was again the major route of dissipation of *(EZ)*-1,3-dichloropropene from the systems. *(EZ)*-1,3-dichloropropene exhibited low persistence and formed the minor (<10% applied radioactivity, AR) degradation products *(EZ)*-3-chloroacrylic acid and *(EZ)*-3-chloroallyl alcohol which exhibited low persistence. Mineralisation to CO_2 accounted for 57%AR at 21 days. At this time unextracted sediment residues accounted for 14%AR. Acceptable surface aquatic system PEC are only available.

FOCUS groundwater 'tier I' modelling indicates that at the spatial scale usually assessed of the treated field, there is a very high potential for the contamination of groundwater by parent *(EZ)*-1,3-dichloropropene and *(EZ)*-3-chloroacrylic acid. The results from an extensive targeted EU groundwater monitoring program are available. With the exception of the monitored areas in France, where critical details regarding the program are missing, this program indicates for the historical intensity of use of 1,3-D in the monitored areas, at the points of drinking water abstraction that were sampled, groundwater contamination by parent *(EZ)*-1,3-dichloropropene > 0.1µg/L had not occurred. Contamination above this level by *(EZ)*-3-chloroacrylic acid had occurred but rarely (2 samples from different wells out of the 50 taken in the Spanish region of Caceres where the concentrations were 0.116 and 0.413 µg/L). In all other monitored wells (92) *(EZ)*-3-chloroacrylic acid was < 0.1µg/L. It has been concluded that there is information missing that is needed to finalise the groundwater exposure assessment in relation to 11 manufacturing process impurities.

(EZ)-1,3-dichloropropene volatilises from soil even though it is applied below the soil surface. The flux losses from the soil have been measured in field studies in the USA that have been assessed as being representative for EU conditions. Member State experts' and the EFSA considered sufficient information has been provided to conclude that the *(EZ)*-1,3-dichloropropene that will reach the upper atmosphere will degrade relatively rapidly and that this compound and its potential atmospheric degradation products are unlikely to have an adverse effect on the chemistry of the upper atmosphere, as they will be relatively short lived in this environmental compartment. For 10 manufacturing

process impurities, quantitative structure activity relationship (QSAR) calculations, on the rate of photo-oxidative reactions with hydroxyl radicals in the upper atmosphere, indicate that these impurities could be subject to long range transport through the atmosphere.

Studies to address the data gaps identified in the EFSA Scientific Report (2006)72 were provided for the resubmission. Confirmatory data on the compliance of the ecotoxicological test batches to the new specifications are still missing. The indoor use in glasshouse is defined as a permanent structure to which entry of birds and mammals is limited and hence the risk to birds and mammals for the indoor uses is regarded to be low. A high acute risk to earthworm-eating and insectivorous birds and mammals and a long-term risk to earthworm-eating and insectivorous mammals was identified for the outdoor uses. The risk was addressed in a refined risk assessment for herbivorous, insectivorous and earthworm-eating birds and mammals, based on worst case concentrations from residue studies in plants, insects and earthworms. All TER values for acute, short-term and long-term risk meet Annex VI triggers, indicating a low risk to birds and mammals from the intended outdoor use.

Available data indicated a similar level of aquatic toxicity for *(EZ)*-1,3-dichloropropene and 3-chloroallyl alcohol to fish and *Daphnia* which was higher that the toxicity of 3-chloroacrylic acid. *(EZ)*-1,3-dichloropropene was however less toxic to algae and *Lemna* than the two metabolites, which had a similar toxicity. Based on the acute endpoints both the active substance and the metabolites should be classified as very toxic to the aquatic environment. The EFSA Scientific Report (2006) concluded that the acute and long term risk to aquatic organisms from the indoor use via drip irrigation could be regarded as low without the need for risk mitigation measures. The risk associated with this use will therefore not be considered further. For the outdoor use the risk to aquatic organisms was assessed as low based on CHAIN-2D CODE model exposure data including 3 m buffer zones for *(EZ)*-1,3-dichloropropene, 3-chloroallyl alcohol and 3-chloroacrylic acid.

Extended laboratory studies on *Folsomia candida*, *Hypoaspis aculeifer*, *Poecilus cupreus*, *Pardosa* spp. and *Aleochara bilineata* are available but have several deficiencies (exposure method, late introduction of test species and lack of positive control product). In addition a field study was considered to inadequate (poor test design). A new field study from North Italy assessing the effect of telone II on arthropods and earthworms indicated no significant effects on arthropods. Transient effects on earthworms were observed, lasting less than 6 months post-treatment. Several shortcomings in the field study were however identified (e.g. use of other pesticides, low collection rate of collembolan and earthworms). Member state experts agreed that the new field study should only be used to refine the risk assessment for the intended use (tomatoes and soil injection) and only in case the statistical power of the field study could be confirmed.

A high acute risk to earthworms was observed. The risk may be addressed by the field study mentioned above. However, the statistical power of the study still needs to be confirmed. The applicant provided a supportive study on abundance and diversity of earthworms in South Europe. Field surveys in November and February indicated low number of earthworms in fields potential treated with soil fumigants.

The risk to non-target soil micro-organisms was assessed as low based on higher tier field studies. Buffer zones of 3 m were required to address the risk to non-target plants. It could not be excluded that 1,3-D might be harmful if the waste water goes to sewage treatment plants. A concern was raised that washing water from cleaning tools should not be disposed into surface water due to effects on activated sludge.

KEY WORDS:

(EZ)-1,3-dichloropropene, peer review, risk assessment, pesticide, nematicide

TABLE OF CONTENTS

Summary 1
Table of contents 6
Background 8
The active substance and the formulated product 11
Conclusions of the evaluation 11
1. Identity, physical/chemical/technical properties and methods of analysis 11
2. Mammalian toxicity 12
2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics) 13
2.2. Acute toxicity 13
2.3. Short term toxicity 13
2.4. Genotoxicity 14
2.5. Long term toxicity 15
2.6. Reproductive toxicity 16
2.7. Neurotoxicity 16
2.8. Further studies 16
2.9. Medical data 18
2.10. Acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD) 18
2.11. Dermal absorption 19
2.12. Exposure to operators, workers and bystanders 20
3. Residues 22
3.1. Nature and magnitude of residues in plant 22
3.1.1. Primary crops 22
3.1.1. Succeeding and rotational crops 24
3.2. Nature and magnitude of residues in livestock 24
3.3. Consumer risk assessment 24
3.4. Proposed MRLs 25
4. Environmental fate and behaviour 25
4.1. Fate and behaviour in soil 25
4.1.1. Route of degradation in soil 25
4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products 26
4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products 26
4.2. Fate and behaviour in water 27
4.2.1. Surface water and sediment 27
4.2.2. Potential for ground water contamination of the active substance their metabolites, degradation or reaction products 28
4.2.3. Potential for ground water contamination by the process impurities present in the technical product 30
4.3. Fate and behaviour in air 31
5. Ecotoxicology 32
5.1. Risk to terrestrial vertebrates 33
5.2. Risk to aquatic organisms 35
5.3. Risk to bees 37
5.4. Risk to other arthropod species 37
5.5. Risk to earthworms 38
5.6. Risk to other soil non-target macro-organisms 39
5.7. Risk to soil non-target micro-organisms 39
5.8. Risk to other non-target-organisms (flora and fauna) 39
5.9. Risk to biological methods of sewage treatment 40
6. Residue definitions 40
6.1. Soil 40

6.2. Water 40
6.2.1. Ground water 40
6.2.2. Surface water 40
6.3. Air 41
6.4. Food of plant origin 41
6.5. Food of animal origin 41
6.6. Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments 42
6.6.1. Soil 42
6.6.2. Ground water 42
6.6.3. Surface water and sediment 43
6.6.4. Air 43
List of studies to be generated, still ongoing or available but not peer reviewed 44
Conclusions and Recommendations 45
Critical areas of concern 48
References 49
Appendices 50
Abbreviations 101

BACKGROUND

Commission Regulation (EC) No 451/2000[10] 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[11], regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. *(EZ)*-1,3-dichloropropene 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 *(EZ)*-1,3-dichloropropene, hereafter referred to as the DAR (Spain, 2004), to the EFSA on 16 January 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 10 May 2004 to the Member States and the applicant Task Force, which originally consisted of Dow AgroScience BV and BASF Agro BV. BASF sold the business of *(EZ)*-1,3-dichloropropene to Kanesho Soil Treatment BVBA on 17 December 2003 and therefore was replaced in the Task Force.

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 8 November 2004 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 at the Federal Office for Consumer Protection and Food Safety (BVL) in Braunschweig, Germany, in April and May 2005. The reports of these meetings have been made available to the Member States electronically.

Following the consultation of experts a question in relation to the mechanism of the tumours observed in rat and mouse was agreed to be forwarded to the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR). However, first of all in relation to the (overall) toxicological properties EFSA considered that further information on the mode of action of the tumours might not add, except from an academic point of view, substantial evidence in order to conclude on the risk assessment. Secondly, there were numerous data requirements and data gaps identified for (*EZ*)-1,3-dichloropopene which should also be considered.

A discussion of the outcome of the consultation of experts following the procedure set out in Commission Regulation (EC) 451/2000 took place with representatives from the Member States on 8 February 2006 leading to the conclusions set out in the EFSA Conclusion finalised on 12 May 2006 (EFSA Scientific Report (2006) 72).

Following the Commission Decision of 20 September 2007 (2007/619/EC)[12] concerning the non-inclusion of *(EZ)*-1,3-dichloropropene in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicants, Dow AgroScience B.V. and Kanesho Soil Treatment BVBA made a resubmission application for the

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inclusion of *(EZ)*-1,3-dichloropropene in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[13]. The resubmission dossier included further data in response to the areas of concern identified in the review report (European Commission, 2007) as follows:

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fungicide and herbicide, depending on the dose rate used. In general, an application of *(EZ)*-1,3-dichloropropene by soil injection and/or drip irrigation is followed by partial sterilisation of the soil. It should be noted that the applicants stated that only the use as a nematicide would be supported in the EU review programme. The conclusion of the peer review of the resubmission was reached on the basis of the evaluation of the same representative use as a nematicide.

A list of the relevant end points for the active substance as well as the formulations is provided in appendix A.

The documentation developed during the resubmission peer review was compiled as a **Peer Review Report** (EFSA, 2009) comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's Additional Report:

- the comments received
- the resulting reporting table (rev. 1-1 of 17 July 2009)

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 30 September 2009)

Given the importance of the Additional Report including its addendum (compiled version of September 2009 containing all individually submitted addenda) and the Peer Review Report with respect to the examination of the active substance, these documents are considered respectively as background documents A and B to this conclusion. The documents of the Peer Review Report and the final addendum developed and prepared during the course of the initial review process are made publicly available as part of the background documentation to the original conclusion, EFSA Scientific Report (2006) 72, finalised on 12 May 2006 (EFSA, 2006).

By the time of the presentation of this conclusion to the EU-Commission, the rapporteur Member State has made available amended parts of the draft assessment report which take into account mostly editorial changes. Since these revised documents still contain confidential information, the documents cannot be made publicly available. However, the information given can basically be found in the original draft assessment report together with the peer review report which both is publicly available.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

No ISO common name is allocated for *(EZ)*-1,3-dichloropropene (IUPAC), because the chemical name is reasonably short and distinctive. A common abbreviation is 1,3-D.

(EZ)-1,3-dichloropropene is an unclassified nematicide (in terms of chemical class). It penetrates the nematodes through the cuticle and orifices (in particular the mouth) and acts by destroying the ability of cells to transport and use oxygen. It has the potential to disrupt physiological processes that depend on enzyme activity. Additionally, depending on the dose rate, it has various secondary effects (insecticidal, herbicidal, fungicidal) on a variety of organisms. In general, an application of *(EZ)*-1,3-dichloropropene by soil injection and/or drip irrigation is followed by partial sterilisation of the soil.

The representative formulated products for the evaluation under the resubmission were the same as for the original submission, 'Telone EC Drip (EF-1478)', an emulsifiable concentrate (EC), registered under different trade names in Southern European countries and 'Telone Injected (XRM-5048)' a liquid formulation (AL), registered under different trade names in the EU.

The evaluated representative uses as a nematicide utilise 2 application techniques to bare soil: either introduction of the formulated product into the drip irrigation system ('EF-1478') or the product is injected into the soil at 15-20 cm depth ('XRM-5048') to control nematodes in soil where tomatoes or peppers will be grown. Application rates up to 283 kg *(EZ)*-1,3-dichloropropene per hectare ('EF-1478') and up to 224 kg per hectare in ('XRM-5048'), have been presented for evaluation. *(EZ)*-1,3-dichloropropene can be used as nematicide, insecticide, fungicide and herbicide, depending on the dose rate used. It should be noted that the applicant stated that only the use as a nematicide will be supported in the EU review programme.

CONCLUSIONS OF THE EVALUATION

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

The minimum purity of (EZ)-1,3-dichloropropene as manufactured should not be less than 965 g/kg (at least 450 g/kg the of the Z or cis isomer and at least 320 g/kg of the E or trans isomer)14. Both isomers have been considered to contribute to the pesticidal activity. At the moment no FAO specification exists.

During the evaluation process both applicants have sent either separate or joint specifications, but at a final stage the applicants have not submitted a joint specification to cover both Dow AgroSciences (DAS) and Kanesho Soil Treatment (KST) sources. Information on all the specified impurities has been assessed in the toxicology section from both applicants and therefore no assessment on the equivalence of the technical materials was conducted.

It should be noted that the applicant Dow AgroSciences (DAS) has submitted data for more than one production site, however, at a final stage DAS was only seeking approval for the technical grade (EZ)-1,3-dichloropropene manufactured in Europe. In order to address the requirements from the RMS and EFSA during the peer review process regarding the identity of polychlorinated impurities in (EZ)-1,3-dichloropropene technical, Dow AgroSciences sent consecutive multibatch analysis and the number of impurities analyzed for and identified had increased. The newly identified impurities were below 1 g/kg. A number of the impurities were quantified against analytical standards. A number of impurities between 0.1 and 1 g/kg were identified by GC-MS and quantified in the absence of reference standards against a response factor of a closely eluting known impurity. The proposed technical specification was considered acceptable.

[14] It should be noted that *cis*-1,3-dichloropropene and the relevant impurity 1,2-dichloropropane are listed in annex I of Commission Regulation 2076/2002. However, the COM has confirmed that Article 2 of Commission Regulation 2076/2002 is not applicable in these cases.

Kanesho Soil Treatment (KST) submitted a new multibatch study for each of the sources used by their supplier, however some impurities were quantified with no validated analytical methods, and as a consequence a data gap was identified for reliable analysis of batches with validated analytical methods. The proposed specification of Kanesho Soil Treatment should be considered as provisional until a reliable analysis of batches is available.

The technical material contains 1,2-dichloropropane, which initially was considered as relevant from a toxicological point of view (DAR, Volume 4, p 10). During the resubmission the RMS considered the impurity as non-toxicologically relevant, based on toxicological information summarised in the addendum to the additional report (see Section 2.8).

The content of (EZ)-1,3-dichloropropene in the representative formulations is 920 g/kg (pure) in 'Telone EC Drip (EF-1478)' and 965 g/kg (pure) in 'Telone Injected (XRM-5048)'.

The main data regarding the identity of *(EZ)*-1,3-dichloropropene and its physical and chemical properties are given in Appendix A.

It should be noted that the formulation 'EF-1478' is stable after 2 years storage except for the emulsion characteristics. It should be mentioned however that there is no information about the emulsion characteristics of the formulation under the special conditions of the application through the irrigation system and Member States should pay particular attention to this issue.

Beside this, sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of *(EZ)*-1,3-dichloropropene in the technical material and in the representative formulation, as well as for the determination of the respective impurities in the technical material and the formulation. Enough data are available to ensure that at least limited quality control measurements of the plant protection products are possible.

Adequate methods are available to monitor all compounds given in the respective residue definition, i.e. *(EZ)*-1,3-dichloropropene in food of plant origin; *(EZ)*-1,3-dichloropropene and *(EZ)*-3-chloroacrylic acid[15] in soil and water; *(EZ)*-1,3-dichloropropene in air.

The methodology used is GC with EC, MS or FI detection. A multi-residue method like the Dutch MM1 or the German S19 is not applicable to due the nature of the residues.

An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed (see 3.2).

2. Mammalian toxicity

(*EZ*)-1,3-dichloropropene (1,3-D) was discussed at the EPCO experts' meeting for mammalian toxicology (EPCO 23) in May 2005 and in the PRAPeR experts' meeting TC 17 in 2009. During the EPCO meeting it was concluded that the toxicological data package only covered the DAS source. With the resubmission the two applicants did not submit a joint specification but two separate proposals. The two specifications, one from Dow and one from Kanesho, are different in terms of impurity profile and were considered separately.

The toxicological properties of the new technical specifications as proposed in Vol 4 of the Additional Report, including toxicological consideration of the several impurities present and the compliance to the batches tested in the mammalian toxicity data package, was considered by the experts. The toxicological assessment of most impurities is confined to acute toxicity. Mutagenic potential of impurities specified above 0.1% has not been investigated, in particular for impurities which were not

[15] (*EZ*)-3-chloroacrylic acid: (2*EZ*)-3-chloroprop-2-enoic acid

present in batch TSN101035, the only batch used in genotoxicity studies whose analytical profile was provided. Only the Kanesho specification presented a concern over 3 impurities due to their amount in the proposed specification. Quantitative Structure-Activity Relationship (QSAR) screening for these 3 impurities showed several structural alerts: mutagenicity, carcinogenicity, hepatotoxicity, nephrotoxicity. The only toxicological information submitted was estimates of rat oral LD50 values made using the QSAR approach. The comparison with the former proposed specification and with the batches tested in the mammalian toxicology data package is missing. The RMS concluded that they were not relevant. An analytical profile of the batch used in genotoxicity testing is available from the Dow applicant. According to the RMS, only a few impurities are mentioned in this batch as reported in the volume 4 of the DAR (Spain, 2004). The experts compared these impurities and concluded that they were comparable to the DAS specification as proposed in the Additional Report. For both specifications the comparison with the batches tested in the dossier is missing. It was concluded that for the Kanesho specification further genotoxicity testing according to the guidance document on relevant impurities is needed; for DAS and Kanesho a confirmation is requested concerning the compliance of the new specifications to the batches tested in the toxicological data package. It was noted that if a profile of the batches tested is not available, the applicants will in any case have to show that the new specification is toxicologically acceptable. It is noted that the relevance to consumers and the environment of all the impurities present in the new proposed specifications, in consideration of the high amount of 1,3-D applied has not be sufficiently investigated. Little toxicological information was presented in the Additional Report.

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

(*EZ*)-1,3-dichloropropene is rapidly absorbed and extensively metabolised. The excretion is also rapid, mainly in urine (51%) and air (20%) within 24 hours and (*EZ*)-1,3-dichloropropene was not detected in the urine. Based on the presence of mercapturic acid and its sulfoxide in urine, GSH conjugation is probably the main metabolic pathway. Two metabolites, (*EZ*)-chloroallyl alcohol[16] and (*EZ*)-chloroacrylic acid, were also identified, suggesting hydrolysis as another main metabolic pathway. Finally, the formation of epoxides mediated by cytochrome P450 has been proposed as a minor metabolic route based on published data. There was no evidence of accumulation.

2.2. Acute toxicity

The acute toxicity is high i.e. oral LD_{50} 110 mg/kg bw in rats and dermal LD_{50} is 333 mg/kg bw for rabbits (1200 mg/kg bw for rats). The LC_{50} is 2.70 mg/L air. 1,3-D is irritant to skin but not to eyes. However, according to medical data, the EPCO meeting concluded that 1,3-D should also be classified as irritant to eyes and to the respiratory system (see 2.9). Furthermore, it gave positive results in a Buehler test.

In November 2005, the Technical Committee for Classification and Labelling agreed on the following classification: T; R24/25 “Toxic in contact with skin and if swallowed”, R20 “Harmful by inhalation”, R36/37/38 “Irritant to eyes, respiratory system and skin”, R43 “May cause sensitization by skin contact”, R65 “May cause lung damage if swallowed” (see 2.9).

2.3. Short term toxicity

The short-term effects of (*EZ*)-1,3-dichloropropene were studied in two 90-day studies in the rat and one in the mouse, as well as one 1-year study in the dog.

In the rat, the main effects observed were hyperkeratosis and basal cell hyperplasia in stomach (at 15 mg/kg bw/day) after oral administration. The oral NOAEL is 5 mg/kg bw/day.

During inhalatory exposure, hyperplasia of the respiratory epithelium is observed at 30 ppm (≅ 27 mg/kg bw/day). The inhalatory NOAEL is 10 ppm or 9.72 mg/kg bw/day.

[16] (*EZ*)-3-chloroallyl alcohol: (2*EZ*)-3-chloroprop-2-en-1-ol

In the mouse, the main effect was body weight decrease at 50 mg/kg bw/day after oral administration. Following inhalation exposure, males showed a slight degeneration of olfactory neuroepithelium and hyperplasia of respiratory epithelium (at 90 ppm ≅ 150 mg/kg bw/day), and females, aggregates of mononuclear cells in submucosa of urinary bladder (≅50 mg/kg bw/day).

The main effects noted in dogs were hypochromic and microcytic anaemia and a decrease in body weight at 15 mg/kg bw/day. The NOAEL is 2.5 mg/kg bw/day.

2.4. Genotoxicity

The genotoxicity of 1,3-D has been investigated in a comprehensive range of *in vitro* and *in vivo* assays, including gene mutation, chromosomal aberration, DNA damage and DNA binding as endpoints.

Positive results were obtained for *in vitro* chromosome aberrations in mammalian (CHL) cells. In general, the clastogenicity was not confirmed *in vivo,* for somatic or germinal cells, with the only exception of positive results obtained in one mouse bone marrow micronucleus study. Results from this study were not considered acceptable for evaluation since the purity was not reported. Nevertheless, it cannot be ruled out that the *in vivo* clastogenicity of 1,3-D for somatic cells mainly due to neither the route of administration (i.p.) nor the range of doses (150-250 mg/kg bw/day) that induced a positive response were used in the negative mouse bone marrow micronucleus test.

Positive mutagenic effects were also observed. 1,3-D induced gene mutations in bacterial systems (presence or absence of S9 mix), however, the low purity (53% in a mutation assay in *S. Typhimurium*) or the use of genotoxic stabilizer or generation of reactive impurities during attempts to purify test material, hampers the interpretation of the results.

In relation to DNA damage, negative results were obtained for both *in vitro* and *in vivo* UDS assays and positive for both rec-assay and *in vivo* alkaline elution assay. 1,3-D induced increases in DNA fragmentation when administered to rats by gavage or i.p., at 62.5-250 mg/kg, in liver, kidney and gastric mucosa. DNA fragmentation observed in liver suggests that microsomal oxygenase-catalyzed biotransformation played a role in the occurrence of DNA lesions; and DNA fragmentation observed in stomach mucosa could be a sign of direct action. When the two routes of administration were used, DNA fragmentation was higher with the oral route in liver and the converse occurred in kidney. In all cases, DNA fragmentation increased in the first 3 hours after treatment and was partially repaired after 24 hours. The absence of DNA fragmentation in bone marrow, lung or brain could be explained by a lower concentration and/or by a lower activity of the enzyme systems involved in its metabolic activation. The inhibition of cytochrome P450 activity caused a reduction in the degree of liver DNA fragmentation; this fact supported the role of cytochrome P450 in the activation of 1,3-D for DNA lesions. Besides, 1,3-D by itself produced a dose-dependent reduction of the liver GSH level, an effect that presumably hinders its detoxification and thus favours its DNA-damaging activity.

Negative results were obtained in *in vitro* tests DNA binding.

The genotoxicity of 1,3-D was extensively discussed at the EPCO meeting. Some studies showed clear indications for DNA fragmentation *in vivo*, however, negative results were demonstrated in micronucleus, UDS and dominant lethal tests. Finally, it was agreed that the weight of evidence indicated that 1,3-D is an *in vivo* genotoxic agent for somatic cells, acting directly or after activation by cytochrome P450, and glutathione protects against the genotoxicity. The classification of Mutagenic Category 3, R68 was proposed at the meeting.

In November 2005, the Technical Committee for Classification and Labelling agreed not to classify 1,3-D as mutagenic, unless epichlorhydrin (a known carcinogen) had been used as a stabiliser. The applicants confirmed that the current product is not stabilised with epichlorhydrin.

2.5. Long term toxicity

Rats

In rats, stomach and liver were identified as the main target organs, when exposure was via the diet. The non-glandular or squamous portion of the stomach had a mild change of the mucosal lining termed basal cell hyperplasia. An increase in hepatocellular adenomas was observed at 25 mg/kg bw/day, at the end of 24-month of treatment; this increase, although not statistically significant, was also present in males ingesting 12.5 mg/kg bw/day. In addition, a hepatocellular carcinoma was observed in a male from the 25 mg/kg bw/day group. Most livers contained some eosinophilic and or basophilic foci of altered cells. Foci are often considered to be preneoplastic lesions.

Historical control data submitted and summarised in Addendum I (September, 2005) included in the Final Addendum to the DAR (Spain, 2005) was discussed at the EPCO meeting. It was concluded that the increased incidence of the hepatocellular adenomas in males at 12.5 and 25 mg/kg bw/day were treatment related and that 2.5 mg/kg bw/day was the oncogenic NOAEL in the rats. However, no conclusion on a possible mechanism was made. The NOAEL for the systemic chronic toxicity was also considered to be 2.5 mg/kg bw/day (the lowest dose level tested).

During a 2-year inhalation study of vapour of 1,3-D, the olfactory region of the nasal cavity was the target organ. The nature of the microscopic changes observed (decreased thickness and erosions of epithelium) in male and female rats exposed to 60 ppm suggested irritation as the cause. There were not statistically significant tumour increases. The NOAEL for systemic chronic toxicity was considered to be 20 ppm (17.74 mg/kg bw/day).

Mice

Significant changes in the urinary bladder were observed mice (18 months) treated with the highest dose of 25 mg/kg bw/day (gavage), such as increases in transitional cell hyperplasia and hyaline change of the lamina propria, considered to reflect responses to chronic irritation, as well as increases in stromal hyperplasia, stromal hypertrophy and accumulation of brown pigment in reticuloendothelial cells. In addition, there was a slight increased incidence of benign submucosal mesenchymal tumours, considered to represent a proliferative lesion, when compared to the control group. The presence of test material or metabolites in the urinary bladder may induce local irritation resulting in a proliferative connective tissue response. The NOAEL for both systemic toxicity and oncogenicity was considered to be 10 mg/kg bw/day. The NOAEL for systemic toxicity during exposure via the diet was 5 mg/kg bw/day based on reduced body weights.

During inhalation of vapours of 'Telone II', non-neoplastic lesions present at 24 months were noted to be similar to the previous intervals (6 and 12 months). These lesions were mainly changes in the urinary bladder of both males and females treated with 20 and 60 ppm and characterised by a moderate hyperplasia of the transitional epithelium. This hyperplastic reaction was occasionally accompanied by an inflammatory reaction in the lamina propria of the urinary bladder. Other effects were focal hyperplasia and hypertrophy of the respiratory epithelium in the nasal turbinates, observed at 60 ppm and also in females exposed to 20 ppm. Furthermore, a slight hyperplasia of the epithelial lining from the non-glandular portion of the stomach was observed in males exposed to 60 ppm. The only tumorigenic response was an increased incidence of benign lung tumors in males exposed to 60 ppm. Therefore, the NOAEL was considered to be 5 ppm (i.e. 7.69 mg/kg bw/day) for chronic toxicity and 20 ppm (30.75 mg/kg bw/day) for oncogenicity.

Conclusion

The experts in the EPCO meeting concluded that 1,3-D induced benign tumours in the liver of rats and in both urinary bladder epithelium and lung of mice. In addition, one hepatocellular carcinoma was observed in rats. Preneoplastic lesions (foci) were also present in rat liver. However, the mechanism of action for tumour formation was not identified. Although results indicated that (*EZ*)-1,3-

dichloropropene can be mutagenic, the relevance of these results to mammalian tumour formation was uncertain owing to the high concentrations or doses used (see 2.4). The mechanistic studies, using GSH levels as endpoint, which showed that (*EZ*)-1,3- dichloropropene at doses used in chronic bioassays depleted GSH in target organs, were consistent with GSH protection by conjugation with 1,3-D; however, the saturation of this mechanism of detoxification could lead to tissue injury, cytotoxicity and genotoxicity. However, although (*EZ*)-1,3-dichloropropene may be not genotoxic at low-dose exposures that do not interfere significantly with normal function of GSH chronic bioassay, data showing the protective effect of GSH against tumour formation were lacking. Furthermore, concerns were raised due to the structural resemblance to known carcinogens.

The classification as a possible human carcinogenic Category 3, R40 was discussed but, as there were uncertainties regarding the mechanism for the tumours, a final conclusion could not be drawn. The issue was to be forwarded to the PPR panel. R40? was highlighted in the list of endpoints and was considered to be provisional until the mechanism of formation of tumours is known.

In November 2005, the majority of the Technical Committee for Classification and Labelling experts agreed not to classify 1,3-D as carcinogenic, unless epichlorhydrin (a known carcinogen) had been used as a stabiliser. The applicants confirmed that the current product is not stabilised with epichlorhydrin.

2.6. Reproductive toxicity

In an inhalatory 2-generation reproduction toxicity study, rats were exposed to 10, 30 and 90 ppm for 6 hours/day. Decrease in body weight during the treatment period in both the F0 and F1 adult rats at the 90 ppm dose was considered evidence of parental toxicity and the reproductive NOAEL for this study was set to 90 ppm. Gastric ulcers were observed and their relevance was discussed at the EPCO meeting. The experts concluded that as they were higher than historical control data they should be regarded as adverse. The NOAEL based on this finding is also 90 ppm (87 mg/kg bw/day).

Developmental toxicity of (*EZ*)-1,3-dichloropropene was studied in rats and rabbits by inhalation exposure. In rats, maternal toxicity as reduction in body weights, body weight gains and food consumption was observed at all dose levels. Additionally, relative kidney weights were observed to be increased in the 120 ppm group. No NOAEL for maternal toxicity could be established in this study. No foetal adverse effects and no teratogenic effects were observed at any dose level. Therefore, the NOAEL for development in rats was set at 120 ppm.

In rabbits, effects on body weight were observed at the dose levels of 60 and 120 ppm. Additionally, a single death of unknown cause was reported in the 120 ppm group. The NOAEL for maternal toxicity in rabbits was established at 20 ppm. No signs of developmental toxicity or teratogenicity were observed in the rabbit study. Thus, the highest dose tested, 120 ppm, was set as the NOAEL for developmental toxicity in rabbits.

2.7. Neurotoxicity

Studies were not submitted and not required as 1,3-D did not give any indication of neurotoxicological potential.

2.8. Further studies

Metabolites

Toxicokinetics study demonstrated that (*EZ*)-3-chloroallyl alcohol and (*EZ*)-3-chloroacrylic acid are absorbed to a high extent.

The oral LD_{50} is 91 mg/kg bw for both 3-chloroallyl alcohol and 3-chloroacrylic acid, being more toxic to females than males, and has to be classified as **T, R25**.

The acute dermal LD_{50} (rabbit) was 316 mg/kg bw for 3-chloroallyl alcohol and has to be classified as **T, R24**. There were no studies assessing dermal toxicity of 3-chloroacrylic acid.

3-chloroallyl alcohol was considered to be non-irritant to skin, and no studies have been submitted about 3-chloroacrylic acid. Neither of the compounds was considered to be skin sensitizers (Buehler test).

The 90-day toxicity studies in rat with both metabolites reflected histopathological findings in liver and kidney for 3-chloroallyl alcohol and 3-chloroacrylic acid. The NOAEL was established as 3 mg/kg bw/day for 3-chloroallyl alcohol and 10 mg/kg bw/day for 3-chloroacrylic acid.

With respect to the two intermediates, 3-chloroallyl alcohol and 3-chloroacrylic acid, no activity was found *in vitro* mutagenicity and *in vivo* clastogenicity assays with the only exception of a weak mutagenic activity of the alcohol in the mouse lymphoma mutation assay. Both compounds were found to be less active than 1,3-D in *in vitro* assays.

Developmental toxicity potential of 3-chloroallyl alcohol and 3-choroacrylic acid administered by gavage was evaluated in rats. 3-chloroallyl alcohol induced decreases in foetal body weights at maternal toxic doses (25 mg/kg bw/day), and 3-choroacrylic acid, increases in total resorptions and decreases in foetal body weights at maternal toxic doses (65 mg/kg bw/day). No teratogenicity was observed in any case. The developmental NOAEL was considered to be 10 mg/kg bw/day for 3-chloroallyl alcohol and 25 mg/kg bw/day for 3-choroacrylic acid.

The mutagenic potential of urinary excretion products

The potential mutagenicity of the urine from mice exposed to (*EZ*)-1,3-dichloropropene as well as of several compounds, which have been identified as urinary excretion products of 1,3-D or are theorized to be potential excretion products of (*EZ*)-1,3-dichloropropene, has been evaluated by means of the Salmonella/mammalian microsome assay.

Both urine and disulfide metabolite of (*EZ*)-1,3-dichloropropene were not mutagenic. N-acetylcysteine, sulfoxide/sulfone, thioglycolic acid and cysteine conjugates of (*EZ*)-1,3-dichloropropene were mutagenic for TA100 in the absence of S9 from rat liver, although the maximum increase in the number of revertants induced by N-acetylcysteine conjugate was only 2.9-fold control value. The sulfoxide/sulfone and cysteine conjugates of 1,3 dichloropropene also caused an increase in the number of TA98 revertants (in the absence of S9 from rat liver), albeit smaller than that observed with TA100. While these 1,3-D conjugates were found to be mutagenic at relatively high concentrations (5-10 mg/plate), it is estimated that, based upon pharmacokinetics data, their concentration in the urine of either sex of mice dosed with (*EZ*)-1,3-dichloropropene in this study would not have been high enough to expect a positive urine assay.

Mechanistic studies

There is a number of specific studies performed in order to elucidate the mode of action. Studies on the impact of GSH were performed both *in vitro* and *in vivo*. It was demonstrated that the GSH conjugation play a significant role in detoxification and that 1,3-D might act via decreasing the levels of GSH.

Impurities

The issue of toxicological relevance of the polychlorinated impurities was raised as an open point at the EPCO experts´ meeting (see chapter 1). However, as no specific toxicological data were available this point had to remain open. Dependent on the identity on the polychlorinated impurities it might be necessary to require new toxicological studies. The issue was not further discussed in the TC17.

Furthermore, the technical material contains 1,2-dichloropropane which itself is an active ingredient. Initially in the DAR, the RMS regarded this as a relevant impurity. There are toxicological studies performed with batches in the range of 1.4%-2%.During the resubmission the RMS considered the impurity as non-toxicologically relevant, based on toxicological information summarised in the addendum to the additional report. The issue was not discussed in the TC17, however, EFSA notes that the information provided in the addendum was not sufficient to further address the issue of relevance.

2.9. Medical data

In production plants, a review of medical surveillance exam data of employees disclosed no abnormalities suspected to be of an occupational etiology. The medical data suggest that 1,3-dichloropropene is moderate in acute oral toxicity; ingestion may cause gastrointestinal distress, adult respiratory distress syndrome, hematological and multiorgan failure including pancreatic damage, hepatorenal function impairment and death. Aspiration into the lungs may occur during ingestion or vomiting, resulting in rapid absorption and injury to other body systems. Excessive inhalation exposure may cause irritation to the upper respiratory tract (nose and throat) and lungs, or even death. Respiratory symptoms, including pulmonary edema, may be delayed. Skin exposure may cause irritation or a burn, or may cause allergic dermatitis. Eye exposure may cause severe eye irritation or corneal injury. According to these data, the EPCO meeting concluded that 1,3-D should be classified as irritating to eyes (R36) and irritating to the respiratory system (R37). Furthermore, it ~~i~~was proposed to classify as R65 "Harmful, may cause lung damage if swallowed" due observed adverse effect, according to the criteria given in Directive 67/548/EEC. In November 2005, the Technical Committee for Classification and Labelling agreed on the following classification: T; R24/25, R20, R36/37/38, R43, R65 (see chapter 2.2).

2.10. Acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD)

After the EPCO meeting the reference values were considered as provisional due to the possible mutagenic and carcinogenic properties of (*EZ*)-1,3-dichloropropene.

ADI

The NOAEL of 2.5 mg/kg/day based from the 24-month study in rats in which foci of altered cells in the liver and cell hyperplasia in the stomach were observed at 12.5 mg/kg bw/day was used. As 1,3-tumours are observed during long-term exposure to (*EZ*)-1,3-dichloropropene and the mechanism was not clarified as well as its possible relevance for humans, an adequate margin of safety was selected. The experts agreed with the rapporteur Member State proposal that the margin should be at least 1000 between the ADI and the dose level where tumours are evident. As the LOAEL for tumours is 12.5 mg/kg bw/day an additional safety factor of 2 was agreed to be added. The ADI was set at 0.0125 mg/kg bw/day, with the use of the safety factor of 200.

During the meeting TC 17 some experts highlighted that the increased safety factor was dependent on the presence of tumours at the LOAEL. However, it was noted that the Technical Committee for Classification and Labelling did not classify based on these effects, and the reason for the non-classification decision by the Technical Committee for Classification and Labelling was considered: some experts did not agree with this decision. The nature of the effects was still considered as well as their relevance for humans. Some doubts about the mechanism behind the tumour formation were highlighted. The need to continue to apply a higher safety factor was discussed in depth. The majority of experts agreed to lower the safety factor to 100, the RMS and one MS proposed to keep the 200 SF. Therefore, the **ADI was increased to 0.025 mg/kg bw/day** (based on the NOAEL of 2.5 mg/kg bw/day, SF 100).

AOEL

As 1,3-D is applied via drip irrigation, used for greenhouses and through the irrigation system, the major risk associated is evidently, the 1,3-D evaporated. Only the systemic AOEL is considered.

During the EPCO meeting the AOEL wais proposed to be based on the 90-day rat inhalation study, 10 ppm i.e. 9.72 mg/kg bw/day supported by the 2-year mouse inhalation study with a safety factor of 100 applied. There was a margin of safety of 1000 in relation to the observed tumours in the mouse at 100 mg/kg bw/day. The AOEL was rounded to 0.1 mg/kg bw/day, safety factor 100.

During the EPCO experts´ meeting it was agreed in accordance with assumptions from the rapporteur Member State that as inhalation exposure is the main route of exposure and all data from operator exposure are expressed as atmospheric concentration (mg/m^3). The rapporteur Member State was asked to re-calculate the inhalatory AOEL for humans based on the systemic AOEL of 0.1 mg/kg bw/day which would correspond of a dose of 0.1 ppm.

In addendum III (Sept. 2005) included in the compiled final addendum to the DAR (Spain, 2005), the RMS presented a re-calculation of the inhalatory AOEL based on the systemic AOEL (two options were provided). The majority of experts in TC 17 were in favour of considering the rat results without considering a conversion rate for humans.

AOEL = 10 ppm / 100 = 0.1 ppm

Conversion factor is 1 ppm = 0.0045 mg/L

0.1 ppm = 0.00045 mg/L = 0.00045mg/0.001m^3 = 0.45 mg/m^3

The resulting AOEC is then 0.45 mg/m3 (0.1 ppm).

The need to consider the difference in respiration rate between the rat and humans was discussed, and whether it is justified to convert the AOEL value derived from the rat into an AOEL based on the human respiration rate. After the TC 17, comments on the appropriateness of the approach to be taken were received: considering the agreed approach, the fact that the rat has a higher respiration rate than humans was dismissed. However, compared to what was provided by the RMS, the calculation was proposed not to take into account the rat respiration rate (as the available AOEL in the list of end points is already expressing an internal dose in rat), but only the human respiration rate, to calculate from an internal value to an external value. According to this proposal the AOEC would be 0.6 mg/m3. This value is not peer reviewed.

ARfD

The rapporteur Member State had not proposed an ARfD. However, at the EPCO meeting it was agreed to allocate one as it might be the situation in future that residues could reach ground water. The NOAEL of 20 mg/kg bw/day from the 2 week dog study was chosen.

The ARfD is 0.2 mg/kg bw, with the safety factor of 100 added.

The value was confirmed in the PRAPeR TC 17.

2.11. Dermal absorption

No data is submitted for Telone drip or Telone injection and the rapporteur Member State states that no dermal absorption would occur for the proposed uses. This was discussed during the experts´ meeting and was agreed. Furthermore, it was concluded that if dermal absorption would occur the default value of 100% would be used.

2.12. Exposure to operators, workers and bystanders

During the EPCO meeting the exposure assessments were considered as inconclusive in relation to the mutagenic and carcinogenic properties of (*EZ*)-1,3-dichloropropene and based on the provisional reference values.

There were several studies evaluating directly the exposure of 1,3-D to operators and re-entry workers and the measurements of atmospheric concentration during and after application could serve to evaluate bystander exposure. The 1,3-D is applied to bare soil and consisted of two scenarios. The estimations based on field measurements, no agreed models exist.

During the PRAPeR TC 17 the exposure assessment to operator, worker and bystander during drip irrigation and soil injection was re-considered, and a re-calculation was requested from the RMS due to the new AOEC established.

Drip irrigation

It can be applied via drip irrigation, used for greenhouses and through the irrigation system, which implies no professional applicators. The operator only has to calibrate the system (with water). The major risk for exposure is evidently, the 1,3-D evaporated as well as if the system fails and the operator has to correct it.

In the original assessment PPE was needed in order not to exceed the AOEC as demonstrated by the worst case scenario during mixing loading (330% of the AOEL was measured). If PPE (gloves and coverall) and RPE (respiratory mask with filter for organic vapours) was worn the exposure was reduced to 16% The concentration of 1,3-D was high during the first days, but decreased, and after around 2-3 days the level of AOEC is reached.

During the PRAPeR TC 17 it was noted that the RMS considered only the inhalation exposure for operators. Some MSs indicated that the dermal exposure should be considered as well for the mixing and loading operations. However the dermal exposure was considered by the experts of no concern as it is a limited/transient exposure route.
According to the addendum (September 2009) included in the compiled final addendum to the Additional Report (Spain, 2009b), the operator was exposed to 0.99 mg/m3 (TWA 8h), which represented 220% of the AOEC (0.45 mg/m3). In this situation, the use of a respiratory mask would reduce levels of 1,3-D to 0.05 mg/m3, which represents 11% of the AOEC.

Soil injection

This procedure is usually made by professional applicators that use a more sophisticated and closed system. During transfer and application, the operator is exposed to vapours of 1,3-D. In the Addendum III (September, 2005) included in the compiled final addendum to the DAR (Spain, 2005) new calculations of the exposure were presented (due to revised AOEC).

PPE was needed in order not to exceed the AOEC as demonstrated by the worst case scenario during mixing loading where 776% of the AOEC was measured. If PPE (gloves and coverall) and RPE (respiratory mask with filter for organic vapours) were worn the exposure was reduced to approximately 21-38% of the AOEC.

During the PRAPeR TC 17 the operator exposure during soil injection activities was re-discussed. Operator exposure is based again on field measurements. This was accepted by the experts.

Table 6.14.4-3 of addendum 5 to Vol 3 B.6 from the final addendum to the Additional Report (Spain, 2009b) was discussed. Atmospheric concentrations were found above the AOEC. However the use of RPE lowers the values below the AOEC. As the AOEC was lowered, these values should be re-

calculated with the new AOEC. A column to the table 6.14.4-3 giving the % of AOEC when RPE is used was considered as useful.

The protection (RPE) should be protective as to 95% of the inhalation exposure (as proposed by the RMS in the addendum 5 to Vol 3 B.6).

Worker exposure (following what is reported in the DAR) indicates the operator that, at 14 days removes the plastic sheets: there is the need to recalculate the exposure considering the new AOEC and the use or not of RPE.

Some concerns were raised by the experts on the reliability of the few field measurements with huge standard deviations (see table 6.14.4-2 of the addendum 5 to Vol 3 B.6), as the whole risk assessment is based on mean air concentration with these drawbacks. The use of a 75th (or higher) percentile might be more appropriate.

The MSs proposed to re-calculate the risk assessment with this approach, however the experts could not reach an agreement on the appropriate percentile for the data available, and it was agreed that the RMS should make a proposal and calculate this new approach. It was highlighted however that the results would not be peer-reviewed.

The RMS presented a proposal in the addendum 5 to Vol 3 B.6. A study evaluated the operator exposure in 37 operators engaged in mixing/loading and application of 1,3-D. In this study, the 75th percentile of 1,3-D values (TWA 8h) was 4.83 mg/m3, which represented 1073% AOEC. The use of respiratory protection reduced the exposure to levels under the proposed AOEC (54%) (**EFSA notes** that this assessment is not peer reviewed).

Worker exposure

Generally, the worker re-entering soon after treatment has to adopt the same protective measures as the operators (such as PPE and RPE).

Drip irrigation

After 21 days (when planting takes place) no residues of 1,3-D were detected. Thus, the risk for exposure could be said to be negligible.

During the PRAPeR TC 17 it was noted that a minimum re-entry time for southern MSs in the GAP table states 14 days (from the applicant). Field data are available showing that at day 3 after application the measured concentration is 0.22 mg/m^3 (below the AOEC), whereas in another study the concentration is below the AOEC after 6 days.

According to the addendum 5 to Vol 3 B.6, one study (MG33) showed that in this situation, levels of 1,3-D can be much higher than the AOEC (149% AOEC), however, the use of respiratory masks can reduce the levels to values below the AOEC (7%).

Soil injection

After injection, 1,3-D is rapidly evaporated to the atmosphere and no activities are required until planting, at least 14 days after last application. For the activity of installing the sheeting or bed shaping immediately after 1,3-D injection, workers can be exposed to levels higher than AOEL (200-2000% of the AOEC). Therefore, for these re-entry activities (if necessary), the use of appropriate PPE and respiratory protection is needed.

Normal re-entry tasks are carried out at day 26 for planting activities. In this situation, the levels of exposure were under AOEC (<5%). However, there are some other re-entry activities, such as bed shaping, install sheeting, sprinkler maintenance and rock removal that are usually carried out before

the normal re-entry period. Install sheeting represented the worst case of re-entry worker exposure (1266% of the AOEC), therefore, for install sheeting and shaping, workers must use respiratory protection (64% AOEC in install sheeting) (**EFSA notes** that this assessment is not peer reviewed).

Bystander exposure

Drip irrigation

Bystanders may be exposed to average levels ranging from 0.6 to 1.4 mg/m$^{3.}$ These values represented the average of 0-6 hr and 0-2.4 hr, respectively, and the distance for bystander risk assessment is usually 8-10 m. Other studies showed that those bystanders walking or standing at > 5 m from the greenhouse would be exposed to levels well below the proposed AOEC, even in the case of recent application.

During the PRAPeR TC 17 bystander exposure outside the greenhouse was considered. A minimal distance of 5 m from the greenhouse was proposed by one MS for bystanders. One out of several measurements at 3 m outside the greenhouse showed a higher value than the AOEC. Risk mitigating measures could be proposed to minimize the risk for bystanders, as allowing the application only to professional operators, or limit the access of bystanders near the treated areas.

According to the addendum submitted in September 2009, at > 7mt from the site of application, bystanders would be exposed to levels below AOEC (37.5% AOEC), however, it must be taken into account that bystanders can walk near a greenhouse in which 1,3-D is being applied. In this situation, a study showed that at a distance of 1m and during the first 6 h of 1,3-D application, bystanders can be exposed to levels above the AOEC (>100%).

Soil injection

Application of 1,3-D by injection to the soil did not suppose any exposure for bystanders walking near the fields recently applied.

Some studies reported data on atmospheric concentration of 1,3-D in/near the fields treated with 1,3-D. The worst case (edge of the field) showed average values of 0.094 mg/m3, which represented 21% AOEC (**EFSA notes** that this assessment is not peer reviewed).

3. Residues

(EZ)-1,3-dichloropropene (1,3-D) was discussed in the experts' meeting for residues in May 2005 (EPCO 24). In residues there was no experts' discussion held on the additional report of April 2009 (Resubmission procedure).

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

Metabolism studies in tomatoes, oranges, sugar beet and soybeans following soil application of radio labelled 1,3-D have been submitted.

The metabolism of radio labelled ^{14}C 1,3-D was investigated in tomatoes following a soil application at approximately 1.5 fold the maximum recommended rate for the representative use on selected fruiting vegetables, i.e. tomatoes and peppers in Europe. At harvest, total radioactive residues in tomato fruits and foliage were 0.30 mg/kg and 2.24 mg/kg 1,3-D equivalents, respectively. No 1,3-D per se was detected in any fruit or foliage sample at harvest. The alcohol metabolite of 1,3-D (3-chloro allyl alcohol) was present at levels ≤0.033 mg/kg 1,3-D equivalents in both, the fruit and foliage. In tomato fruits, the majority of radioactive residues was characterised as composed of sucrose, carbohydrates, and cellulose. In foliage, the radioactive residue was shown to be comprised of plant pigments, sugars, small organic acids and bases. Even though a high amount of applied 1,3-D is

expected to volatilise, the results of the study support a degradative pathway for residual 1,3-D which results in the incorporation of the radioactive atoms into natural plant constituents.

In orange fruits, the radioactive residue increased with time from application, indicating that ^{14}C was absorbed and translocated throughout the orange tree. Comprehensive characterisation of orange fruit residues demonstrated incorporation of the radiolabel into natural plant constituents, primarily organic acids such as malonic and citric acid. Characterisation of the sugar beet radioactive residue was conducted in multiple ways. Natural incorporation of the radioactivity was demonstrated by isolating $^{14}CO_2$ in a fermentation experiment as well as through isolation of radioactive protein, amino acids, organic acids, sucrose, cellulose and hemicelluloses. In soybeans, the radioactive residue was shown to be comprised of fatty acids, amino acids, sugars, and cellulose. In soybean forage, the radioactive residue was characterised as composed of pigments, osazones, organic acids, sugars, and cellulose.

Based upon the findings in the metabolism studies, naturally occurring plant constituents represented the majority of the radioactive residue in tomatoes, oranges, sugar beets and soybeans. 3-chloroallyl alcohol was identified as a minor metabolite in tomato fruits and leaves only.

Additional information on uptake, translocation and accumulation of ^{14}C 1,3-D and/or ^{14}C 3-chloroallyl alcohol in bush beans, tomato and carrot are available from a published report, corresponding with the findings in the primary crop metabolism studies summarized above.

The plant residue definition for risk assessment and monitoring purposes is proposed as (*EZ*)-1,3-dichloropropene.

A large number of residue trials with 1,3-D has been conducted on a wide range of crops for a period of over 30 years in several countries (Northern and Southern Europe, USA, Japan, Australia and Philippines), representing a wide and varied range of climatic and global agronomic conditions. On the representative crops tomatoes and peppers, a limited number of trials carried out in Japan and USA (California and Florida) between 1971 and 1985 have been submitted. The applicant considered those trials relevant for uses in Southern Europe, assuming European trials would most likely generate similar residue results.

The experts in the ECPO 24 meeting on residues considered that the indoor use of 1,3-D (up to 283 kg a.s./ha) might represent the critical GAP in terms of possible residues. The experts considered furthermore that greenhouse trials should be comparable throughout the world provided that the GAP is comparable. Following the experts' advice the rapporteur Member State presented all trials covering the indoor use in fruiting vegetable in an addendum (September 2005) which is included in the compiled final addendum to the DAR (Spain, 2005). 1,3-D was the residue determined in all trials. Residues were all below the limit of quantification (LOQ) of 0.01 mg/kg or, where stated, even below the LOD of 0.001 mg/kg. This is supported by residue trials available on other crop groups where 1,3-D residues at harvest were all below LOQ.

Studies on effects on residue levels from industrial processing and/or household preparations are not required since the supervised trials demonstrated no residues of 1,3-D above LOQ occur in any of the crops that may be further processed.

However, it is noted that these studies were designed to investigate the residue behaviour of 1,3-D and thus don't provide any information regarding the residue behaviour of the chlorinated impurities present in the technical material. Chlorinated impurities are applied to the soil in high amounts when using 1,3-D at the intended rate. Therefore, the experts' meeting for residues EPCO 24 in 2005 agreed that further information from the applicant is required on the relevance of such chlorinated impurities in terms of consumer exposure and consumer safety.

In the resubmission dossier of 2009 three additional residue studies were provided to allow some further clarification on human health risk assessment.

Two of these three studies were carried out in order to provide some empirical evidence that the chlorinated impurities present will behave similarly to 1,3-D and will not result in any residues in the crop at harvest. Parent 1,3-D and six chlorinated impurities (1, 2, 3, 5b, 5c and 8a) were analysed in these two studies. Eight trials each (Italy and Spain 2007) were conducted in tomato and pepper according to the critical GAP for both pre-plant soil injection and drip applications. No residues of 1,3-D or of the six mentioned impurities were found in any of the trials (LOQ 0.01 mg/kg).

In a third study (4 trials, Italy 2005) parent *(EZ)*-1,3-dichloropropene (*E*- and *Z*- isomers) was analysed in young tomato plants after the soil treatment. No residues of either *E*- or *Z*- 1,3-dichloropropene were found (LOQ 0.005 mg/kg per isomer).

1,3-D and its six studied impurities did not leave detectable residues in the crop.

3.1.1. Succeeding and rotational crops

A study to confirm that residues of 1,3-D in succeeding crops, even in the worst case situation of a crop failure, would not be present above the LOQ of 0.01 mg/kg was submitted.

This study describes the nature of the residue in wheat, lettuce, carrots, and radishes following a pre-planting application of ^{14}C-1,3-D at a rate approximately 1.5 fold the maximum recommended rate for the representative uses. Thirty days after application the crops were planted. No 1,3-D, or the alcohol or acid metabolite, was found in any of the harvested crops. The majority of the radioactive residue was characterised or identified as being associated with natural products such as pigments, simple sugars and carbohydrates, and structural components (cellulose), demonstrating the complete degradation of 1,3-D in succeeding crops.

With regard to the issue of impurities applied together with 1,3 D to the soil the same conclusion as for primary crop residues will be applicable due to the mode of application (pre-plant soil applications in primary crops) (refer to 3.1.1 and 3.3 of this document).

3.2. Nature and magnitude of residues in livestock

It was considered not relevant to define a residue of concern in food of animal origin, because the representative use of 1,3-D is on fruiting vegetables which are normally not fed to livestock. However, studies on the metabolism of 1,3-D in lactating goat and laying hens have been submitted and evaluated in the DAR for information purposes. No further data are currently required.

3.3. Consumer risk assessment

Estimates of dietary exposure of consumers to 1,3-D conducted with the EFSA PRIMo and the proposed MRL for 1,3-D of 0.01 mg/kg (LOQ) indicate that the chronic exposure is well below (<10%) of the ADI for 1,3-D of 0.025 mg/kg bw, and the acute exposure is well below (<2%) the ARfD for 1,3-D of 0.2 mg/kg. It was concluded unlikely that any European diet will lead to a dietary risk for consumers in terms of 1,3-D residues.

However, even though there is no concern regarding consumer exposure to 1,3-D residues per se, a lack of data for hazard characterisation and the assessment of residue behaviour of 1,3-D impurities did not allow the consumer risk assessment to be finalised during the first peer review in 2005. The experts' meeting for residues EPCO 24 had unanimously agreed that further information on chlorinated impurities is required to conclude on consumer safety.

New residue trials were conducted. 1,3-D and its six analysed impurities (1, 2, 3, 5b, 5c and 8a) do not leave detectable residues in the crop. As impurity levels in the formulation are much lower as the content of the active substance 1,3-D and all compounds are supposed to be of similar volatility, residues in crops are not likely to represent a risk to health of consumers.

The RMS concluded in the Additional Report that, since impurities are supposed to have similar volatility and physico-chemical properties as 1,3-D, uptake and residue formation in crops would also not be significantly different to that of 1,3-D. Therefore, given the no residue situation for 1,3-D and six impurities in the residue trials, there would be no concern for the health of the consumer.

However, EFSA noted that not all impurities in the updated specification are structurally similar and confirmation is outstanding on how similar the pertinent physico-chemical properties (e.g. volatility & water solubility etc.) might be. The Member State experts in the section of fate and behaviour discussed whether the available QSAR estimated physico-chemical properties for impurities 9a, 9b, 10, 11 and 12 and their comparison to the physico chemical properties data for 1,3-D and associated argumentation would be sufficient. The fate and behaviour experts considered that this QSAR information alone was insufficient and identified a data gap that also needed to include impurity 13, where the RMS had provided the QSAR estimates that were discussed. Moreover it was concluded by the experts that information on the hydrolysis products of impurities 4, 5a, 6, 7 and 8b is required (refer to 4.2.3).

Whether or not the argumentation of the RMS to use the submitted residue trials with 1,3-D and six impurities to reach an overall conclusion on the residue behaviour is valid **will depend on the information to address the data gaps in the section fate and behaviour.**

During the review process it was also brought forward by the RMS (addendum 2 to Vol 3 B.7 of June 2009, included in the compiled final addendum to the Additional Report (Spain, 2009b)) that a calculation of contributions of impurities to the mammalian toxicity of *(EZ)*-1,3-dichloropropene showed that none of them was found to be relevant if present at their maximum allowable concentration in the formulated product. Thus residues of 1,3-D and its impurities should not represent a risk to health of consumers. However, the experts in the meeting on mammalian toxicology found there were deficiencies in the toxicological testing of impurities in the updated specification and that further data are required (see Chapter 2).

Therefore the conclusion of the RMS with regard to the risk for the consumer can not be supported **until a final conclusion on impurities is reached in the section on mammalian toxicology.**

3.4. Proposed MRLs

Based on the limit of quantification, an MRL of 0.01 mg/kg for 1,3-D is proposed as appropriate for the use on peppers and tomatoes.

4. Environmental fate and behaviour

(EZ)-1,3-dichloropropene (1,3-D) was discussed at the meetings of Member State experts for environmental fate and behaviour (EPCO 21) in April 2005 and (PRAPeR TC 15) in September 2009.

4.1. Fate and behaviour in soil

4.1.1. Route of degradation in soil

In laboratory studies on 4 top soils maintained under aerobic conditions (20°C 20-40% maximum water holding capacity (MWHC)) dosed with *(EZ)*-1,3-dichloropropene-UL-^{14}C (Cis/*Trans* or Z/E ratio 60:40), the degradates *(EZ)*-3-chloroacrylic acid (maximum 37% of applied radioactivity (AR) at day 28) and *(EZ)*-3-chloroallyl alcohol (maximum 1.4%AR at day 3) were identified. A third component in soil extracts was resolved by chromatography but not identified, however it never accounted for > 5%AR. Mineralisation to CO_2 accounted for 11-37%AR at 49-77 days (times of study termination). These values for soil radioactivity not extracted by acidified acetone were 9-29%AR. In an experiment where one of the top soils had been sterilised, the level of mineralisation was lower (2.6%AR at 77 days) and formation of unextracted residues was higher (43%AR at 77 days). Here the breakdown product *(EZ)*-3-chloroacrylic acid was barely detected (max 0.3%AR) whilst the levels of *(EZ)*-3-chloroallyl alcohol produced were higher accounting for a maximum of 13%AR at 57 days.

Under anaerobic conditions (1 topsoil studied) the same breakdown products were identified as in the aerobic soil experiment (*(EZ)*-3-chloroacrylic acid accounted for a maximum of 55%AR at day 28 and *(EZ)*-3-chloroallyl alcohol accounted for a maximum of 2.6%AR at 3 days). Two further components in soil extracts were resolved by chromatography but not identified, however individually they never accounted for > 1.7%AR. Mineralisation to CO_2 accounted for 32%AR at 100 days. This value for soil radioactivity not extracted by acidified acetone was 20%AR.

Soil photolysis was not studied as 1,3-D does not absorb visible light energy (so there is no potential for direct photolysis) and the applied for intended uses involve application methods that preclude significant amounts of 1,3-D being present at the soil surface, so the potential for light exposure from the intended uses is minimal.

4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products

The major loss process for the dissipation of 1,3-D from soil will be volatilisation (vapour pressure 2982 Pa trans (*E*) isomer and 4850 Pa cis (*Z*) isomer at 25°C). In the 20°C aerobic laboratory studies described at 4.1.1 above, 1,3-D in the organic volatile traps accounted for 23-43%AR at 49-63 days. Single first order dissipation DT_{50} (i.e. calculations excluded the 1,3-D mass in organic volatile traps) calculated by non linear regression for 1,3-D for the 20°C 40% MWHC aerobic laboratory soil studies (4 soils) were 8.8-15.5 days (sum of isomers, mean after normalising to field capacity (-10kPa) moisture content, agreed by experts for use in FOCUS modelling 9.4 days).

When a 2 compartment (including a volatilisation constant estimation) non-linear regression model (i.e. the 1,3-D mass in organic volatile traps was one compartment and that in soil was the second) was used to calculate single first order soil degradation DT_{50}, the resulting estimates were 11.7-27.1 days (sum of isomers). For the one sterile soil investigated, this value was comparable at 18.5 days.

From 20°C 40% MWHC aerobic laboratory soil studies (4 top soils) dosed with *(EZ)*-3-chloroaryl alcohol, single first order DT_{50} calculated by non linear regression were estimated to be 0.1-0.6 days for *(EZ)*-3-chloroaryl alcohol (sum of isomers, mean after normalising to field capacity (-10kPa) moisture content, agreed by experts for use in FOCUS modelling 0.3 days). For *(EZ)*-3-chloroacrylic acid these values calculated from the 4 experiments where 1,3-D was dosed and the 4 experiments where *(EZ)*-3-chloroaryl alcohol was dosed were 0.7-19.8 days (agreed mean normalised modelling value 7.4 days). These metabolites were not present in the organic volatile traps as would be expected from their lower vapour pressures (5-314 Pa at 25°C). Field dissipation studies carried out at 2 sites in the USA (Florida and California) were summarised in the DAR. As the rapporteur and the experts from the Member States chose to only use laboratory soil decline data in the subsequent exposure assessment the results from this small dataset is not discussed further in this conclusion.

4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products

In laboratory batch adsorption studies on 7 soils sterilised by irradiation (to minimise degradation), *(EZ)*-1,3-dichloropropene was determined to have K_{foc} of 18.6 to 83 mL/g (mean 33.7mL/g) 1/n 0.92-1.05 (mean 1/n=1). K_{doc} were 26.2-88.6 mL/g (mean 44.7mL/g). No pattern of correlation between pH and adsorption was apparent. In a soil column leaching study on a further 4 soils, K_{doc} values were calculated to be 20-42 mL/g.

In laboratory batch adsorption studies on 8 soils and a pond sediment sterilised by irradiation (to minimise degradation), *(EZ)*-3-chloroacrylic acid was determined to have K_{doc} of <1 to 17.5 mL/g (mean 3.78mL/g). Results suggest at higher soil pH, adsorption may be reduced slightly.

In laboratory batch adsorption studies on 8 soils and a pond sediment sterilised by irradiation (to minimise degradation), *(EZ)*-3-chloroallyl alcohol was determined to have K_{foc} values of 5.3 to

11.9mL/g (mean 9.4mL/g) 1/n 0.72-0.98 (mean 1/n=0.88). K_{doc} were determined to be 3.6 to 13.9 mL/g (mean 8.23mL/g). No pattern of correlation between pH and adsorption was apparent.

4.2. Fate and behaviour in water

4.2.1. Surface water and sediment

At pH 7 1,3-D hydrolysed under sterile conditions with a single first order DT_{50} at 25°C of 2.69 days (*Z* isomer) and 4.75 days (*E* isomer). The major breakdown product formed was *(EZ)*-3-chloroallyl alcohol (representing up to 78%AR). This compound and *(EZ)*-3-chloroacrylic acid were stable to aqueous hydrolysis.

In a laboratory sterile aqueous photolysis study (pH7), the rate of 1,3-D breakdown in illuminated samples was comparable to that which occurred by hydrolysis in the dark controls. No novel breakdown products were identified in illuminated samples. A photolysis experiment on the metabolite *(EZ)*-3-chloroacrylic acid indicated it was stable to aqueous photolysis.

In the single aerobic sediment water system investigated (laboratory 25°C sediment to water ratio 1:10 w/w) *(EZ)*-1,3-dichloropropene-UL-^{14}C (Cis/*Trans* or Z/E ratio 60:40) was added by syringe to the water layer. At the first sampling time 63%AR was present in the organic volatile traps, with 28.6%AR in the aqueous phase and 4.8%AR in sediment. After 24 hours these values were 35.1%AR, 47.4%AR and 9.8%AR respectively. The first order non linear regression dissipation DT_{50} for the whole system (excluding the radioactivity in the organic volatile traps) for 1,3-D was estimated to be 4.9 days. The single first order DT_{50} for 1,3-D from the water phase was estimated to be 2.6 days with that of the sediment estimated to be 3.23 days (calculated from the maximum measured concentration of 7.2%AR at day 1). Clarification on how the DT_{50} were estimated is included in section B.8.4.1.3.2 of the addendum to the DAR dated March 2005. Unlike the sterile hydrolysis studies no major metabolites were formed. *(EZ)*-3-chloroallyl alcohol accounted for a maximum of 5.7%AR at 1 day with *(EZ)*-3-chloroacrylic acid accounting for a maximum of 9.2%AR at 7 days. Two other unidentified fractions were resolved by chromatography but did not account for >2 or 3.8%AR in the water phase of the system (amounts in the sediment were even lower). Mineralisation to CO_2 accounted for 53%AR at day 21. At this time residues not extracted by acidified acetone followed by aqueous sodium hydroxide from sediment accounted for 14%AR. SETAC guidelines outline that usually sediment water studies are required on two natural sediment water systems. The Member State experts discussed the fact that studies had only been done on a single system, but agreed that in this case, for this substance, further data on an additional sediment water system was not necessary as the route and rate of breakdown were unlikely to be significantly different in another system. The EFSA agrees with this assessment.

In a sediment water system (laboratory 25 °C sediment to water ratio 1:10 w/w) where *(EZ)*-3-chloroallyl alcohol was applied as test substance it was estimated to have single first order DT_{50} of 1.2 days (water and whole system). In a comparable study where *(EZ)*-3-chloroacrylic acid was dosed these value were 5.4 days (water) and 5.63 days (whole system). As the first order DT_{50} of *(EZ)*-3-chloroallyl alcohol in both viable aerobic aquatic systems and soil were low (0.1-1.2 days), it was only necessary to calculate an initial *EZ*)-3-chloroallyl alcohol PEC surface water, as a result of its formation from the parent compound in aquatic systems. Significant long term exposure of *(EZ)*-3-chloroallyl alcohol to aquatic organisms is therefore not envisaged.

Acceptable PEC surface water were provided for the drip irrigation use for glasshouse crops (a worst case value based on monitored air concentrations adjacent to glasshouses in bystander exposure studies). This is outlined in detail in section B.8.11.2.1 of the addendum to the DAR (April 2005) included in the compiled final addendum to the DAR (Spain, 2005). For the direct soil injection uses (both open field and glasshouse) acceptable estimates of surface water concentrations were provided in the Additional Report (addendum 3 to B.8 revision of 24/06/09) with further clarifications on the soil hydrological descriptions in some of the models used in addenda 4 (August 2009) and 5 (September 2009) to B.8. These PEC surface water were estimated using the DripFume/ Chain_2D

models and the FOCUSsw models (just drainage scenarios with FOCUS). The estimates included surface water inputs via deposition from the atmosphere, surface runoff and drainage. Formal data gaps were identified for the applicant to add published references that outlined the DripFume/Chain_2D models process descriptions to the regulatory dossier. Concentrations were estimated where applications are made 1 and 3 m away from an adjacent surface water body.

4.2.2. Potential for ground water contamination of the active substance their metabolites, degradation or reaction products

Member State experts agreed that as an indication of which worst case leaching situations across the EU were most vulnerable the 'tier I' FOCUSPELMO 3.3.2 groundwater modelling assessment as outlined at section B.8.6.1 of the addendum to the DAR dated March 2005 was appropriate. (The experts considered the assumptions used in the higher tier modelling presented could not be supported). This modelling considers outdoor applications at the beginning of July each year at 187 kg a.s./ha for northern European scenario Chateaudun and 224 kg a.s./ha for southern European scenarios, with the application being made at a soil depth of 25cm. The crop defined in simulations was tomatoes. This reflects the supported outdoor uses applied for, except the timing of application possible for the supported uses would include a wider application window then just early summer, which is the only timing for which simulations have been provided. This 'tier I' modelling included the default assumptions for changing (reducing) degradation rate with soil depth defined by FOCUS for each scenario and the following substance properties:

Henry's Law constant of 0 $Pa.m^3.mol^{-1}$ (as the laboratory soil DT_{50} used as input for 1,3-D already includes the volatilisation losses in the laboratory experiments) arithmetic mean 20°C -10kPa single first order soil DT_{50} 1,3-D 9.4 days, *(EZ)*-3-chloroallyl alcohol 0.3 days, *(EZ)*-3-chloroacrylic acid 7.4 days; The metabolites were modelled as if they had been applied as a parent compound at a soil depth of 25cm assuming the maximum molar formation fraction observed in laboratory degradation studies for *(EZ)*-3-chloroacrylic acid of 37% (this extrapolation from *(EZ)*-3-chloroacrylic acid to *(EZ)*-3-chloroallyl alcohol is acceptable and conservative as the maximum formation of *(EZ)*-3-chloroallyl alcohol that was observed was 13%AR under sterile soil conditions, that can be considered representative of formation that may occur in deeper, less microbially active soil layers); 1,3-D K_{doc} 44.7mL/g 1/n 1, *(EZ)*-3-chloroallyl alcohol K_{doc} 8.2 mL/g 1/n 0.88, *(EZ)*-3-chloroacrylic acid K_{doc} 3.78 mL/g 1/n 1.15[17]. The simulations utilised a Q10 of 2.2 and Walker equation coefficient of 0.7.

This modelling predicted that annual average recharge concentrations leaving the top 1m soil layer of a treated field will be above the parametric 0.1 µg/L drinking water limit for 1,3-D (0.143-78µg/L) in situations represented by the Chateaudun, Piacenza, and Porto FOCUS groundwater scenarios. The only scenarios where tomatoes are defined as a crop for which the active substance was not predicted to exceed 0.1 µg/L were Sevilla and Thiva. Annual average recharge concentrations of *(EZ)*-3-chloroallyl alcohol were predicted to be < 0.1 µg/L at all the pertinent scenarios. For *(EZ)*-3-chloroacrylic acid the annual average recharge concentrations were predicted to be > 0.1 µg/L at all scenarios (0.4µg/L-144µg/L). The rapporteur and Member State experts agreed that based on the results of the parent sterile hydrolysis study (see section 4.2.1) and parent sterile laboratory soil degradation study (see section 4.1.2) it would be appropriate at the next tier to modify the default depth dependant degradation factors used for the parent 1,3-D. However this would not be appropriate for the metabolites as these were stable to sterile hydrolysis and the published study carried out where saturated subsoil was dosed and incubated with *(EZ)*-3-chloroallyl alcohol (section B.8.4.1.4 of the DAR) did not consistently demonstrate rapid degradation in saturated subsoil. Whilst the results for some 'tier II' modelling where parent 1,3-D had modified (faster) subsoil degradation rates is outlined at section B.8.6.1 of the addendum to the DAR dated March 2005, the way this had been implemented

[17] Note, according to FOCUS guidance it is not appropriate to use K_{doc} values with average 1/n values that are associated with K_{foc} values. When an average 1/n value is used the corresponding average K_{foc} value should be used. However in this case, making this change, would not be expected to change the overall picture regarding the number of scenarios where metabolites exceed the regulatory trigger. For 3-chloroacrylic acid lower leachate concentrations would be calculated.

in the modelling was not accepted by the Member State experts. The consequence of carrying out some new 'tier II' modelling where depth dependant degradation factors for parent 1,3-D were appropriately parameterised, would be expected to reduce the predicted concentrations of parent 1,3-D (however concentrations would still be > 0.1µg/L at, at least the Piacenza scenario).

As the modelling indicates a significant problem for groundwater contamination particularly for *(EZ)*-3-chloroacrylic acid but also for parent 1,3-D, the results of a program of targeted groundwater monitoring carried out across the EU were included in the dossier and considered as part of the assessment. (Work carried out in the USA is also summarised in the DAR, however as the EU information is more pertinent the American studies are not discussed further in this conclusion). The monitoring was carried out in Spain (25 wells in the regions of La Rioja, Caceres, Cadiz, Palma de Mallorca and Almeria with water abstraction depths of 3 to 289m), Italy (25 wells in the regions of Sicilia, Campania, Lazio, Emilia Romagna and Veneto with a depth to the aquifer surface of 1.5 to 40m), France (23 wells in the regions of Landes, Pyrenees Orientales, Haut Rhin, Manche and Vaucluse with water abstraction depths when reported of 7 to 100m) and the UK (25 wells in the regions of Lincolnshire, Norfolk and North Nottinghamshire with water abstraction depths of 16 to 80m), over 2 years. Summaries of these monitoring data can be found in the addenda to the DAR dated March 2005 (section B.8.10.1) and April 2005 (Spanish data). The validated limits of quantification for the analytical methods used for each isomer were: 1,3-D 0.1µg/L, 3-chloroallyl alcohol 0.1µg/L, 3-chloroacrylic acid 0.05µg/L. The EFSA considers the original study reports provide the necessary detailed information on soils, cropping, hydrogeology, climate and well characteristics with the notable exception of the report on the work in France where only the details on well characteristics were adequately presented. In the resubmission application (see addendum 3 to B.8 revision of 24_06_09 annex 8.1, which is included in the compiled final addendum to the Additional Report (Spain, 2009b)) limited clarification was provided in relation to the French monitoring sites but the detail is not that which is necessary and information is still missing on the cropping associated with the monitored wells in France. The usefulness of the French monitoring data in supporting a groundwater exposure assessment therefore remains compromised. Addendum 3 to B.8 revision of 24_06_09 annex 8.1 also contains the results of a targeted monitoring program (appropriately documented) carried out in Greece (19 wells in the Chrysoupoli and Trifilia basins in the poloponese and Timbaki and Lerapetra basins in Crete with water abstraction depths of 1 to 10m). An appropriate assessment of the groundwater vulnerability of all the monitored sites is also reported in addendum 3 to B.8 revision of 24_06_09 annex 8.1, though a formal data gap has been identified for published information that provides more details on the methodology used to rank the wells monitored to complete the information available in the regulatory dossier.

Evidence of the extent of use of 1,3-D in the area of recharge to the aquifer feeding the sample wells in the reports was inadequately documented in the original assessment (finalised May 2006) but further information was included in the resubmission and can be found in Addendum 3 to B.8 revision of 24_06_09 with corrections to the units in sales figures included in Addendum 4 to B.8 of August 2009. In order to use this monitoring data for regulatory purposes, better evidence of active substance use at the most detailed local level available pertinent to the groundwater catchments monitored should ideally have been provided. What is clear (with the exception of the work in France where cropping detail is inadequately reported) is that pertinent crops where soil sterilants may be used (vegetables, vines, tobacco, sugar beet potatoes and greenhouse horticulture) are cultivated over a reasonable proportion of the area of each groundwater catchment and that significant sales have been made by merchants in these regions. The applicant also provided clarification of the label recommended use rates on these crops in these areas over the duration of the monitoring. Unfortunately this additional information was provided after the Additional Report was submitted to EFSA by the RMS, so could not be considered in the peer review in view of the restrictions concerning additional information for stage 2 active substances according to Commission Regulation (EC) No. 33/2008. Consequently the provision of this information has been considered a data gap in this conclusion. As the available sales figures are for larger geographical areas than the monitored catchments, the quantities of 1,3-D that were actually applied to the soil in which these crops were grown, that overlay the aquifers that samples were taken from is not completely clear. Risk managers

need to consider if the above information provides them with sufficient reassurance of the coincidence of product use, at the applied for intended use rates, on land overlying the aquifers monitored, such that they would rely on the evidence from the targeted monitoring program. EFSA considers that for the French sites in the monitoring program there is considerable uncertainty that the monitored wells were sufficiently geographically associated with areas of high usage.

To conclude, the available FOCUSgroundwater 'tier I' modelling data indicate that annual average leachate concentrations leaving the top 1m soil layer of both *(EZ)*-1,3-dichloropropene (3 out of 5 the FOCUS scenarios defined for tomatoes) and *(EZ)*-3-chloroacrylic acid (All 5 FOCUS scenarios) for a field (outdoor) treated in accordance with the notified intended use will be significantly greater than 0.1µg/L. These concentrations for *(EZ)*-3-chloroacrylic acid were > 10µg/L at 3 of the 5 scenarios (up to 144µg/L). At the spatial scale of the treated field in a shallow aquifer directly below the treated field there is a high potential for groundwater contamination above the parametric drinking water limit.

However at the spatial scale of the groundwater aquifer catchments monitored, where water was sampled from wells used for the extraction of drinking water, for the actual pattern of 1,3-D used in these catchments, contamination of the groundwater samples was always < 0.1µg/L for either isomer of 1,3-dichloropropene and usually < 0.1µg/L for either isomer of 3-chloroacrylic acid. (The exception was 2 samples from different wells out of the 50 samples taken in the Spanish region of Caceres, where residues of 0.116 and 0.413µg/L were quantified). If risk managers consider it has been satisfactorily confirmed that at appropriate spatial scale there has been significant use of 1,3-D in these catchments for a prolonged period, then the EFSA considers there is good evidence that **for these monitored abstraction points, in these aquifers, for the historical intensity of use**, groundwater contamination at the point of abstraction will be less than the drinking water limit for 1,3-D and usually less than the drinking water limit for *(EZ)*-3-chloroacrylic acid.

Member States should of course be aware that the recharge of these aquifers that were monitored will have had large contributions from untreated areas, which can potentially dilute concentrations at the point of abstraction and that this potential dilution is not included in leaching assessments based on FOCUS modelling, (and though not available for this substance, lysimeter or field leaching studies) which reflect a much smaller spatial scale.

Member States should also be aware that any increase in use of this active substance (in terms of area of the catchment treated) would of course have the potential to increase the concentrations that would be present in groundwater at the point of abstraction compared to the levels in the monitoring discussed here.

4.2.3. Potential for ground water contamination by the process impurities present in the technical product

To address the concern raised in the original assessment (finalised May 2006), the resubmission application included information to address the groundwater contamination potential of polychlorinated impurities produced whilst manufacturing 1,3-D. This information can be found in Addendum 3 to B.8 revision of 24_06_09 with some additional QSAR calculations for impurity 13 that were completed by the RMS that were presented in addenda 4 to B.8 (August 2009). Risk managers should note that the application rates of the impurities considered to still need further consideration following the resubmission application, are in the range of 22 to 1132 g/ha. This range is comparable to application rates of many plant protection product active substances. The information provided by the applicant in their resubmission dossier and evaluated by the RMS includes monitoring data from the Greek monitoring sites (as already discussed at 4.2.2) that indicated that contamination of groundwater by 12 of the process impurities might be considered to be unlikely. However the analytical method development indicated that 5 of these impurities (4, 5a, 6, 7 and 8b) were rapidly hydrolysed. Information on the hydrolysis products of impurities 4, 5a, 6, 7 and 8b was provided in a revised Vol 3 B.8 (June 2009), however, due to the restrictions on additional information for stage 2 active substances according to Commission Regulation (EC) No. 33/2008 this information could not be considered by the peer review. A data gap was therefore identified for the groundwater

contamination potential of hydrolysis products of impurities 4, 5a, 6, 7 and 8b to be addressed. The Member State experts discussed whether the available QSAR estimated physico-chemical properties for impurities 9a, 9b, 10, 11 and 12 and their comparison to the physico-chemical properties data for 1,3-D and associated argumentation would be sufficient to exclude the groundwater contamination potential of these impurities. The experts considered that this QSAR information alone was insufficient and that some measurements of the key properties (vapour pressure, water solubility Kow/Koc and aqueous hydrolysis) for at least a reasonable sample of these compounds should be provided to give confidence that the QSAR estimates were giving reasonable values. The experts expected that for at least some of these compounds, results from measurements of these properties might be available in published literature. A data gap was therefore identified and is included in this conclusion, that also needed to include impurity 13, where the RMS had provided the QSAR estimates that were discussed. Argumentation on the groundwater exposure potential from impurity 13 that could be considered by the peer review is not available.

4.3. Fate and behaviour in air

(1,3-dichloropropene is volatile (vapour pressure 2982 Pa trans (*E*) isomer and 4850 Pa cis (*Z*) isomer at 25°C). Even when incorporated in deeper soil layers in accordance with the applied for intended uses volatilisation will be the major route of dissipation in the environment.

Route and rate of degradation in air.

Experiments where rate of the photo oxidative reaction of 1,3-D with hydroxyl radicals (at 2 x 10^6 radicals cm^3) was measured gave estimated half lives of 7 hours for *E* and 12 hours for *Z*-1,3-dichloropropene. For the reaction with ozone at a background level in the troposphere of 80 µg/m^3 (0.04 ppm), the half-lives of *Z*- and *E*-, 1,3-dichloropropene were calculated (based on a measured reaction rate with ozone) to be 52 and 12 days.

Formyl chloride and chloroacetaldehyde have been identified as reaction products of 1,3-D with both hydroxyl radicals and ozone. Reaction with ozone also yields chloroacetic acid, hydrogen chloride, carbon dioxide, carbon monoxide and formic acid. In section B.8.7.1 of the addendum to the DAR dated March 2005, information from the published literature is cited that identifies that these breakdown products also occur in the atmosphere from other sources (both natural (formic and acetic acids) and anthropogenic (formic acid and haloacetic acids)). The risk from the additional amount of haloacetic acids that will originate from the use of 1,3-D, compared to other high production volume chemical sources of these compounds (based on the United Nations Environment Program high production volume existing chemicals screening information dataset) was expected (by the fate and behaviour experts from the Member States) to be minimal. Note the references cited from the published literature have not been peer reviewed by the EFSA.

Stratospheric ozone depletion potential.

In section B.8.7.3 of the addendum to the DAR dated March 2005 the potential for 1,3-D to deplete the stratospheric ozone layer was presented and discussed by Member State experts. Experts agreed that atmospheric 1,3-D will be relatively short lived (half life of 7-12 hours as a result of indirect photo oxidation reactions). They also agreed that its atmospheric breakdown products (already identified in the discussion above) would also be efficiently removed from the lower troposphere, as they are water soluble or react in solution to form water soluble products (i.e. they will be re deposited on land or in the oceans). They concluded that the breakdown products would be very short lived in the atmosphere. It was therefore concluded that the plant protection use of 1,3-D is unlikely to have any detrimental effect on the stratospheric ozone layer.

Volatilisation monitoring studies

As 1,3-D has a high vapour pressure, air monitoring was carried out at eight sites in the USA after application rates ranging between 132.16 kg a.s./ha (0.7-0.47 N) and 274.94 kg a.s./ha (1.46-0.97N).

The results for 7 sites were summarised in the DAR with those for a further site in California summarised in section B.8.7.2 of the addendum to the DAR dated March 2005. The following information can be taken from these studies:

- They confirm that a significant loss of applied 1,3-D to the atmosphere can be expected

- Maximal concentrations can be found 48 h after the application

- The concentration of 1,3-D was higher at night than in the light period for soil injected application studies, but in the drip irrigation study afternoon air concentrations were higher than those measured at night..

- Generally, concentration of 1,3-D in air tended to decline with the distance away from the treated plot. However, wind direction and speed must be taken into account in the movement of the 1,3-D in the air. The highest concentration was found 25 m away from the edge of a treated field at a height of 1.5m (3415ug/m^3 during 12 h of sampling).

For the California volatilisation monitoring study summarised in the addendum to the DAR dated March 2005 and the Imperial and Salinas valley sites described in the DAR, the United States Environmental Protection Agency air dispersion Gaussian plume Industrial Source Complex Short Term (ISCST) model, was shown to reasonably represent measured air concentrations at these sites. These volatilisation monitoring studies have shown that volatilisation is the main route of dissipation of 1,3-D from the treated area. No air monitoring data was provided for the notified use under glasshouse conditions. In section B.8.7.2 of the addendum to the DAR dated March 2005, the ISCST model was used to calculate predicted environmental concentrations in air for 2 European Scenarios, one based on meteorological data from Spain the second from Belgium. The flux losses from soil used as input to the model were from US field trial sites. In the resubmission application information was provided to confirm that these US field trial sites can be considered representative of European conditions (see Addendum 3 to B.8 revision of 24_06_09).

In the resubmission application, Atkinson calculations for the rate of reaction of the process impurities in the upper atmosphere with hydroxyl radicals were provided. These calculations give an indication that the atmospheric half life of 10 of these impurities (which will be applied at up to 28 to 340 g/ha) are greater than 2 days. Therefore there is the potential for long range atmospheric transport of these compounds.

5. Ecotoxicology

(EZ)-1,3-dichloropropene (1,3-D) was discussed at the EPCO experts' meeting for ecotoxicology (EPCO 22) in April 2005. 1,3-D was discussed at PRAPeR Expert Meeting TC 16 (September 2009), based on the Additional Report (entitled Addendum V, dated March 2009 and revised June 2009). The Additional Report was prepared to address the critical areas of concern and outstanding data requirements, as specified in the EFSA conclusion report (EFSA Scientific Report (2006) 72).

For the evaluation of Annex I inclusion the representative uses of 1,3-D were for indoor applications (defined as permanent structures) to bare soil via drip irrigation as Telone EC Drip (EF-1478), and outdoor applications to open fields by soil injection as Telone Injected (XRM-5048, also known as Telone II) and sealing by compaction. The supported application rates are up to 283 kg 1,3-D/ha for indoor uses and up to 224 kg 1,3-D/ha for outdoor uses, with a maximum of one application per year.

The indoor use in glasshouse is defined as a permanent structure to which entry of birds and mammals is limited.

The need for further data concerning polychlorinated impurities was discussed. The meeting decided that bridging studies are needed if new impurities are identified in the new five batch analyses which are not covered by the batches tested in the section on ecotoxicology. The potential risk from

polychlorinated impurities was addressed in Addendum V (June 2009), based on similar or lower toxicity compared to 1,3-D and a lower magnitude of exposure of non-target organisms than 1,3-D (at least 386-fold). Furthermore the duration of exposure was not considered to differ appreciably from that of (*EZ*)-1,3-dicloropropene. EFSA however notes that confirmation is still needed on the compliance of the new specifications to the batches tested in ecotoxicological data package.

1,2-dichloropropane is regarded as a relevant impurity from a toxicological point of view. During the original peer review process the ecotoxicological relevance of this impurity was never discussed. An assessment was not possible due to lack of data. The EFSA considered it necessary that the applicant addresses the ecotoxicological relevance of this impurity. In the case that the compound is considered relevant, the levels of 1,2-dichloropropane in the ecotoxicological studies must be confirmed. An assessment presented in the Addendum V (revised June 2009) indicated that 1,2-dichloropropane should be considered as not ecotoxicologically relevant, based on the ecotoxicological profile of 1,2-dichloropropane from data used in FAO specifications, and the fact that the maximum proportion in the technical product is 0.01%.

5.1. Risk to terrestrial vertebrates

Acute and short-term toxicity studies were submitted to address the risk to birds. No long-term toxicity study with birds was available in the original peer review. Such a study was requested by the rapporteur Member State in the original DAR and the need for such a study was confirmed by the EPCO expert's meeting. The long-term risk to birds for outdoor uses can only be concluded once this study becomes available.

A long-term toxicity study with bobwhite quail (*Colinus virginianus*) was assessed and accepted in the Addendum V (June 2009).

The risk is assessed for an herbivorous, insectivorous and earthworm-eating bird. The EPCO expert's meeting agreed that a refinement of the acute risk to insectivorous and earthworm-eating birds is not necessary for indoor uses (see definition above). Consequently the EFSA considers that also a risk assessment for herbivorous birds is not necessary for the indoor uses of 1,3-D. The risk to birds for the indoor uses of 1,3-D is considered to be low.

The ETE for herbivorous birds for the outdoor uses of 1,3-D in the DAR was based on the PECsoil and a 70% uptake of applied radio-activity in plants as no residue study was available to calculate the ETE. This approach was not accepted by the EPCO expert's meeting and a new residue study in plants is required. The risk to herbivorous birds for the outdoor uses of 1,3-D can only be concluded once this study becomes available.

A residue study in tomatoes in Italy was provided and assessed in Addendum V (June 2009). The study indicates that *(EZ)*-1,3-dichloropropene is not systemic and food uptake by birds and mammals from plants grown in treated soil was considered minimal (residue level were below of detection of 0.002 mg a.s./kg).

The ETE for earthworm-eating birds for the outdoor uses of 1,3-D in the DAR was based on the PECsoil and an estimated earthworm bioconcentration factor as the method of application is not a standard scenario foreseen in the Guidance document SANCO/4145/2000. Based on this first tier risk assessment the acute risk to earthworm-eating birds is considered high and the short-term risk can be considered as low. A data requirement for the applicant to address this risk was set. In the addendum 2 of April 2005 a residue study on earthworms is summarised to address this risk to earthworms eating birds. The EPCO expert's meeting decided that this study could not be used to refine the risk assessment as the results are too variable and not representative for Mediterranean conditions and considered that there is still a high risk to earthworm- eating birds and hence kept the data requirement open.

A residue study in insects and earthworms from tomato fields injected with Telone II in Italy was provided and assessed in Addendum V (June 2009). The maximum measured residue levels on any sampling occasion were 1.52 mg/kg for insects and 0.40 mg/kg for earthworms. The residue patterns in earthworms and arthropods indicate that no residues were found after two to three weeks. Although shortcomings in the study were identified (e.g. limitation in chemical analysis and few low abundance of earthworms) the RMS accepted the study. It was noted during the peer review that the concentration detected in earthworms under N. European conditions was more that one order of magnitude higher compared to the Italian residue study. Member State experts considered that new invertebrate residue data would only be representative for this application method, crop type and under S. European conditions.

The ETE for insectivorous birds for the outdoor uses of 1,3-D in the DAR was based on the ETE for earthworm-eating birds as the method of application is not a standard scenario foreseen in the Guidance document SANCO/4145/2000 and no residue studies on soil dwelling arthropods are available. Based on this first tier risk assessment the acute risk to insectivorous birds was considered high and the short term risk could be considered as low. Since it could not be excluded that birds feed on dead insects it was agreed in the experts' meeting that the acute risk needs to be further addressed. The rapporteur Member State reacted in September 2005 in the evaluation table that they considered the risk to insectivorous birds covered by the risk assessment for earthworm eating birds. The EFSA did not agree with this statement as refinement of these risks is commonly based on residue studies and/or behaviour of focal species which can differ significantly between earthworm-eating and insectivorous birds and in the opinion of the EFSA it cannot be predicted what will be the worst-case situation without data to support this assumption. Therefore also for insectivorous birds the risk could be concluded for the outdoor uses of 1,3-D before the applicant provided a refinement of the risk assessment.

A refined risk assessment for herbivorous, insectivorous and earthworm-eating birds was provided in Addendum V (June 2009) based on worst case concentrations from the residue studies in plants, insects and earthworms. All TER values for acute, short-term and long-term risk meet Annex VI triggers, indicating a low risk to birds from the intended field use.

The acute and long-term endpoints to be used in the risk assessment for mammals were discussed in the EPCO expert's meeting. The meeting decided that the acute risk should be based on an LD_{50} of 130 mg a.s./kg bw to protect both sexes. Furthermore the meeting decided to maintain the NOAEL of 2.5 mg/kg bw/day as proposed by the rapporteur Member State. The meeting decided to send a general question to the PPR Panel on the choice of endpoints to assess the long term risk to mammals. This generic question was forwarded to the PPR Panel by the EFSA. The opinion of the Panel is still awaited. The EFSA proposes to take this opinion into account at MS-level once it becomes available.

As for birds, the risk is assessed for a herbivorous, insectivorous and earthworm eating mammal. The risk to mammals for the indoor uses is considered to be low (see definition above).

The risk to herbivorous mammals for the outdoor uses of 1,3-D can only be concluded once the outstanding residue study becomes available (see discussion for birds above).

The ETE for earthworm eating and insectivorous mammals was based on the same assumptions as for birds (see above). Also for mammals a high acute risk was identified in the first tier risk assessment in addition to a high long term risk. A data requirement to address these risks was set. As stated above the EPCO expert's meeting decided that the submitted earthworm residue study (see addendum 2) could not be used to refine these risks. Therefore the data requirement for the notifier to submit a refined risk assessment for mammals was open.

The EFSA proposed that, after receipt of the outstanding data requirements, the revision of the acute risk assessment would be based on the LD_{50} of 130 mg a.s./kg bw.

Member State experts confirmed the ecological relevant long-term NOAEC mammals of 5 mg Telone II/kg body weight/day based on effects on body weight to be used for the long-term risk assessment for mammals. This endpoint was based on the results from 90d-oral exposure study in rat, and it had been used to calculate the refined risk assessment for herbivorous, insectivorous and earthworm-eating mammals.

A refined risk assessment for herbivorous, insectivorous and earthworm-eating mammals was provided in Addendum V (June 2009) based on worst case concentrations from the residue studies in plants, insects and earthworms. All TER values for acute and long-term risk meet Annex VI triggers, indicating a low risk to mammals from the intended field use. A study on the presence of mammals on fields treated with Telone II was provided by the applicant, and it was considered useful by RMS to confirm low risk to mammals. Member State expert agreed that the study could support the conclusion of the mammalian risk assessment; however, the limited number of mammals captured limited the general applicability of the study.

Exposure of birds and mammals via contaminated drinking water is not expected since the method of application in the field is via soil injection. Drip irrigation is only supported for indoor uses.

The logPow of 1,3-D is below 3 and therefore the risk fish eating birds and mammals is considered to be low.

The risk to mammals from inhalation of 1,3-D is calculated in the DAR. The resulting TER value indicates a low risk to mammals from inhalation of 1,3-D. The EFSA would like to point out that the PEC_{air} concentrations are still under discussion in the section on Fate and behaviour and that this risk assessment might need to be reviewed as a consequence of this discussion.

Exposure levels have not been changed and no further assessment of risk from inhalation of 1,3-dichloropropene was provided in Addendum V (June 2009).

In conclusion, the risk to birds and mammals for the indoor uses is considered to be low (see definition above). A high acute risk to earthworm eating and insectivorous birds and mammals and a long term risk to earthworm eating and insectivorous mammals is identified for the outdoor uses. No long term toxicity study with birds is available. A residue study on plants is awaited to assess the risk to herbivorous birds and mammals. The risk to birds and mammals can only be concluded once the outstanding data become available.

5.2. Risk to aquatic organisms

Fish, aquatic invertebrates and algae are sensitive and show a similar toxicity on an acute time scale to *(EZ)*-1,3-dichloropropene. Aquatic organisms are more sensitive to *(EZ)*-1,3-dichloropropene on a chronic time scale. The lowest chronic endpoint is the NOEC for fish. No studies with the formulation are available and none are considered necessary as the formulation contains at least 92% active substance. The risk assessment for algae is based on endpoints for growth rate as endpoints for biomass were not available. The EPCO expert's meeting set a data requirement for the applicant to submit the endpoints for algae based on biomass. Once these become available the risk assessment needs to be revised based on the lowest endpoint (either on an endpoint based on biomass or on growth rate).

No risk assessment for the direct soil injection method of application indoors and outdoors can be performed as the applicant is asked to submit PEC in surface water (drainage and run-off route of entry and potential for wet and dry deposition from the air must be assessed, see point 4.2.1). Consequently the applicant is also asked to perform a risk assessment for aquatic organisms with these PEC surface water values. If in this new risk assessment PEC_{twa} values are used to assess the long term risk, an argumentation, e.g. regarding the time to onset of effects, should be given. The risk to aquatic organisms from the use as a direct soil injection method of application indoors and outdoors can only

be concluded once these data become available. Given the high application rate (up to 224 kg a.s./ha) and aquatic endpoints below 1 mg a.s./L risk mitigation measures might become necessary.

An aquatic risk assessment for the use via drip irrigation (indoor use) with the initial PEC_{sw} values, agreed in the EPCO 21 expert meeting on Fate and behaviour, is available in addendum 3 of September 2005. The EFSA agrees with the presented risk assessment but considers it not necessary to conduct a chronic risk assessment for algae and *Lemna gibba* as these studies are not long term studies. From this risk assessment the acute and long term risk to aquatic organisms from the indoor use via drip irrigation can be regarded as low without the need for risk mitigation measures.

Acute toxicity studies on fish, aquatic invertebrates and algae with the metabolites *(EZ)*-3-chloroallyl alcohol and *(EZ)*-3-chloroacrylic acid are available. Algae are more sensitive to these metabolites than to the parent compound. *(EZ)*-3-chloroacrylic acid is less toxic to fish and daphnia than the parent compound and *(EZ)*-3-chloroallyl alcohol shows a similar toxicity to these organisms as the parent compound. No risk assessment for the direct soil injection method of application indoors and outdoors can be performed for the same reasons as mentioned above. A risk assessment for the use via drip irrigation with the initial PEC_{sw} values, agreed in the EPCO 21 expert meeting on Fate and behaviour, is available in addendum 3 of September 2005. The acute risk to aquatic organisms can be regarded as low without the need for risk mitigation measures. No chronic studies with the metabolites were considered necessary by the EPCO Expert's meeting. The rapporteur Member State requests in the addendum of September 2005 long term studies with the metabolite *(EZ)*-3-chloroacrylic acid on fish and *Daphnia magna* as this metabolite has been identified and requires further consideration based on potential levels in ground and surface water. The EFSA agrees with this request.

Long-term toxicity studies for fish and *Daphnia* exposed to the metabolite *(EZ)*-3-chloroacrylic acid were assessed and accepted by RMS in Addendum V (June 2009). Additionally in Addendum V (June 2009) algae toxicity data were recalculated also to provide growth rate based endpoints for *(EZ)*-1,3-dichloropropene, 3-chloroallyl alcohol and 3-chloroacrylic acid. The same was requested for *Lemna* during the peer-review of the resubmitted data. Additional calculation for *Lemna* growth rate was submitted by the applicant for *(EZ)*-1,3-dichloropropene, 3-chloroallyl alcohol and 3-chloroacrylic acid and assessed by RMS in Addendum VI (August 2009).

Studies on the toxicity of *(EZ)*-1,3-dichloropropene and the metabolites *(EZ)*-3-chloroallyl alcohol and *(EZ)*-3-chloroacrylic acid on *Lemna gibba* are available. *Lemna gibba* is more sensitive to the metabolites than to the parent compound. Again a risk assessment for the direct soil injection method of application indoors and outdoors can not be performed for the same reasons as mentioned above. A risk assessment for the use via drip irrigation is available in addendum 3 of September 2005. The acute risk to *Lemna gibba* from this use can be regarded as low without the need for risk mitigation measures.

The risk assessment to aquatic organisms for the intended outdoor uses were revised in Addendum V (June 2009), based on revised PECsw values covering drift, drainage and run-off for *(EZ)*-1,3-dichloropropene, 3-chloroallyl alcohol and 3-chloroacrylic acid. All TER values meet the Annex VI triggers indicating a low risk to aquatic organisms for the intended field use. The new growth rate endpoint calculations for *Lemna* provided during the peer review could, however, not be taken in to account due to Commission regulation 33/2008. EFSA notes that the data were considered not to affect the outcome of the aquatic risk assessment for the intended GAP use (given a large margin of safety for *Lemna* based on the biomass endpoint. A data gap for the growth rate endpoint was maintained for formal reasons and in case of other potential used at national level.

As the logPow is below 3 for *(EZ)*-1,3-dichloropropene and the metabolites *(EZ)*-3-chloroallyl alcohol and *(EZ)*-3-chloroacrylic acid, the risk for bioconcentration in fish for these substances is considered to be low.

5.3. Risk to bees

No acute contact and oral toxicity studies on bees are considered necessary as the product will be applied on bare soil and exposure of bees via systemic translocation of the pesticide in plants is considered to be negligible based on available data.

The need for an inhalation toxicity study with bees was discussed in the EPCO expert's meeting. As the active substance can be found in the air even at distances of 800 m from the field (see section on Fate and behaviour), the meeting decided to set a data requirement for the applicant to submit an inhalation study with bees and a calculation of relevant PEC values to conduct the risk assessment for the inhalation toxicity to bees. The EFSA considers this a data requirement for both the indoor and outdoor uses as it is considered that the active substance can leave the glasshouse via air when the glasshouse is ventilated.

Subsequently, an inhalation test with bees (*Apis mellifera*) exposed to vapour of Telone II for 6 hours was provided by the applicant and assessed in Addendum V (June 2009). For the purposes of a Tier I assessment of the potential inhalation risk to bees the measured $NOEC_{inhalation}$ of 115 mg a.s./m^3 was compared to an estimated worst case exposure concentrations of 1,3-D, based on maximum measured concentrations adjusted to the GAP application rate. The bee $NOEC_{inhalation}$ was found to be 19-fold higher than the estimated maximum air concentration, indicating a low risk to bees from inhalation of the soil fumigant following the intended use.

5.4. Risk to other arthropod species

Extended laboratory studies on *Folsomia candida*, *Hypoaspis aculeifer*, *Poecilus cupreus*, *Pardosa* spp. and *Aleochara bilineata* are available but have several drawbacks. In the studies on *F. candida* and *H. aculeifer* the product was injected at 30 cm depth. The section on Fate and behaviour recommends that the initial PEC_{soil} is calculated for an injection depth of 20 cm. It is the opinion of the EFSA that the deeper injection depth during the study could have underestimated the effect. Furthermore the tested organisms were introduced to the tested soil 1 day after application in all the studies. This implies that, given the volatile nature of the product, the immediate impact at application is not known. No effects from the positive control product were observed in the studies on *P. cupreus*, *A. bilineata* and *Pardosa* spp.

Observed effects 1 day after treatment (DAT) were below 30% for *H. aculeifer*, *P. cupreus*, *A. bilineata* and *Pardosa* spp. 1 DAT 78% effect on mortality was observed for *F. candida*. No adverse effects of Telone II treated soil were observed when *F. candida* was introduced 22 days after treatment of the soil.

A field study is available, but this study is considered to give only limited information as the observations were only made 2 years after application, the randomised design was poor and there was a very high variability in the results. Hence this study is not used in the risk assessment.

Given the observed effects on *Folsomia candida* the rapporteur Member State asked the applicant to further address the risk to non-target arthropods. The EPCO expert's meeting confirmed this data requirement. The rapporteur Member State considers that this data requirement only applies for the outdoor uses of 1,3-D. The EFSA agrees that this is indeed the most important for the outdoor uses. Regarding the indoor uses, the EFSA would like to point out that *F. candida* and other soil non-target arthropods are likely to come into contact with *(EZ)*-1,3-dichloropropene as the product is applied to full soil. Therefore this could affect the function of the soil indoors. The risk to non-target arthropods for the outdoor uses can only be concluded once the outstanding data become available.

A new field study from North Italy was provided by the applicant, assessing the effect of telone II on above ground and soil-dwelling invertebrates and earthworms in fields used for tomato production. The study was assessed in Addendum V (June 2009). Statistical analysis indicated no significant effects for macro-arthropods and micro-arthropods investigated in Telone II treated and untreated plots at any of the post-treatment sampling intervals for an application rate of 224 kg as/ha (soil injection).

Transient effects on earthworms were observed, lasting less than 6 months post-treatment. Several shortcomings in the field study were identified during the peer review. Exposure concentrations were not verified, no collembolan were sampled during the first three months of the study, a low number of earthworms were collected during the study and all experimental plots (including control plots) were treated with a number of different insecticides, fungicides and herbicides during the study (in total 14 applications). The RMS considered the field study suitable to address the risk to invertebrates and earthworms from the intended GAP use. Member State experts however agreed that the new field study should only be used to refine the risk assessment for the intended use (tomatoes and soil injection) and only in case the statistical power of the field study could be confirmed. It was noted that other uses exceeding the intended GAP application would generate a data gap to address the risk to non-target arthropods and earthworms.

5.5. Risk to earthworms

A study on the acute toxicity to earthworms from *(EZ)*-1,3-dichloropropene is available. As the LogPow is below 2, no correction factor for the organic content of the test soil is required. The acute risk assessment was revised in the addendum 3 of September 2005 using the initial PEC_{soil} values at the correct mixing depths as agreed by the EPCO expert's meeting on Fate and behaviour. The EFSA agrees with this revised acute risk assessment. The corresponding TER-values (TER=0.15-0.74) breach the Annex VI trigger value, indicating a high acute risk to earthworms for all the uses evaluated. A field study was submitted to address this concern. This study was discussed at the EPCO expert's meeting. The meeting agreed to await the announced new field study in UK potato fields to address several comments which were raised on the existing study. Therefore the following data gap was identified: Applicant to submit a study on the recovery potential of earthworms after application of the active substance. As there was a concern that this announced study might not address southern European conditions the applicant was also asked to submit an argumentation on the use of the announced study in southern European conditions. The rapporteur Member State considers that this data gap only applies for the outdoor uses of 1,3-D. The EFSA agrees that this is indeed most important for the outdoor uses. Regarding the indoor uses, the EFSA would like to point out that earthworms are likely to come into contact with *(EZ)*-1,3-dichloropropene as the product is applied to full soil. Therefore this could affect the function of the soil indoors. The risk to earthworms for the outdoor uses can only be concluded once the outstanding data become available.

A long term risk assessment for earthworms is considered necessary as the acute TER is below 10 although the DT_{90} for soil in the laboratory is below 100 days and only 1 application is envisaged. In the available long term study on earthworms with *(EZ)*-1,3-dichloropropene, the earthworms were exposed to treated soil which was aged for 7 days. The long term risk assessment was revised in the addendum 3 of September 2005 using the initial PEC_{soil} values at the correct mixing depths as agreed by the EPCO expert's meeting on Fate and behaviour. The EFSA does not agree with the presented risk assessment. The expert meeting on Fate and behaviour decided that for long term risk assessment PECsoil values at a mixing depth of 30 cm have to be used for the risk assessment as over time the active substance will move into deeper layers. This is a similar principle as used to calculate PEC_{twa} values. The Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) states that initial PEC values need to be used as nominal dose levels in the test match initial concentrations in the field. This means that, in this case, the PECsoil at a mixing depth of 20 cm should have been used instead of a mixing depth of 30 cm if the study would have been with freshly treated soil. But as the treated soil was aged for 1 week before the earthworms were exposed it would have been more appropriate in this case to use the 7 day time weighted average value at a mixing depth of 30 cm. This PEC value is lower than the value used in the addendum 3 of September 2005 and therefore the EFSA considers it not necessary to revise this assessment. Based on this assessment the long term risk to earthworm from exposure to 7 day old treated soil can be regarded as low. The long term risk to earthworms exposed to freshly treated soil can only be concluded once the outstanding field data become available (see above).

A new field study including earthworms was provided (see 5.4). Member State experts agreed that the results of the field study could only be used to address the risk from the intended GAP use (tomatoes and soil injection) and only in case the statistical power of the field study could be confirmed. As supportive information the applicant submitted a field survey of the abundance and diversity of earthworms in soils commonly used for growing vegetable crops in three regions of Sicily. Low numbers of earthworms were found in the soil in November 2005 and February 2006 in these locations where fumigation/sterilisation may be required for the control of nematodes.

It should be noted that the announced field study in UK potato fields was not submitted by the applicant as it was considered not to be relevant for the intended GAP use.

5.6. Risk to other soil non-target macro-organisms

No studies are triggered for this Annex point as the DT_{90} in the laboratory is below 100 days for the active substance and the major soil metabolites *(EZ)*-3-chloroallyl alcohol and *(EZ)*-3-chloroacrylic acid.

Studies were submitted on *F. candida* and *H. aculeifer*. These are discussed under point 5.4. The risk to other soil non-target macro-organisms for the outdoor uses can only be concluded once the outstanding data requirement becomes available. Regarding the indoor uses, the EFSA would like to point out that *F. candida* and other soil non-target arthropods are likely to come into contact with *(EZ)*-1,3-dichloropropene as the product is applied to full soil. Therefore the EFSA would like to point out that MS should be aware that this could affect the function of the soil indoors.

5.7. Risk to soil non-target micro-organisms

The effects of the lead formulation Telone II were tested on soil microbial respiration and nitrogen transformation. Effects from 40.23% to 96.9% were observed on day 90 at the end of the study while the test soils were incubated with fresh untreated soil on day 49. A field study was submitted to address this concern. This study was discussed at the EPCO expert's meeting. The meeting agreed to ask for a new field study to address several comments which were raised on the existing study. Therefore the following data gap was set: Applicant to submit a field study to address the risk to soil micro-organisms. This study should also cover the risk to soil micro-organisms from exposure to soil metabolites. The rapporteur Member State considers that this data gap only applies for the outdoor uses of 1,3-D. The EFSA agrees that this is indeed most important for the outdoor uses. Regarding the indoor uses, the EFSA would like to point out that soil micro-organisms are likely to come into contact with *(EZ)*-1,3-dichloropropene as the product is applied to full soil. This could affect the function of the soil indoors. The risk to soil micro-organisms for the outdoor uses can only be concluded once the outstanding data become available.

A new study was submitted by the applicant comparing the rates of soil respiration and nitrogen transformation in soil samples collected from the field in South Europe (Italy) from untreated plots and plots treated with 224 kg Telone II/ha. The study was assessed in Addendum V (June 2009). Data showed that soil respiration and nitrogen turnover did not deviate significantly from untreated soil (less than 25% deviation from control) within 4.5 months. The soil evaluated in this new study was sampled after metabolites of 1,3-D would have been formed within the soil, and as such any residual toxicity due to the metabolites was also assessed as part of this study. It was concluded that treatment with 1,3-D will result in a temporary disruption of soil function, particularly in terms of nitrogen transformation processes. However, under field conditions these effects were not long-lived, and in a South Europe field study.

5.8. Risk to other non-target-organisms (flora and fauna)

A study on the effects of *(EZ)*-1,3-dichloropropene and the metabolites *(EZ)*-3-chloroallyl alcohol and *(EZ)*-3-chloroacrylic acid on the emergence and vegetative vigour of 6 dicotyledonous and 4 monocotyledon species is evaluated and summarised in the addendum 1 of March 2005. A potential risk to non-target plants was identified as the NOEC value of 11.25 mg a.s./kg soil for tomato and

onion is below the initial PEC_{soil} value of 62.33-74.66 mg a.s./kg soil. This was discussed at the EPCO expert's meeting. The meeting decided that the risk should be further quantified and TER values at a few metres from the field should be known. Therefore the following data gap for the applicant was identified: Applicant to submit an appropriate risk assessment to non-target plants including PEC values in soil for the off-crop area at different distances from the field. The EFSA is of the opinion that this assessment should be based on an ER_{50} value as stated in the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002). This value is not reported in the addendum. The risk to non-target plants can only be concluded once this risk assessment becomes available.

A risk assessment to non-target plants for the outdoor use was provided in Addendum V (June 2009). TER values were above the Annex VI trigger when a buffer zone of 3m was applied for *(EZ)*-1,3-dichloropropene, 3-chloroallyl alcohol and 3-chloroacrylic acid.

The effects of the metabolites *(EZ)*-3-chloroallyl alcohol and *(EZ)*-3-chloroacrylic acid in this study were not discussed at the EPCO Experts' meeting. It is difficult to compare the results for the metabolites with the results for the parent as the metabolites were tested at much lower dose rates. Nevertheless effects of both metabolites on vegetative vigour and emergence were observed. No data on the herbicidal and/or other pesticidal activity of *(EZ)*-3-chloroacrylic acid is available. The EFSA proposes to make such data available as this metabolite exceeds the 0.1 µg/L trigger value in groundwater.

In Addendum V (June 2009) it was concluded that 3-chloroacrylic acid should be considered a relevant metabolite in relation to groundwater, as pesticidal screening data provided by the applicant indicated higher herbicidal activity of 3-chloroacrylic acid compared to *(EZ)*-1,3-dichloropropene.

5.9. Risk to biological methods of sewage treatment

Telone drip and Telone injected have an inhibitory effect on the respiration of activated sludge as indicated by the 3h EC_{50} of 384 µg a.s./L (erroneously reported as 384 mg a.s./L in the DAR). It cannot be excluded that 1,3-D might be harmful if the waste water goes to sewage treatment plants. In case of national registration, Member States should be aware that washing water from cleaning tools should not be disposed into surface water.

6. Residue definitions

6.1. Soil

Definitions for risk assessment: *(EZ)*-1,3-dichloropropene, *(EZ)*-3-chloroallyl alcohol, *(EZ)*-3-chloroacrylic acid

Definitions for monitoring: *(EZ)*-1,3-dichloropropene and possibly *(EZ)*-3-chloroacrylic acid, however an identified data gap needs to be filled before this definition can be finalised.

6.2. Water

6.2.1. Ground water

Definitions for exposure assessment: *(EZ)*-1,3-dichloropropene, *(EZ)*-3-chloroallyl alcohol, *(EZ)*-3-chloroacrylic acid

Definitions for monitoring: *(EZ)*-1,3-dichloropropene, *(EZ)*-3-chloroacrylic acid

6.2.2. Surface water

Definitions for risk assessment:

water: *(EZ)*-1,3-dichloropropene, *(EZ)*-3-chloroacrylic acid [*(EZ)*-3-chloroallyl alcohol short term exposure only]

sediment: none

Definitions for monitoring: *(EZ)*-1,3-dichloropropene, *(EZ)*-3-chloroacrylic acid

6.3. Air

Definitions for risk assessment: *(EZ)*-1,3-dichloropropene

Definitions for monitoring: *(EZ)*-1,3-dichloropropene

6.4. Food of plant origin

Definitions for risk assessment: *(EZ)*-1, 3-dichloropropene

Definitions for monitoring: *(EZ)*-1, 3-dichloropropene

6.5. Food of animal origin

Definitions for risk assessment: not required for representative uses

Definitions for monitoring: not required for representative uses

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

6.6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
(EZ)-1,3-dichloropropene	Topsoil single first order DT_{50} (20°C 40%MWHC) 8.8-15.5 days Low to moderate persistence	See 5.5, 5.6 and 5.7
(EZ)-3-chloroallyl alcohol (only major in sterilised / low microbial activity soil)	Topsoil single first order DT_{50} (20°C 40%MWHC) 0.1-0.6 days Very low persistence	No conclusion possible due to outstanding data gap for earthworms and soil micro-organisms.
(EZ)-3-chloroacrylic acid	Topsoil single first order DT_{50} (20°C 40%MWHC) 0.7-20 days Very low to moderate persistence	No conclusion possible due to outstanding data gap for earthworms and soil micro-organisms.

6.6.2. Ground water

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
(EZ)-1,3-dichloropropene	K_{doc} 26-89mL/g Very high to high mobility	Yes 3 out of 5 pertinent FOCUS groundwater scenarios (concentrations 0.14-78µg/L) Monitoring data available.	Yes	Yes	Yes
(EZ)-3-chloroallyl alcohol	K_{doc} 3.6-13.9mL/g Very high mobility	No	No data available; no assessment required.	No assessment required Toxic (R25/R24) oral LD_{50} 91 mg/kg bw dermal LD_{50} 316 mg/kg bw Not genotoxic	No assessment required. Data available (fish, *D. magna*, algae, *L. gibba*). Similar to higher toxicity than parent.

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
(EZ)-3-chloroacrylic acid	K_{doc} <1-17.5mL/g Very high mobility	Yes all 5 pertinent FOCUS groundwater scenarios (concentrations 0.4-144µg/L, 3 of the 5 scenarios > 10 µg/L) Monitoring data available.	No data available.	Relevant Toxic (R25) oral LD_{50} 91 mg/kg bw Not genotoxic	Relevant because of higher toxicity to algae and *Lemna gibba*.

6.6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
(EZ)-1,3-dichloropropene	Very toxic to fish, toxic to *Daphnia* and algae. High chronic toxicity to fish and *Daphnia*.
(EZ)-3-chloroacrylic acid (when groundwater becomes surface water)	Data available (fish, *D. magna,* algae, *L. gibba*). Higher toxicity than parent for algae and *L. gibba*.
(*(EZ)*-3-chloroallyl alcohol short term exposure only	Data available (fish, *D. magna,* algae, *L. gibba*). Similar to higher toxicity than the parent.

6.6.4. Air

Compound (name and/or code)	Toxicology
(EZ)-1,3-dichloropropene	Toxic via inhalation (R25) during acute exposure.

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

- Reliable analysis of batches with validated analytical methods (relevant for the applicant Kanesho Soil Treatment, data gap identified by the RMS and confirmed in the peer review process, date of submission unknown; refer to chapter 1).

- Further genotoxicity testing according to the guidance document on relevant impurities is needed (relevant to all uses for the Kanesho specification; submission date unknown; refer to chapter 2)

- A confirmation is requested concerning the compliance of the new specifications to the batches tested in toxicological data package (relevant to all uses for Kanesho specification and DAS specification; submission date unknown; refer to chapter 2)

- Dependent on the identity on the polychlorinated impurities, it might be necessary to require new toxicological studies (refer to point 2.8).

- The reference 'Computers and Electronics in Agriculture archive Volume 56, Issue 2 (April 2007) Pages 111-119 ISSN:0168-1699 should be added to the dossier (refer to point 4.2.1).

- The references 'Simunek, J. and M. Th. van Genuchten. 1994. The CHAIN_2D Code for Simulating Two-Dimensional Movement of Water, Heat, and Multiple Solutes in Variably-Saturated Porous Media, Version 1.1. Research Report No. 136' and 'U. S. Salinity Laboratory, USDA, ARS, Riverside, California . Available from the following website:http://www.ars.usda.gov/Services/docs.htm?docid=8914'should be added to the dossier (refer to point 4.2.1)..

- The reference 'Aller, L et al 1997 EPA/600/2-87/035' should be added to the dossier (refer to point 4.2.2). .

- Information on use rate recommendations over the groundwater monitoring duration or in the preceding years to the commencement of monitoring is required for the regions monitored. This information was provided by the RMS in the revised Vol 3-B8 (June 2009) but in line with Commission Regulation (EC) No. 33/2008 no additional information, could be accepted in relation to stage 2 active substances (refer to point 4.2.2).

- If Member State risk managers would wish to use the targeted groundwater monitoring data from France to support regulatory decision making, documentary evidence at the appropriate spatial scale is missing to confirm that there has been significant use of *(EZ)*-1,3-dichloropropene over a prolonged period in the vicinity of the groundwater wells included in the French program of targeted groundwater monitoring. The key missing information from this French program is the association and extent of potentially treated crops with the monitored wells (submission date unknown; refer to point 4.2.2).

- A groundwater exposure assessment for process impurity 13 that could be considered by the peer review is not available. This information was provided by the RMS in the revised Vol 3-B8 (June 2009) but in line with Commission Regulation (EC) No 33/2008 neither additional information, nor the submission of new studies can be accepted in relation to stage 2 active substances (refer to point 4.2.3.

- An assessment of the potential hydrolysis products of process impurities 4, 5a, 6, 7 and 8b and their potential to leach to groundwater that could be considered by the peer review is not available. This information was provided by the RMS in the revised Vol 3-B8 (June 2009) but in line with Commission Regulation (EC) No 33/2008 neither additional information, nor the

submission of new studies can be accepted in relation to stage 2 active substances (refer to point 4.2.3.

- Measured data (water solubility, vapour pressure, Kow/Koc, hydrolysis rate) for impurities 9a, 9b, 10, 11, 12, 13 or other related impurities are missing and would be needed to further validate the available QSAR estimates. At the very least published information (if available) should be considered and an argumentation on how this can be extrapolated to any missing information would be needed. Once reliable estimates of these properties are available, an updated argumentation on the groundwater exposure potential of these impurities will be outstanding (submission date unknown, refer to point 4.2.3).

- A confirmation is requested on the compliance of new specifications to the batches tested in ecotoxicological data package (relevant to all uses for Kanesho specification and Dow specification; submission date unknown; refer to section 5)

- Applicant to submit growth rate endpoint calculations for *Lemna* for *(EZ)*-1,3-dichloropropene, 3-chloroallyl alcohol and 3-chloroacrylic acid (relevant for all representative uses; data gap identified during the peer review; calculations has been submitted and assessed by RMS in Addendum VI (August 2009) but was not peer review due to Commission regulation 33/2008; refer to section 5.2)

- Applicant to submit an assessment to confirm the statistical power of the field study (Small, 2006) with soil-dwelling invertebrates and earthworms (relevant for all representative uses; data gap identified in PRAPeR TC 16 (September 2009); no submission date proposed yet; refer to section 5.4 and section 5.5).

CONCLUSIONS AND RECOMMENDATIONS

OVERALL CONCLUSIONS

The conclusion was reached on the basis of the evaluation of the representative uses as nematicide as proposed by the applicants. The application to bare soil comprise either introduction of the formulated product into the drip irrigation system ('EF-1478') or soil injection at 15-20 cm depth ('XRM-5048') to control nematodes in soil where tomatoes or peppers will be grown. The application rates are up to 283 kg *(EZ)*-1,3-dichloropropene per hectare ('EF-1478') and up to 224 kg per hectare ('XRM-5048'), respectively. *(EZ)*-1,3-dichloropropene can be used as nematicide, insecticide, fungicide and herbicide, depending on the dose rate used. In general, an application of *(EZ)*-1,3-dichloropropene by soil injection and/or drip irrigation is followed by partial sterilisation of the soil. It should be noted that the applicants stated that only the use as nematicide will be supported in the EU review programme.

The representative formulated products for the evaluation were 'Telone EC Drip (EF-1478)', an emulsifiable concentrate (EC), registered under different trade names in Southern European countries and 'Telone Injected (XRM-5048)' registered under different trade names in some Member States of the EU. The formulation 'Telone Injected (XRM-5048)' is coded as "any other liquid" (AL).

Adequate methods are available to monitor all compounds given in the respective residue definitions. Only single methods for the determination of residues are available since multi-residue-methods like the German S19 or the Dutch MM1 are not applicable due to the nature of the residues.

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

(*EZ*)-1,3-dichloropropene is rapidly absorbed and extensively metabolised in the rat. The acute oral and dermal toxicity is high and the inhalatory toxicity is moderate, proposed classification and risk

phrases are T; R24/25 "Toxic by dermal exposure and if swallowed" and R20 "Harmful by inhalation". It is a skin irritant and sensitizer, proposed classification and risk phrases are R38 "Irritant to skin" and R43 "May cause sensitization by skin contact". According to medical data 1,3-dichloropopene should be classified as irritant to eyes too and to the respiratory system, proposed classification and risk phrases are R36/R37 "Irritating to eyes and respiratory system" and R65 "May cause lung damage if swallowed". The Technical Committee for Classification and Labelling in 2005 agreed not to classify 1,3D as mutagenic or carcinogenic, unless epichlorhydrin (a known carcinogen) had been used as a stabiliser. The applicants confirmed that the current product is not stabilised with epichlorhydrin. No reproduction toxicity or neurotoxicity was observed. The metabolites (*EZ*)-3-chloroallyl alcohol and (*EZ*)-3-chloroacrylic acid are both toxic. Dependent on the identity on the polychlorinated imp, it might be necessary to require new toxicological studies. The Acceptable Daily Intake (ADI) is 0.025 mg/kg bw/day, with the use of the safety factor of 100. The systemic Acceptable Operator Exposure Level (AOEL) is 0.1 mg/kg bw/day, safety factor 100. As inhalation exposure is the main route of exposure and all data from operator exposure are expressed as atmospheric concentration (mg/m^3), an additional inhalatory human AOEC was assigned which is 0.45 mg/m^3. The ARfD is 0.2 mg/kg bw, with the safety factor of 100 added**.** The operator and worker exposure during drip irrigation activities is below the AOEL with the use of PPE and RPE; the estimated exposure levels for a bystander at >7 m from the site of application are below the AOEC, for closer distances are exceeding the AOEC. During soil injection activities the operator, worker and bystander exposure estimates show levels below the AOEC (operator and worker wearing RPE).

The degradation and metabolism of 1,3-D has been studied comparatively in fruit (tomatoes and citrus), root vegetables (sugar beet), pulses and oilseeds (soybeans) following application of radio labelled material to the soil surrounding the tree or to the soil in which seeds were planted. Additional information from succeeding crop studies is given on leafy crops (lettuce) and cereals (wheat).

Even though a high amount of applied 1,3-D is expected to volatilise from soil, the results of the available studies indicate that 1,3-D is also absorbed into plants, translocated and degraded. Naturally occurring plant constituents contained the majority of radioactivity recovered in edible plant parts, indicating complete metabolism of 1,3-D. Consequently, no 1,3-D residues above the limit of quantification (LOQ) are expected to be present in primary or succeeding crops. This was confirmed by supervised residue trials data.

In the resubmission dossier of 2009 a number of additional residue trials were provided to allow some further clarification with regard to manufacturing process impurities that are applied to the soil in high amounts when 1,3 D is used at the notified application rate.

1,3-D and six impurities (1, 2, 3, 5b, 5c and 8a) were analysed. 1,3-D and its six studied impurities did not leave detectable residues in the crop.

However, even though potential chronic and acute dietary exposure to residues of 1,3 D per se from tomatoes and peppers is well below the ADI (<10%) and ARfD (<2%) , respectively the consumer risk assessment cannot be considered as finalised in relation to 11 manufacturing process impurities. The consumer risk assessment is pending a conclusion on the fate and behaviour of these 11 identified impurities in the environment, and/or with regard to toxicological data on manufacturing process impurities in the updated specification in the section on mammalian toxicology.

The information submitted on the fate and behaviour in the environment is generally sufficient to enable the required environmental exposure concentrations to be estimated that were considered necessary by the EU peer review for environmental risk assessment, with the notable exception of there being assessments missing for groundwater exposure levels of process impurities (that will be applied in significant amounts) and for some of these process impurities exposure levels of their hydrolysis products.

It is concluded that the 1,3-D that will reach the upper atmosphere as a result of volatilisation will degrade relatively rapidly and that this compound and its potential atmospheric degradation products

are unlikely to have an adverse effect on the chemistry of the upper atmosphere, as they will be relatively short lived in this environmental compartment. It cannot be precluded that there is the potential for long range atmospheric transport of 10 process impurities that will be applied in significant amounts.

The available 'tier I' FOCUS modelling assessment of the potential for groundwater exposure identifies that there is a high potential for annual average leachate concentrations leaving the top 1m soil horizon directly under a treated field of parent *(EZ)*-1,3-D (3 out of 5 FOCUS groundwater scenarios) and *(EZ)*-3-chloroacrylic acid (All 5 FOCUS groundwater scenarios) to be above the parametric drinking water limit of 0.1µg/L. For 3 of the 5 FOCUS groundwater scenarios, these concentration for *(EZ)*-3-chloroacrylic acid were > 10µg/L. The results from an extensive targeted groundwater monitoring program where samples were taken from wells at the point of commercial drinking water extraction are available. If risk managers chose to use this monitoring work to support regulatory decision making, they must be aware that the evidence from the targeted monitoring is just for the historical intensity of use, in the monitored groundwater catchments, in the vicinity of the monitored abstraction points. Also for the French monitored wells, data gaps remain for further information regarding aspects of the pertinence of this monitoring.

Studies to address the data gaps identified in the EFSA Scientific Report (2006)72 were provided for the resubmission. Confirmatory data on the compliance of the ecotoxicological test batches to the new specifications are still missing. The indoor use in glasshouse is defined as a permanent structure to which entry of birds and mammals is limited and hence the risk to birds and mammals for the indoor uses is regarded to be low. A high acute risk to earthworm eating and insectivorous birds and mammals and a long term risk to earthworm eating and insectivorous mammals was identified for the outdoor uses. The risk was addressed in a refined risk assessment for herbivorous, insectivorous and earthworm-eating birds and mammals, based on worst case concentrations from residue studies in plants, insects and earthworms. All TER values for acute, short-term and long-term risk meet Annex VI triggers, indicating a low risk to birds and mammals from the intended outdoor use.

Available data indicated a similar level of aquatic toxicity for *(EZ)*-1,3-dichloropropene and 3-chloroallyl alcohol to fish and *Daphnia* which was higher that the toxicity of 3-chloroacrylic acid. *(EZ)*-1,3-dichloropropene was however less toxic to algae and *Lemna* than the two metabolites, which had a similar toxicity. Based on the acute endpoints both the active substance and the metabolites should be classified as very toxic to the aquatic environment. The EFSA Scientific Report (2006)72 concluded that the acute and long term risk to aquatic organisms from the indoor use via drip irrigation could be regarded as low without the need for risk mitigation measures. The risk associated with this use will therefore not be considered further. For the outdoor use the risk to aquatic organisms was assessed as low based on CHAIN-2D CODE model exposure data including 3 m buffer zones for *(EZ)*-1,3-dichloropropene, 3-chloroallyl alcohol and 3-chloroacrylic acid.

Extended laboratory studies on *Folsomia candida*, *Hypoaspis aculeifer*, *Poecilus cupreus*, *Pardosa* spp. and *Aleochara bilineata* are available but have several deficiencies (exposure method, late introduction of test species and lack of positive control product). In addition a field study was considered to inadequate (poor test design). A new field study from North Italy assessing the effect of telone II on arthropods and earthworms indicated no significant effects on arthropods. Transient effects on earthworms were observed, lasting less than 6 months post-treatment. Several shortcomings in the field study were however identified (e.g. use of other pesticides, low collection rate of collembolan and earthworms). Member state experts agreed that the new field study should only be used to refine the risk assessment for the intended use (tomatoes and soil injection) and only in case the statistical power of the field study could be confirmed.

A high acute risk to earthworms was observed. The risk may be addressed by the field study mentioned above. However, the statistical power of the study still needs to be confirmed. The applicant provided a supportive study on abundance and diversity of earthworms in South Europe.

Field surveys in November and February indicated low number of earthworms in fields potential treated with soil fumigants.

The risk to non-target soil micro-organisms was assessed as low based on higher tier field studies. Buffer zones of 3 m were required to address the risk to non-target plants. It could not be excluded that 1,3-D might be harmful if the waste water goes to sewage treatment plants. A concern was raised that washing water from cleaning tools should not be disposed into surface water due to effects on activated sludge.

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- The indoor use in glasshouse is defined as a permanent structure to which entry of birds and mammals is limited (refer to point 5.1).
- PPE (gloves and coverall) and RPE (respiratory mask with filter for organic vapours) is needed in order to have an exposure below the AOEL.

- A buffer zone of 3 m is required to address the risk to non-target plants from the intended outdoor use as soil fumigant.

ISSUES THAT COULD NOT BE FINALISED

- The specification of Kanesho Soil Treatment is considered provisional until a reliable analysis of batches is available.
- As the representative uses evaluated have very high application rates (170-283 kg a.s./ha), there is the potential for significant amounts of identified impurities in the technical material to be added to the environment. Further information on their fate and behaviour in the environment and consequent groundwater exposure levels is necessary to finalise the groundwater exposure assessment. (This relates to impurities 9a, 9b, 10, 11, 12 and 13 and hydrolysis products of impurities 4, 5a, 6, 7 and 8b)
- The consumer risk assessment is pending on a conclusion on the fate and behaviour of identified impurities in the environment, and/or with regard to impurities in the updated specification in the section on mammalian toxicology (see bullet points above).
- The risk to non-target arthropods, earthworms and non-target soil macro-organisms from the intended outdoor use as soil fumigant could be addressed by a higher tier risk assessment, based on a field study (Small, 2006), in case the statistical power of the study can be confirmed.

CRITICAL AREAS OF CONCERN

- The groundwater exposure assessment and consumer risk assessment is not finalised in relation to 11 manufacturing process impurities.
- With the available information, there are indications that 10 manufacturing process impurities could be subject to long range transport through the atmosphere.
- A very high potential for the contamination of vulnerable shallow groundwater immediately below a treated area by both the parent *(EZ)*-1,3-dichloropropene and its relevant toxic breakdown product *(EZ)*-3-chloroacrylic acid, above the parametric drinking water limit of 0.1µg/L was identified by standard FOCUS modelling.

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Spain, 2009b. Final Addendum to the Additional Report on 1,3-dichloropropene compiled by EFSA, September 2009

EFSA (European Food Safety Authority), 2006a. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance 1,3-dichloropropene. EFSA Scientific Report (2006) 72.

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APPENDICES

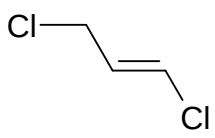
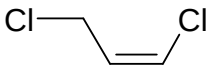
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Active substance (ISO Common Name) ‡	*An ISO Common name was not allocated for this active substance* 1,3-dichloropropene (common abbreviation: 1,3-D)
Function (e.g. fungicide)	Nematicide; insecticide; fungicide; herbicide

Rapporteur Member State	Spain
Co-rapporteur Member State	--

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	(*EZ*)-1,3-dichloropropene
Chemical name (CA) ‡	1,3-dichlor-1-propene
CIPAC No ‡	675
CAS No ‡	542-75-6
EEC No (EINECS or ELINCS) ‡	208-826-5
FAO Specification ‡ (including year of publication)	No FAO specifications available
Minimum purity of the active substance as manufactured ‡ (g/kg)	965 g/kg. Minimum for *Z* or *cis* 1,3-D 450 g/kg Minimum for *E* or *trans* 1,3-D 320 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	1,2-dichloropropane Max. 0.1 g/kg Open
Molecular formula ‡	$C_3H_4Cl_2$
Molecular mass ‡	110.97 g/mol
Structural formula ‡	 *E* or *trans*-isomer  *Z* or *cis*-isomer

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	***cis*-isomer**: – 85 ºC (188 K) ***trans*-isomer**: < –25 ºC (lowest temperature achieved in the test).
Boiling point (state purity) ‡	***cis*-isomer**: 103.8 – 105.2 ºC ***trans*-isomer**: 114.5 ºC.

Temperature of decomposition	Not applicable
Appearance (state purity) ‡	**Technical**: clear colourless liquid with odour of chlorinated solvents.
Surface tension	***cis*-isomer**: 69.6 ± 0.4 mN/m at 20 °C ***trans*-isomer**: 61.0 mN/m
Vapour pressure (in Pa, state temperature) ‡	***cis*-isomer**: 298 K (25 ºC) = 4850 Pa ***trans*-isomer**: 298 K (25 ºC) = 2982 Pa
Henry's law constant (Pa m^3 mol^{-1}) ‡	***cis*-isomer**: H = 170 Pa m^3 mol^{-1} (20 ºC) ***trans*-isomer**: H = 101 Pa m^3 mol^{-1} (20 ºC)
Solubility in water ‡ (g/L or mg/L, state temperature)	***cis*-isomer** (20 ºC): 2.45 g/L ***trans*-isomer** (20 ºC): 2.52 g/L Water solubility is not pH dependent
Solubility in organic solvents ‡ (in g/L or mg/L, state temperature)	Technical (98.7%)
	n-octanol > 250 g/L *n*-heptane > 250 g/L Xylene > 250 g/L 1,2-dichlroethane > 250 g/L Methanol > 250 g/L Acetone > 250 g/L ethyl acetate > 250 g/L ***cis*-isomer** (98.9%) *n*-octanol > 545 g/L Heptane > 610 g/L Xylene > 551 g/L 1,2-dichlroethane > 479 g/L Methanol > 599 g/L Acetone > 589 g/L
	ethyl acetate > 533 g/L ***trans*-isomer** (97.8%) *n*-octanol > 584 g/L heptane > 607 g/L xylene > 551 g/L 1,2-dichlroethane > 458 g/L methanol > 587 g/L acetone > 597 g/L ethyl acetate > 544 g/L
Partition co-efficient (log P_{OW}) ‡ (state pH and temperature)	***cis*-isomer**: log K_{ow} = 1.82 at 20°C ***trans*-isomer**: log K_{ow} = 2.1 at 20°C

	Not pH dependent.
Hydrolytic stability (DT_{50}) ‡ (state pH and temperature)	***trans*-isomer** 25 ºC: pH 4: 4.9 days pH 7: 4.75 days pH 9: 4.75 days ***cis*-isomer** 20 ºC: pH 5: 8.4 days pH 7: 9.7 days pH 9: 8.8 days ***Data for cis*-isomer *are not peer reviewed***
Dissociation constant ‡	Not applicable. No ionisable compound.
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	***cis*-isomer**: Distilled water (201.5 nm): ε = 4741 $dm^3 \cdot mol^{-1} \cdot cm^{-1}$ 0.001 M aqueous HCl (202.7 nm): ε = 4409 $dm^3 \cdot mol^{-1} \cdot cm^{-1}$ 0.01 M aqueous NaOH (209.2 nm): ε = 2668 $dm^3 \cdot mol^{-1} \cdot cm^{-1}$ There is not appreciable absorbance at any wave length above 250 nm. ***trans*-isomer**: Distilled water (201.0 nm): ε = 7220 $dm^3 \cdot mol^{-1} \cdot cm^{-1}$ (pH = 6.3) 0.1 M aqueous HCl (204 nm): ε = 8520 $dm^3 \cdot mol^{-1} \cdot cm^{-1}$ (pH = 1.0) 0.1 M aqueous NaOH (267 nm): ε = 51.1 $dm^3 \cdot mol^{-1} \cdot cm^{-1}$ (pH = 13.0). This absorbance was considered to be due to a hydrolysis product by the authors of the study. Only at very basic pH (pH = 13.0) absorbance above 250 nm is observed probably due to the formation of a hydrolysis product.
Flammability ‡(state purity)	**Technical compound.** Flash point 27.0 ºC. Therefore, 1,3 D should be classified as flammable compound.
Explosive properties ‡(state purity)	**Technical compound:** Technical 1,3-dichloropropene is not explosive.
Oxidising properties (state purity)	Not oxidising

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		
Tomatoes and Peppers	France (North zone)	1,3D Injection (DAS Telone 2000)	F	Nematodes	AL	1180 g/L	Soil injection	Preplanting	1	-	-	-	187	-	2 – 3 weeks (3),(4), (5) (6)
Tomatoes and Peppers	Italy (South zone)	1,3D Injection (DAS Telone II[1])	F	Nematodes	AL	1180 g/L	Soil injection	Preplanting	1	-	-	-	224	-	28 days (3),(4), (5) (6)
Tomatoes and Peppers	Italy (South zone)	1,3D Injection (DAS Telone II[1])	G	Nematodes	AL	1180 g/L	Soil injection	Preplanting	1	-	-	-	224	-	28 days (3),(4), (5) (6)
Tomatoes and Peppers	Greece-Italy-Spain (South zone)	1,3D Drip Irrigation EC (DAS Condor, Telone EC, Dorlone EC[2])	G	Nematodes	EC	1132 g/L	Drip irrigation	Preplanting	1	-	-	-	170-283	-	2-4 weeks (3),(4), (5) (6)

(1) KST Tradenames for 1,3-D Injection product are D-D 95, DD Inyectable, D-D Soil Fumigant

(2) KST Tradename for 1,3-D Drip Irrigation EC are D-D 92, DD Emulsionnable, D-D Top 90 EC

(3) The risk assessment has revealed a data gap(s) in section 5 for non-target earthworms and soil macro-organisms.
(4) The risk assessment has revealed a risk (exceedance of relevant threshold) in section 5.
(5) The risk assessment for the consumer is pending further information to be submitted in section 2 and 4 and is thus not finalised.
(6) The groundwater exposure assessment in relation to 11 manufacturing process impurities is not finalised.

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)	All abbreviations used must be explained	(l)	PHI - minimum pre-harvest interval
	(g)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(m)	Interval between application and planting

Methods of Analysis

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

Technical as (principle of method)	**DAS: GC-TCD** with a DB-1701 capillary column. External standard calibration. **Kanesho: GC** (internal standardisation). **GC-MS** was used as confirmatory method.
Impurities in technical as (principle of method)	**DAS: GC-TCD** with a DB-1701 capillary column. External standard calibration and **GC-FID** Confirmation by **GC-MS** **Kanesho: GC** (internal standardisation). Confirmatory method: **GC-MS**
Plant protection product (principle of method)	**EF 1478 (Telone Drip)** Method: **GC-FID** with a 5% phenyl/95% methyl silicone capillary column (external or internal standard (1,2,4-trimethylbenzene) techniques). **XRM 5048 (Telone II) is in fact the technical material** Method for relevant impurity 1,2-dichloropropane in formulations**: GC-FID**

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	**Method GRM 99.09.R1.** (high aqueous crops) **GC-MS** using a DB-VRX capillary column (2-bromo-1-chloropropane as an internal standard). Monitoring three characteristic ions, *m/z* 75, 110, and 112. **LOQ** = 0.003 mg / kg (method validated by an independent laboratory). **Method PTRL Europe (Report No. P/B 567G)** (cereals and dry crops, high aqueous crops, acidic crops, and oily crops) **GC-ECD** using a nonpolar capillary column, DB-624. Confirmatory method: **GC-ECD** using a polar capillary column. GC/MS was not assessed for confirmation (lack of sensibility). **LOQ** = 0.005 mg/kg for both *cis*- and *trans*-1,3-D. Method validated by an independent laboratory for two representative crops (high aqueous crops and oily crops).
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	*No method required, since no residue definition is proposed.*
Soil (principle of method and LOQ)	**Method GRM 94.13.** The extraction of 1,3 D and 1,2 dichloropropane from soil is accomplished by one of two methods: For low-level range (0.0002-0.2 mg/kg), a slurry of soil and water is heated and stirred. The volatile analytes are purged by sparging with helium and are captured on a sorbent-containing trap.

	For the high-level range (0.2-160 mg/kg), the soil sample is extracted with methanol. An aliquot of the methanol is diluted with water and then sparged with helium. The analytes are captured on a sorbent-containing trap. The analytes are desorbed and analysed by **GC-MS** using a DB-VRX capillary column. The method utilises 2-bromo-1-chloropropane as an internal standard. **LOQ** = 0.0002 mg/kg for each isomer *cis* and *trans*. **Method GRM 94.18** (*cis* and *trans*-3-chloroallyl alcohol). GC-MS, LOQ: 0.0004 mg/kg for each isomer (fortified 0.0004 – 2.09 mg/kg) **Method GRM 94.17** (*cis* and *trans*-3-chloroacrylic acid). GC-MS, LOQ: 0.0002 mg/kg for each isomer (fortified 0.0002 – 2.0 mg/kg)
Water (principle of method and LOQ)	**Method GRM 94.11.** The extraction of 1,3-D (*cis* and *trans*) from water and analysed by **GC-MS** (two characteristic ions, *m/z* 75 and *m/z* 112) using a DB-VRX capillary column. The method utilises 2-bromo-1-chloropropane as an internal standard. Additional ions (e.g., *m/z* 110) may be used for confirmation. **LOQ** = 0.05 µg/mL for each isomer (*cis* and *trans*) (Validated by an independent laboratory). **Method GRM 94.15** (*cis* and *trans*-3-chloroallyl alcohol). GC-MS, LOQ: 0.1 µg/L for each isomer. **Method GRM 94.14** (*cis* and *trans*-3-chloroacrylic acid). GC-MS, LOQ: 0.05 µg/L for each isomer. (Water origin not reported)
Air (principle of method and LOQ)	**Method DOWN 100530 (validated in report HEH2.12-38-26):** Air sampling tubes packed with charcoal to trap residues of (*EZ*)1,3-D. Extracted with chilled carbon disulphide and analysed by **GC-FID** using a DB-1701 capillary column or by **GC-ECD** using a DB-624 capillary column. **LOQ** = 5 µg/tube (equivalent to 1.16 µg/m3) for each isomer. (LOQ in air will depend on the sampling time and flow. No breakdown is observed for periods up to 48 h and 4320 L of air).

Body fluids and tissues (principle of method and LOQ)	**Method: HET DR-0349-4926-001. For cis and trans 1,3-D mercapturic acid conjugates in urine**. Derivatization to form the pentafluorobenzyl derivatives of 1,3-D MA (mercapturic acid). Internal standard: D4 analogs of *cis*- and *trans*-1,3-D MA (mercapturic acid conjugates of 1,3-D. Analysis by GC with negative chemical ionisation/tandem MS (**GC/NCI/MS/MS**) using a DB-1701 capillary column. Three characteristic ions, *m/z* 107, 109, and 111 are monitored. LOQ: 0.00025 mg/kg. **Method for blood (Sept. 2003):** **GC-ECD**. Two different GC-ECD conditions are used for primary and confirmatory method. Confirmatory method uses a different more polar stationary phase. (LOQ = 0.05 mg/L as sum of isomers).

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

with regard to physical/chemical data	R10 Flammable

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapid and complete, based on urinary, faecal and CO_2 excretion in rat and mouse, accounting > 90 % dose after 48 h of single oral administration of 1 and 50 mg/kg and 1 and 100 mg/kg, respectively. Inhalation route: rat: >73-79 % human: cis-isomer: 72-80 % and trans isomer: 77-82 % within 15 min after cessation of exposure (based on expired air concentrations)
Distribution ‡	At 48 hours post-dosing, practically eliminated. About 6 % of the dose remained in tissues and carcass of rat, in which highest values were found in non-glandular stomach, glandular stomach, bladder, liver and kidneys.
Potential for accumulation ‡	No evidence of accumulation in rats or humans
Rate and extent of excretion ‡	Oral administration in rat (50 mg/kg): 93.5 % eliminated within 48 h, mainly via urine (61.3 %), faeces (17.1 %) and CO_2 (15.1 %). Inhalation route in human: 89-99 % within 24 h. Mainly via urine (cis isomer-75 %, trans-isomer-25 %) Biphasic excretion. Half-lives: cis-isomer: phase 1-4.2 h; phase 2-12.3 h; trans-isomer: phase 1-3.2 h; phase 2-17.1 h
Metabolism in animals ‡	Extensively metabolised. The major route was Glutathione-conjugation. The hydrolysis was a second route affording dimercapturate and CO_2 and the minor route was the epoxidation of DCP or DCP-glutathione. Three main metabolites: dimercapturate, C-3-Chloroallyl alcohol and C-3-Chloroacrylic acid. Based on indirect evidence of mutagenesis study, epoxides could be formed.
Toxicologically relevant compounds ‡ (animals and plants)	1,3-dichloropropene. The metabolites C-3-Chloroallyl alcohol and C-3-Chloroacrylic acid.
Toxicologically relevant compounds ‡ (environment)	1,3-dichloropropene. The metabolites C-3-Chloroallyl alcohol and C-3-Chloroacrylic acid.

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	110 mg/kg bw	**R25**
Rat LD_{50} dermal ‡	1200 mg/kg bw 333 mg/kg bw (rabbit)	 **R24**
Rat LC_{50} inhalation ‡	2.70 mg/L air /4h (whole body, vapour exposure)	**R20**
Skin irritation ‡	Irritant	**R38**

Eye irritation ‡	Irritant	**R36**
Skin sensitisation ‡	Sensitising (Buehler test)	**R43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Stomach (rat, hyperkeratosis and basal cells hyperplasia), liver (mice and rat, hepatotoxicity), decreased bodyweight (dog, mouse) nasal cavity (rat and mice, inhalation exposure, hyperplasia of respiratory epithelium) and urinary bladder (mice, females). Hypochromic and microcytic anaemia in dogs.	
Relevant oral NOAEL ‡	5 mg/kg bw/day (90-day rat) 150 mg/kg bw /day (mouse) 2.5 mg/kg bw/day (1-year dog)	
Relevant dermal NOAEL ‡	No data - not required	
Relevant inhalation NOAEL ‡	0.046 mg/L (10 ppm) i.e. 9.72 mg/kg/day (rat, 13-week)	

Genotoxicity ‡ (Annex IIA, point 5.4)

	Some studies show clear indications for DNA fragmentation *in vivo*;-negative results are demonstrated in micronucleus, UDS and dominant lethal tests. Not classified by the Technical Committee for Classification and Labelling (31st ATP)	

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

Target/critical effect ‡	Depression of in life body weights (rats and mice) Basal cell hyperplasia of the non-glandular mucosa of stomach, foci of altered cells in the liver (rats). Hyperplasia of the urinary bladder, hyperplastic changes of the respiratory epithelium (mice).	
Relevant NOAEL ‡	2.5 mg/kg bw/day (2-year dietary, rat) 7.69 mg/kg bw/day (2-year inhalation study, mouse)	
Carcinogenicity ‡	Benign lung tumours at 60 ppm and submucosal mesenchymal tumours in the urinary bladder at 25 mg/kg bw/day (in mice). Hepatocellular adenoma in liver (in rats) at 25 mg/kg bw/day. Not classified by the Technical Committee for	

	Classification and Labelling (31st ATP)	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental toxicity: decreased body weight and gastric ulcers. No adverse effects on reproduction identified following exposure by the inhalatory route.	
Relevant parental NOAEL ‡	By inhalation: 0.1362 mg/L (30 ppm)	
Relevant reproductive NOAEL ‡	By inhalation: 0.4086 mg/L air (90 ppm)	
Relevant offspring NOAEL ‡	By inhalation: 0.4086 mg/L air (90 ppm)	

Developmental toxicity

Developmental target / critical effect ‡	By inhalation route: Decreased maternal bodyweight and bodyweight gain and decreased food and water consumption in rats No adverse effects on development identified following exposure by the inhalatory route. No teratogenicity.	
Relevant maternal NOAEL ‡	By inhalation rat: < 0.0908 mg/L (< 20 ppm) By inhalation rabbit: 0.0908 mg/L (20 ppm)	
Relevant developmental NOAEL ‡	By inhalation rat: 0.5448 mg/L (120 ppm) By inhalation rabbit: 0.5448 mg/L (120 ppm)	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data-not required	
Repeated neurotoxicity ‡	No data-not required	
Delayed neurotoxicity ‡	No data-not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Reaction of 1,3-D with glutathione: Spontaneous reaction with GSH is slow. Enzyme-catalysed + GSH reaction is rapid. Trans-isomer was degraded 4-5 times slower than cis-isomer. Glutathione transferase activities in several cells: Mammalian cells contained higher levels of GST enzymes than bacteria cells. It could explain positive findings in *in vitro* bacterial genotoxicity assays and negative findings in *in vivo* assays. Effects on tissue non-protein sulfhydryl content and blood concentration time profile-probe study in male Fischer 344 rats: GSH conjugation is an important pathway for the depression of forestomach, glandular stomach, liver and kidney non-protein sulfhydryl content observed in this study, suggesting that the ability of the rat to detoxify 1,3-D in this study may be compromised at an oral dosage of 50 mg/kg. Mechanism of tumorigenicity studies in male B6C3F1 and Fischer 344 Rats: A dose related decreases in tissues (liver rats and lung mice) GSH levels of treated animals was observed. No clear-cut evidence of an effect on either cell proliferation or apoptosis rates in target tissues were observed.
Studies performed on metabolites or impurities ‡	Metabolite 3-chloroacrylyc acid: Tks: absorption: 76% (based on CO_2 and urine excretion) Main metabolic product: CO_2. Rat oral LD_{50} 91 mg/kg bw **R25** Not sensitising (Buehler test) Target organ/critical effect: Kidney (tubule and loop of Henle degeneration)/decrease in food and water consumption. NOAEL 10 mg/kg bw/day (90-day rat study). Tested for developmental toxicity in rats by gavage. Developmental critical effect: increase in total resorptions and decrease in foetal body weights at maternal toxic doses (65 mg/kg bw/day). No teratogenicity. Lowest developmental NOAEL: 25 mg/kg bw/day.
	Metabolite 3-chloroallyl alcohol: No genotoxic potential Tks: absorption: 71-73 % (based on CO_2 and urinary excretion) Main metabolic product: CO_2 Rat oral LD_{50} 91 mg/kg bw **R25**

Rabbit dermal LD_{50} 316 mg/kg bw No skin irritation Not sensitising (Buehler test) Tested for developmental toxicity in rats by gavage. Developmental critical effect: decreased foetal body weights at maternal toxic doses (25 mg/kg bw/day). No teratogenicity. Lowest developmental NOAEL: 10 mg/kg bw/day. Weight of evidence suggests no genotoxic concern.	**R24**
Urinary excretion products of 1,3-D: disulfide, N-acetylcysteine conjugate, thioglycolic acid conjugate and sulfoxide/sulfone conjugate of 1,3-D: Both urine and disulfide were not mutagenic in the *Salmonella*/ mammalian microsome assay. N-acetylcysteine, sulfoxide/sulfone, thioglycolic acid and cysteine conjugates of 1,3-D were mutagenic at relatively high concentrations (5-10 mg/plate), mainly in TA100 strain, in the absence of metabolic activation.	

Medical data ‡ (Annex IIA, point 5.9)

Evidence of irritation to skin and respiratory system. A fatal poisoning reported by accidental ingestion.	**R36/37, R65**

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI	0.025 mg/kg bw/day	rat, 2-year study	100
AOEL (systemic rat)	0.1 mg/kg bw/day	13-week inhalation study in rats supported by the 2-year mice study.	100
AOEL (inhalatory human)	0.1 ppm or 0.45 mg/m^3	13-week inhalation study in rats supported by the 2-year mice study.	100
ARfD ‡	0.2 mg/kg bw	2-week study in dogs	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulations Telone drip (EC containing 936 g 1,3-D/kg), Telone injected (AL containing 97.5% 1,3-D/L)	Main route of exposure is via 1,3-D inhalation. However, if dermal absorption would occur, 100 % default value should be used.

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Estimated exposure i.e. % of the AOEL for: Drip irrigation in green house (non professionals). **Without PPE:** **With PPE and RPE*:** Worst case 220 % Worst case 11% Soil injection (professional users) **Without PPE:** **With PPE and RPE*:** Worst case: 1073 % Worst case 54 %
Workers	Drip irrigation in green house (non professionals). Normal re-entry period: 14 days. Levels ≤11% AOEL or non detectable Re-entry during application Without PPE With PPE and RPE* Worst case 149% Worst case 7% Soil injection (professional users) Normal re-entry period: 14 days. Levels ≤5% AOEL or non detectable Re-entry after recent application (sheet install, bed shaping) Without PPE With PPE and RPE* Worst case 1266% Worst case 64%
Bystanders	Drip irrigation in green house (non professionals). Worst case 37.5 % AOEL High risk (> 100 % AOEL) walking at 1 m and within 6-7 h after application in greenhouse Soil injection (professional users) Worst case: 21% AOEL

* Coverall, gloves and face mask with activated carbon filters

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal	
1,3-dichloropropene	T, Xi, Xn	Toxic, irritating,
	R20	Harmful by inhalation
	R24	Toxic in contact with skin
	R25	Toxic if swallowed
	R36/37/38	Irritating to eyes, respiratory system and skin; Irritant to eyes and skin
	R43	May cause sensitisation by skin contact
	R65	Harmful, may cause lung damage if swallowed

Residues

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

Plant groups covered	Fruiting vegetables (tomato); fruits (citrus); root & tuber vegetables (sugar beet); oilseeds (soybeans)
Rotational crops	Wheat , lettuce, carrots, radishes
Plant residue definition for monitoring	*E*- and *Z*- 1,3 Dichloropropene
Plant residue definition for risk assessment	*E*- and *Z*- 1,3 Dichloropropene
Conversion factor (monitoring to risk assessment)	None

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

Metabolism in live stock is not triggered for the representative uses

Animals covered	Lactating goats; laying hens
Animal residue definition for monitoring	Not necessary for representative use
Animal residue definition for risk assessment	Not necessary for representative use
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

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

.....	No 1,3-D, or alcohol or acid metabolite was detected

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

.....	No degradation of 1,3-D, the alcohol or acid metabolite 240 days

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

Not required. No residues were detected in any of the crops from the residue trials

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: no	Poultry: no	Pig: no
Muscle			
Liver			
Kidney			
Fat			

Milk	
Eggs	

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)
Pepper	Mediterranean (outdoors)	Soil injection: 4x <0.01 mg/kg [1]		0.01	0.01
Pepper	Mediterranean (indoors)	Drip irrigation: 4x <0.01 mg/kg[1]		0.01	0.01
Pepper	Japan[2]	2x < 0.01 mg/kg		0.01	0.01
Tomato	Mediterranean (outdoors)	Soil injection: 4x <0.01 mg/kg [1]		0.01	0.01
Tomato	Mediterranean (indoors)	Drip irrigation: 4x <0.01 mg/kg[1]		0.01	0.01
Tomato	Japan[2]; USA[3]	8x < 0.01 mg/kg		0.01	0.01

Note: There is residue data available on orange, peaches, plums, cherries, almonds, walnuts, wine grape, table grape, raisin, banana, pineapple, Chinese cabbage, broccoli, onion, melon, cucumber, eggplant, pepper, lettuce, spinach, green beans, cottonseed, peanuts, soybeans, potato, dry bean, carrots, radish, sugarbeet (root), sugarbeet (top), yam in which the level of residue was always < 0.01 mg/kg. Other available data are: melon, 4: <0.01 mg/kg (USA); cucumber, 3: <0.01 mg/kg (Japan); eggplant, 2: < 0.01 mg/kg, (Japan)

[1] Moreover, these residue trials showed no residue of 6 analysed impurities on tomato and pepper

[2] Japan trials were performed in greenhouse; residues were below LOD (0.001 mg/kg) each isomer.

[3] USA trials performed in field; residues were below LOQ (0.01 mg/kg) each isomer.

(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

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

The consumer risk assessment cannot be considered as finalised in relation to 11 manufacturing process impurities. The consumer risk assessment is pending a conclusion on the fate and behaviour of these 11 identified impurities in the environment, and/or with regard to toxicological data on manufacturing process impurities in the updated specification in the section on mammalian toxicology.

The proposed MRL of 0.01 mg/kg for 1,3 D in tomato and pepper was used in the calculations presented below.

ADI	0.025 mg/kg/day
TMDI (PRIMo highest diet values) (% ADI)	0.14 % (WHO cluster diet B)
IEDI (% ADI)	Not necessary
Factors included in IEDI	Not necessary
ARfD	0.2 mg/kg bw/day
Acute exposure (PRIMo) (% ARfD)	Tomato: 0.4% (LT adults), 1.5% (BE children) Pepper: 0.4% (UK vegetarian), 1.6% (DE children)

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

Not required.

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

Tomato, pepper	0.01* mg/kg

*) LOQ

Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil[18] (Annex IIA, point 7.1.1.1.1)

Mineralisation after 100 days ‡	11.2-37.6% TAR after 49-77 d, 1,3-D -UL-^{14}C, (n=6) Sterile conditions: 4.7% after 120 d. (n=1)
Non-extractable residues after 100 days ‡	8.8-28.8% TAR after 49-77 days, 1,3-D -UL-^{14}C, (n=6) Sterile conditions: 43% TAR after 77 days (n=1)
Volatilisation	23.3%-42.8% TAR after 49-63 d, 1,3-D -UL-^{14}C, (n=6) Sterile conditions: 14.5% after 77 d. (n=1).
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	M1: 3-chloroacrylic acid: 12.8%-37.3% TAR at 35-28 d. (n=6). Sterile conditions: M2: 3-chloroallyl alcohol 13.4% TAR at 57d (n=1).

Route of degradation in soil - Supplemental studies[6] (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	Mineralisation: 36.7% TAR after 120 d (n=1) Non-extractable residues 22.4% TAR after 120 d. (n=1) Metabolites M1: 3-chloroacrylic acid: 55.1% TAR at 28 d. (n=1)
Soil photolysis ‡	No data. 1,3-D does not absorb visible light.

Rate of degradation in soil[19] (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	Non-linear modelling by ModelMaker® version 3 Software. One compartment

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

Laboratory studies ‡

Parent (dissipation)	Aerobic conditions

[18] It refers to combined isomers

[19] It refers to combined isomers. For 3-chloroarylalcohol and 3-chloroacrylic acid two degradation rates were estimated based on parent degradation study (first value) and 3-chloroallyl alcohol degradation study (second value).

Soil type (location)	pHCl (0.01 M $CaCl_2$)	t. °C / % MWHC	DT_{50} /DT_{90} (d) Z,E-1,3-D	DT_{50} (d) 20°C pF2/10kPa[a]	St. (r^2)	Method of calculation
Sandy clay loam (Marcham)	7.3	20ºC/ 40%	9.3/30.9	9.3	0.95	SFO
Sandy silt loam (Thessaloniki)	7.8	20ºC/ 40%	8.8/29.1	8.8	0.97	SFO
Sand (Cuckney)	6.6	20ºC/ 40%	15.5/51.4	13.5	0.98	SFO
Clay loam (Charentilly)	6.1	20ºC/ 40%	10.7/35.6	9.4	0.98	SFO
Geometric mean Arithmetic Mean Median				9.9 10.1[b] 9.4		
Sandy clay loam (Marcham)	7.3	20ºC/20 MWHC	9.9/32.9	N/A	0.95	SFO
Sandy clay loam (Marcham)	7.3	10ºC/ 40%	24.9/82.9	24.9	0.97	SFO

a FC (10kPa) data taken from table5.2 of FOCUS 2000
b For FOCUS modelling notifier considered an average value of 9.4 d. This deviation does not impact in the results of the risk assessment

3-chloroallylalcohol	Aerobic conditions					
Soil type (location)	pHCl (0.01 M $CaCl_2$)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa[a]	St. (r^2)	Method of calculation
Sandy clay loam (Marcham)	7.3	20ºC/ 40	0.2/0.8	0.2	0.95	SFO
Sandy silt loam (Thessaloniki)	7.8	20ºC/ 40	0.2/0.7	0.2	0.97	SFO
Sand (Cuckney)	6.6	20ºC/ 40 MWHC	0.3/0.9	0.26	0.98	SFO
Clay loam (Charentilly)	6.1	20ºC/ 40 MWHC	0.1/0.4	0.09	0.98	SFO
Sandy clay loam (Marcham)	7.3	20ºC/ 40	0.1/0.4	0.1	0.9913	SFO
Sandy silt loam (Thessaloniki)	7.8	20ºC/ 40	0.6/1.9	0.6	0.9959	SFO
Sand (Cuckney)	6.6	20ºC/ 40 MWHC	0.6/1.9	0.6	0.9987	SFO

Clay loam (Charentilly)	6.1	20ºC/ 40 MWHC	0.5/1.6	0.5	0.9996	SFO
Geometric mean Arithmetic mean Median				0.25 0.32 0.23		
Sandy clay loam (Marcham)	7.3	10ºC/ 40%	0.6/2.1	0.6	0.97	SFO

a FC (10kPa) data taken from table 5.2 of FOCUS 2000

3-chloroacrylic acid	Aerobic conditions					
Soil type (code)	pHCl (0.01 M $CaCl_2$)	t. °C / % MWHC	DT_{50} /DT_{90} (d) Z,E-1,3-D	DT_{50} (d) 20°C pF2/10kPa[a] Z,E-1,3-D	St. (r^2)	Method of calculation
Sandy clay loam (Marcham)	7.3	20ºC/ 40%	6.0/19.2	6.0	0.95	SFO
Sandy silt loam (Thessaloniki)	7.8	20ºC/ 40%	19.2/65.8	19.2	0.97	SFO
Sand (Cuckney)	6.6	20ºC/ 40%	18.2/60.3	15.9	0.98	SFO
Clay loam (Charentilly)	6.1	20ºC/ 40%	10.4/34.6	9.17	0.98	SFO
Sandy clay loam (Marcham)	7.3	20ºC/ 40%	0.7/2.4	0.7	0.9718	SFO
Sandy silt loam (Thessaloniki)	7.8	20ºC/ 40%	3.4/11.2	3.4	0.9712	SFO
Sand (Cuckney)	6.6	20ºC/ 40%	2.0/6.7	2.0	0.9582	SFO
Clay loam (Charentilly)	6.1	20ºC/ 40%	2.0/66	1.99	0.9534	SFO
Geometric mean Arithmetic mean Median				4.47 7.3 4.7		
Sandy clay loam (Marcham)	7.3	10ºC/ 40%	30/99.5	30		SFO

a FC (10kPa) data taken from table 5.2 of FOCUS 2000

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation

	Quincy, Florida, US	Biphasic behaviour. Firstly a fast dissipation took place followed by a much slower degradation.
	Fresno, US	No degradation parameters derived. Not required

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	No calculated, no required

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡								
Soil Type (location)	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n	R^2
Clay Faringdon	3.21	7.5	0.84-1.17	26.2- 36.5	0.60	18.61	1.01	0.995
Sand Cuckney	1.6	6.6	0.45-0.60	28.037.6	0.39	24.37	1.02	0.994
Sandy clay loam Thessaloniki	1.9	7.3	0.39-0.60	49.0 -74.4	0.36	18.9	1.02	0.990
Sandy silt loam Charentilly	0.8	7.8	0.37-0.54	36.9 -54.3	0.32	40	1.04	0.988
Clay loam Marcham	1	6.1	1.11-1.68	58.6 -88.6	0.83	83	0.92	0.999
Clay loam Barnes (US)	4.2	4.8	1.39-1.71	33.2- 40.7	0.91	21.6	0.97	0.998
Silty clay loam Fayette (US)	1.2	6.9	0.44-0.64	36.6- 53.5	0.35	29.2	1.05	0.993
Arithmetic mean			0.82	44.7	0.54	33.7	1.00	
pH dependence, No								

3-chloroallylalcohol ‡								
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n	R^2
Sandy loam (Bertie County)	0.66	5.9	0.0912	13.9	0.0984	14.91	1.04	0.9962
Clay loam (Grand Forks)	4.76	6	0.191	4	0.195	4.10	1.02	0.9998
Loamy Sand (Wake County)	0.41	6	0.051	12.4	0.0481	11.73	1.02	0.9946
Silty clay loam (Charentilly)	1.07	6.3	0.0388	3.62	0.0436	4.07	1.05	0.9832
Loam (Fresno)	0.81	7	0.056	6.93	0.0875	10.80	1.38	0.9545
Silt loam (Thessaloniki)	1	7.9	0.0726	7.22	0.0968	9.68	1.33	0.9984
Clay (Faringdon)	3.22	7.9	0.162	5.02	0.171	5.31	1.07	0.9676
Sandy clay loam (Marcham)	1.25	8	0.134	10.8	0.149	11.92	1.17	0.9943
Silt loam (Washington)	0.9	8.2	0.0915	10.2	0.107	11.89	1.2	0.9952
Arithmetic mean/median			0.10	8.23	0.11	9.38	1.14	
pH dependence (yes or no) No								

3-chloroacrylic acid ‡								
Soil Type (location)	OC %	Soil pH	Kd mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n	R2
Sandy loam (Bertie County)	0.66	5.9	0.115	17.5	0.106	16.06	0.883	0.9632
Clay loam (Grand Forks)	4.76	6	<0.01	<0.01	NC	NC	NC	NC
Loamy Sand (Wake County)	0.41	6	0.0518	12.6	0.0409	9.97	0.872	0.9776
Silty clay loam (Charentilly)	1.07	6.3	<0.01	<0.01	<0.00278	0.259	0.426	10.000
Loam (Fresno)	0.81	7	0.00887	1.1	<0.0129	0.16	0.961	0.9786
Silt loam (Thessaloniki)	1	7.9	0.02	1.99	<0.0241	2.41	1.18	0.99
Clay (Faringdon)	3.22	7.9	<0.01	<0.01	NC	NC	NC	NC
Sandy clay loam (Marcham)	1.25	8	<0.01	<0.01	NC	NC	NC	NC
Silt loam (Washington)	0.9	8.2	0.00691	0.767	<0.0143	1.6	0.907	1
Arithmetic mean/median				3.78				
slightly pH-dependence: when pH decreases Koc increases								

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

Column leaching ‡	Guideline: US EPA Pesticide Assessment Guidelines, Subdivision N, Paragraph 163-1 (1982) Precipitation: 1mL/min 0.01M calcium chloride solution. Time period (d):-- Leachate: 58.8-83.9%TAR Identification of leachete was not available. 1.27-2.82% TAR Retained material in the top 6cm Radioactivity was distributed through the soil columns (1.73-19.22% TAR).
Aged residues leaching ‡	Guideline: US EPA Guideline 163-1 Soil pH: 4.7 Aged for (d): 30 d Precipitation: 3 mL/min over 7 h
	Leachate: 28.8% TAR. 6.6%TAR active substance, 3.5% TAR 3-chloroacrylic acid, 16.1% TAR 3-chloroallyl alcohol, 2.15% TAR carboxilic acids. 54.7% TAR retained material in the top 2 cm.
Lysimeter/ field leaching studies[a] ‡ Note: the monitoring studies carried out in Nebraska, Washington, were not considered representative of the European regions where 1,3-D is intended to be used.	Location: Monterey County, California, US Study type: small-scale retrospective ground water monitoring Number of application 1 Application rate: 66.6 Kg a.s./ha Average annual rainfall (mm): 330 mm Peak annual average concentrations: no detection of active substance. Presence of 3-chloroallyl alcohol cannot be rejected since LOQ was 1 ppb for it.

	Location: Merced County, California, US Study type: small-scale retrospective ground water monitoring Number of applications: 1 Application rate : 191 Kg a.s./ha Average annual rainfall (mm): 306 mm Peak annual average concentrations: no detection of active substance. Presence of 3-chloroallyl alcohol cannot be rejected since LOQ was 1 ppb for it.

a Analysis of 3-chloroacrylic acid was not conducted at any site. Irrigation was not made after application.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 15.5 days Kinetics: SFO Representative worst case from lab studies
Application data	Crop: Fruiting vegetables (tomatoes) % plant interception: pre-plant therefore no crop interception Mix layer: 5 cm (initial), 20 cm (PEC(t)), 30 cm (PEC(t)) Number of application 1 Interval: 365 d Application rate: Injected (field): 224 Kg a.s./ha (South Zone), 187 Kg/ Ha (North Zone) Drip (greenhouse): 283 Kg a.s./ha (South Zone)

$PEC_{(s)}$ (mg/kg)	Single application Actual		
application rate (Kg a.s./ha)	224	187	283
Initial (over 5 cm)			377.33
Initial (over 20 cm)	74.66	62.33	

$PEC_{(s)}$ (mg/kg) at 30 cm	Single application Actual			Single application Time weighted average		
application rate (Kg a.s./ha)	224	187	283	224	187	283
Initial (over 30 cm)				-	-	-
Long term 7d	36.399	30.386	45.986	42.740	35.680	53.997
14 d	26.616	22.219	33.626	36.996	30.885	46.741
21 d	19.462	16.247	32.155	32.282	26.949	45.817
28d	14.231	11.880	17.980	28.389	23.700	35.866
50d	5.321	4.442	6.722	19.883	16.599	25.120

100d	0.569	0.475	0.719	11.004	9.186	13.902

3-chloroacrylic acid Method of calculation	Molecular weight relative to the parent: 0.9597 DT_{50} (d): 19.8 days Kinetics: SFO Representative worst case from lab studies.
Application data	Crop: Fruiting vegetables (tomatoes) Mixed layer : 30 cm Number of application 1 Interval: 365 d Application rate: Injected (field): 80.16 Kg a.s./ha (South Zone), 66.9 Kg/ha (North Zone) Drip (greenhouse): 101.2 Kg a.s./ha (South Zone) Assumed 3-chloroacrylic acid is formed at a maximum of 37.3 % TAR 28 d after application.

$PEC_{(s)}$ (mg/kg) over 30 cm	Single application Actual			Single application Time weighted average		
Application pattern	injected (SE)	injected (NE)	Drip	injected (SE)	injected (NE)	Drip
Initial	17.68	14.76	22.33			
Short term 24h	17.07	14.25	21.56	17.37	14.50	21.95
2d	16.48	13.76	20.82	17.07	14.25	21.57
4d	15.37	12.83	19.41	16.49	13.77	20.84
Long term 7d	13.83	11.55	17.48	15.68	13.09	19.81
28d	6.63	5.54	8.38	11.27	9.4	14.23
50d	3.07	2.56	3.88	8.34	6.97	10.54
100d	0.53	0.45	4.09	4.9	0.67	6.19

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4: z- 1,3-D: 25ºC DT_{50} = 100 h 25ºC (Arrhenius) E-1,3-D: 25 ºC DT_{50} = 118 h 25ºC (Arrhenius) 3-chloroallyl alcohol: 75% initial dose at 16 h. 3-chloroacrylic acid stable 3-chloroallyl alcohol stable
	pH 7: Z- 1,3-D: 25ºC DT_{50}= 64.5 h E-1,3-D: 25 ºC DT_{50}= 114 h . 3-chloroallyl alcohol: 77.1% initial dose at 16 h. 3-chloroacrylic acid stable 3-chloroallyl alcohol stable
	pH 9: Z- 1,3-D: 25ºC DT_{50}= 37.9 h E-1,3-D: 25 ºC DT_{50}= 114 h (r^2=). 3-chloroallyl alcohol: 78.4% initial dose at 16 h. 3-chloroacrylic acid stable 3-chloroallyl alcohol stable
Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} = 651 d (experimental) Continuous irradiation xenon light lamp
Quantum yield of direct phototransformation in water at Σ > 290 nm	1,3-D does not absorb visible light.
Readily biodegradable ‡ (yes/no)	No ready biodegradable

Degradation in water / sediment

Z,E-1,3-D	Distribution 36.6% TAR in water after 1 day, and 2.2%TAR at the end of the study 7.2% TAR in sedimenr after 1 day and 0.6% TAR at the end of the study ; 63.35% TAR volatilised at 0 day)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys. (d)	St. (r^2)	DT_{50}-DT_{90} water (d)	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Loamy sand	7.4	5.9	25ºC	4.9-16.2	0.97	2.58-8.6	0.84			SFO

3-chloroallyl alcohol	Distribution (5.5% TAR in water 1 after d. Max. sed 0.4 % after 3 d)[a]									
Water / sediment system[b]	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-water	r^2	DT_{500} sed	St. (r^2)	Method of calculation
Loamy sand	7.4	5.9	25ºC	1.2-4.0	0.97	1.21	0.97	1.09	0.94	SFO

a These figures comes from the study conducted with the active substance
b degradation parameters derived from a study conducted with 3-chloroallyl alcohol as test item

Z,E-3-chloroacrylic acid	Distribution (8.6% max in water after 3 d. Max. sed 0.6 % after 3-7d)[a]									
Water / sediment system[b]	pH water phase	pH sed	t. °C	DT_{50} whole sys.	St. (r^2)	DT_{50}-water	r^2	DT_{500} sed	St. (r^2)	Method of calculation
Loamy sand	7.4	5.9	25ºC	5.63	0.96	5.4	0.96	6.09	0.95	SFO

a These figures comes from the study conducted with the active substance
b degradation parameters derived from a study conducted with Z,E-3-chloroacrylic acid as test item

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. Max x % after n d	Non-extractable residues in sed. Max x % after n d (end of the study)
Loamy sand	7.4	5.9	40.15% after 14 d 37.9% after 21 d (end of the study)	16.05% after 21 d	16.05% after 21 d

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

Parent Method of calculation	Drip: Deposition; experimental data 1.4 µg/L according to the bystander study Injected: lateral flow, calculation made with CHAIN2_D runoff: experimental data (0.003% application rate) deposition: experimental data (100% deposition of 500 µg/m^3)
Application rate	Injected: 230 Kg a.s./ha Drip: 283 Kg a.s./HA (south zone).
Main route of entry	Drip : Deposition Injected: Lateral Flow; runoff & Deposition

Injected application

Lateral flow: Input Parameters for CHAIN_2D MODEL

Parameter	cis-1,3-D	Trans- 1,3-D
Diffusion coefficient Dg (cm2 d-1)	7199	7182
Adsorption coefficient Kd (cm3 g-1)	0.3	0.3
Hnery's constant	0.056	0.037
DT50 soil (d)	15	15
DT 50 water (d)	15	15
DT50 air (d)	∞	∞
Activation energy (J mol-1)		
Diffusion coefficient Dg	4511	4511
Adsorption coefficient Kd	0	0
Hnery's constant	43207	43207
DT50 soil	43551	43551
DT 50 water	43551	43551

Runoff : For a 0.003% application rate of runoff PECsw was 2.24 ug/la assuming a waterbody of 30 cm depth

Depostion : Deposition is based on the average air concentration showed in the volatilization studies and considering that 100% of the 1,3-D mass from 1 litre if air deposited into 1 litre of water.

	Mass Weight (g/mol)	Lateral transport[1] µg/L		Runoff (µg/L)	Deposition (µg/L)	Overall (µg/L)	
		1 m	3 m			1m	3 m
1,3-D	111	250	0.466	2.24	0.5	252.74	3.18

1 cumulative concentration at 3 m (northern conditions)

Metabolites

Initial PEC sw for metabolites taking into account only the deposition route of entry in Drip irrigation

3-chloroallyl alcohol: Considering an initial concentration 1.4 µg/L; a transformation factor of 0.833 for 3-chloroallyl alcohol and that 1 mole of 1,3-D is transformed in 1 mol of 3-chloroallyl alcohol, the initial PECsw for this metabolite is estimated to be 1.16 µg/L

3-chloroacrylic acid: Considering an initial concentration 1.4 µg/L, a transformation factor of 0.96 for 3-chloroacrylic acid and that 1 mole of 1,3-D is transformed in 1 mol of 3-chloroacrylic acid , the initial PECsw for this metabolite is estimated to be 1.34 µg/L

PEC (sediment)

Not calculated, as partitioning to sediment of extractable radioactive residues in sediment water studies was limited.

Injected application[1]

	Mass Weight (g/mol)	Lateral transport[1] (µg/L)		Runoff (µg/L)	Deposition (µg/L)	Overall (µg/L)	
		1 m	3 m			1m	3 m
1,3-D	111	250	0.466	2.24	0.5	252.74	3.18
3-chlorallyl alcohol (3-CAAL)	92.1	207.2	0.388	1.87	0.416	209.5	2.7
3-chloroacrylic acid (3-CAAC)	106.5	239.86	0.447	2.15	0.48	242.5	3.07

1 Conservative values using only molar weight corrections (and not formation fractions) have been calculated

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	FOCUS gw modelling, Modelling using FOCUS model(s), with appropriate FOCUS gw scenarios, according to FOCUS guidance. Model(s) used: FOCUSPELMO 3.3.2 Scenarios (list of names): Châteaudun, Piacenza, Porto Sevilla, Thiva Crop: tomatoes Arithmetic mean parent DT50lab 9.4 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.2, Walker equation coefficient 0.7). Kdoc: parent, arithmetic mean 44.7mL/g, 1/n 1.0 Arithmetic mean 3-chloroallyl alcohol DT50lab 0.3d (considering the overall mean of the DT50 values from the rate of degradation studies of parent compound and the 3-chloroarylalcohol metabolite. Kdoc: 3-chloroallyl alcohol , arithmetic mean 8.23 mL/g 1/n 0.877 Arithmetic mean 3-chloroacrylic acid DT50lab 7.4 d considering the overall mean of the DT50 values from the rate of degradation studies of parent compound and the 3-chloroarylalcohol metabolite. Kdoc: 3-chloroacrylic acid arithmetic mean 3.78 mL/g 1/n 1.15

Application rate	Injection Application rate: 187 Kg/ha (Châteaudun) 224 Kg/ha. (for the rest) No. of applications: 1 Time of application (month or season): 1st July Depth of application: 25 cm Drip irrigation Application rate: 283 Kg/ha No. of applications: 1 Time of application (month or season): 1st July Note standard climate files used, drip irrigation is a glasshouse use. Estimates below are likely to be overestimates For both injection and drip irrigation simulations, the metabolites were modelled as if they had been applied as a parent compound at a soil depth of 25cm assuming the maximum molar formation fraction observed in laboratory degradation studies for (*EZ*)-3-chloroacrylic acid of 37%

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

Injection

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			3-chloroallyl alcohol	3-chloroacrylic acid
FOCUSPELMO 3.3.2 /tomato	Châteaudun	**12.5**	0.003	**48.2**
	Piacenza	**78**	0.089	**144**
	Porto	**0.143**	0.001	**24.1**
	Sevilla	0.001	<0.001	**0.401**
	Thiva	0.081	<0.001	**1.09**

Drip irrigation

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			3-chloroallyl alcohol	3-chloroacrylic acid
FOCUSPELMO 3.3.2 /tomato	Piacenza	**178**	**0.589**	**374**
	Porto	**0.626**	0.003	**117**
	Sevilla	0.013	<0.001	**3.33**
	Thiva	**0.177**	0.001	**6.42**

Higher tier studies

Monitoring GW studis in UK, Spain, Italy, France and Greece were provided and evaluated. See monitoring section

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

Direct photolysis in air ‡	No data
Quantum yield of direct phototransformation	No data
Photochemical oxidative degradation in air ‡	Experimentally measured Reaction with OH radicals at 2 106 radicals cm-3 DT50= 7 hours for E-1,3-D DT50= 12 hours for Z-1,3-D Reaction with O3 radicals at 1 1012 molecules cm-3 DT50= 12 days for E-1,3-D DT50= 52 days for Z-1,3-D
Volatilisation ‡	from plant surfaces No data submitted no required
	From soil: **Location**: Imperial Valley, California US Study type: volatilisation monitoring Number of applications: 1 Application rate : 112 L/ha Height: 1.5 m above the field Average measured air concentration for 8 days field: 6.4 µg/m^3 (max. 23.6µg/m^3 at day 7) **Location**: Salinas Valley, California US Study type: volatilisation monitoring Number of applications: 1 Application rate : 112 L/ha Height: 1.5 m above the field Average measured air concentration for 14 days at: 30 m: 10.5- 9.9 µg/m^3 (average calculated: 13.7-12.4 µg/m^3) 400 m: 2.4-3.1 µg/m^3 (average calculated: 4.0-5.3 µg/m^3) Mean calculated air concentration for 14 days: 8.8µg/m^3 **Location**: Yerington, Nevada, US Study type: volatilisation monitoring for 7 days Number of applications: 1 Application rate : 120.3 L/ha Maximum measured air concentration for 7days field: 15 cm above field: 2275µg/m^3 (31-42 h). Average: 465 µg/m^3 (n=52) 1.5 m, edge of field: 783µg/m^3 (31-42 h). Average: 94.8 µg/m^3 (n=45). 1.5 m, 30 m from field: 497µg/m^3 (31-42 h). Average: 39.4 µg/m^3 (n=114)

1.5 m, 400 m from field: 47.6µg/m^3 (31-42 h). Average: 5.17µg/m^3 (n=39)

1.5 m, 800 m from field: 33.3µg/m^3 (31-42 h). Average: 3.88µg/m^3 (n=32)

Location: Moses Lake, Washington, US

Study type: volatilisation monitoring for 14 days

Number of applications: 1

Application rate : 233 L/ha

Measured air concentration for 14 days field:

1.5 m, edge of field: max 346µg/m^3 (60-72h). Multidirectional Average: 114 µg/m^3 .

1.5 m, 25 m from field: max. 307 µg/m^3 (24-36h). Multidirectional Average: 64 µg/m^3

1.5 m, 125 m from field: max.514 µg/m^3 (24-36 h). Multidirectional Average: 41.0 µg/m^3

1.5 m, 500 m from field: 139 µg/m^3 (24-36h). Multidirectional Average: 16.4 µg/m^3

1.5 m, 800 m from field: 169 µg/m^3 (0-4h). Multidirectional Average: 14 µg/m^3

Location: Hookerton, North Carolina,US

Study type: volatilisation monitoring for 14 days

Number of applications: 1

Application rate : 187 L/ha

Maximum measured air concentration for 14 days field:

1.5 m, edge of field: max 302µg/m^3 (12-16h). Multidirectional average: 36.6 µg/m^3 .

1.5 m, 25 m from field: max. 357 µg/m^3 (0-4h). Multidirectional Average: 12.7 µg/m^3

1.5 m, 125 m from field: max. 254 µg/m^3 (0-4h). Multidirectional Average: 4.9 µg/m^3

1.5 m, 500 m from field: max. 83.4 µg/m^3 (0-4 h). Multidirectional Average: 1.3 µg/m^3

1.5 m, 800 m from field: 57.2 µg/m^3 (0-4h). Multidirectional Average: 1.1 µg/m^3

Location: Harquahala Valley, Arizona,US

Study type: volatilisation monitoring for 14 days

Number of applications: 1

Application rate : 112 L/ha

Maximum measured air concentration for 14 days field:

1.5 m, edge of field: max 2212µg/m^3 (8-12h). Multidirectional Average: 165 µg/m^3 .

1.5 m, 25 m from field: max. 3415 µg/m^3 (24-36h). Multidirectional Average: 110 µg/m^3

1.5 m, 125 m from field: max. 1633 µg/m^3 (4-8h).

	Multidirectional Average: 53.9µg/m^3 1.5 m, 500 m from field: max. 461µg/m^3 (8-12h). Multidirectional Average: 11.7µg/m^3 1.5 m, 800 m from field: 206µg/m^3 (8-12h). Multidirectional Average: 6.5µg/m^3 1.5 m, 1200 m from field: 168 µg/m^3 (8-12h). Average: 3.8 µg/m^3 1.5 m, 1600 m from field: 87 µg/m^3 (8-12h). Multidirectional Average: 2.4µg/m^3 **Location**: Rio Grande Valley, Texas, US Study type: volatilisation monitoring for 14 days Number of applications: 1 Application rate : 80 L/ha (drip) Maximum measured air concentration for 14 days field: 1.5 m, edge of field: max 1157µg/m^3 (6-12 h). Multidirectional Average: 26.7 µg/m^3 . 1.5 m, 30 m from field: max. 540µg/m^3 (6-12h). Multidirectional Average: 11.3 µg/m^3 1.5 m, 90 m from field: max. 251 µg/m^3 (6-12 h). Multidirectional Average: 4.3 µg/m^3 **Location**: Salinas Valley, California US Study type: volatilisation monitoring for 21 days Number of applications: 1 Application rate : 242 Kg/ha (drip irrigation) Height: 1.5 m above the field Maximum flux 51.9 mg/m^2 /h after application Total mass loss: 28.9 % of applied
Metabolites	No data submitted no required

PEC (air)

Method of calculation	No data submitted. See volatilization studies section

PEC$_{(a)}$

Maximum concentration	See volatilization studies section

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: 1,3-Dichloropropene (Z+E isomers), 3-chloroallyl alcohol, 3-chloroacrylic acid Surface water: 1,3-dichloropropene (Z+E isomers) 3-

	chloroallyl alcohol, 3-chlroacrylic acid. Sediment: None Ground water: 1,3 dichloropropene (Z+E isomers), 3-chloroallyl alcohol, 3-chloroacrylic acid. Air: 1,3-dichloropropene (Z+E isomers)

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

Soil (indicate location and type of study)	No data provided - none requested
Surface water (indicate location and type of study)	Survey of 1,3-D monitoring programmes across Europe. Data available for Germany, Ireland and Netherlands Active substance: Netherlands peak at 2.5 µg/L (before 1993) Creek Basin, Ontario. Monitoring : cis-1,3-D 2.18 µg/L; trans –1.3-D 2.59 µg/L
Ground water (indicate location and type of study)	**Monitoring tap wells from April 2000 to April 2001 in the following US areas**: Central Columbia Plateau; Upper Snake River Basin; Georgia/Florida Drainage Basin. Active substance: peaks between LOQ (0.05 µg/L) and LOD (0.015 µg/L) in Central Columbia Plateau, Upper Snake River Basin, North Platte River Basin, Georgia/Florida Drainage Basin. 3-chloroacrylic acid: < 0.05 to 0.12 µg/L in Arbemarle/Pamlico Sound Basin, 0.05 to 0.07 in Central Columbia Plateau. **Survey of 1,3-D monitoring programmes across Europe.** Data available for Germany, Ireland and Netherlands Active substance: Netherlands 12.4 µg/L (prior to1993) **Monitoring groundwater wells from 2002 to 2004 in the following EU countries:** France, Italy, Spain, UK All countries except Spain no Parent, 3-chloroallyl alcohol or 3-chloroacrylic acid residues determined >0.1µg/L Spain: no Parent or 3-chloroallyl alcohol residues determined >0.1µg/L Confirmed residues of 0.085, 0.116 and 0.094 µg/L of cis 3-chloroacrylic acid were found in 3 out of 50 samples taken in Cáceres region. Confirmed residues of 0.05 and 0.413 µg/L of the trans 3-chloroacrylic acid were found 2 out of 50 samples taken in the Cáceres region. All other samples had no detectable residues.

	Greece; Monitoring of groundwater wells from January 2006 to October 2007 No detectable residues of 1,3-D, 3-chloroacrylic acid or 3-chloroallyl alcohol were found in any of the samples from any of the sample timings. No detectable residues of any of the 6 process impurities included in the monitoring were found in any of the samples from October 2006 to October 07 apart from a residue of 1,2-dichloropropane (1,2-D) ranging from 0.11 µg/L to 0.25 µg/L in one well in the Timbaki region. Extra sampling was proposed in an attempt to identify the possible source of 1,2-D The extra water samples contained residues of 1,2-D ranging from 0.11 µg/L to 0.34 µg/L **As only the 1,2-D impurity was seen in one of the sampling regions (Timbaki well B13HER007) with none of the other process impurities seen (including 2 closely related impurities which are present at higher levels in the 1,3-D technical product), a non-1,3-D source of 1,2-D is suggested for the presence of this impurity around the Timbaki well.**
Air (indicate location and type of study)	See volatilization section

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Not readily biodegradable

Effects on non-target Species

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail	Technical 1,3-D and formulate	Acute	LD_{50} = 139.8 mg a.s./kg $_{bw}$	
Bobwhite quail	Metabolite 1	Acute	Not data	
Anas platyrhynchos	Technical 1,3-D and formulate	Short-term	LD_{50}> 1264	6243
Bobwhite quail	Technical 1,3-D and formulate	Long-term	NOEL = 36	
Mammals ‡				
Rat	Technical 1,3-D	Acute-oral	130 mg a.s./kg bw	
Rat	Technical 1,3-D	Acute inhalation	LD_{50} = 2.7 mg a.s./L	
Rat	Preparation	Acute		
Mice	Metabolite 1	Acute	Not data	
Rat	a.s.	Long-term, 2 years (oral)	NOAEL = 2.5 mg (f/m).	
Rat	a.s.	Short-term, 90 days oral	NOAEL = 5	
Rabbit	a.s.	Reproduction study, inhalation	NOAEL = 0.0908 mg a.s./L	
Additional higher tier studies ‡				

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

Crop and application rate

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 – uptake via diet (Birds)				
Herbivorous bird-224 kg as/ha	Acute		See refinement	10
Birds feeiding earthworms-224 kg as/ha	Acute	87	1.6	10
Insectivorous bird-224 kg as/ha	Acute	78.8	1.7	10

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Herbivorous bird-224 kg as/ha	Short-term		See refinement	10
Birds feeding earthworms-224 kg as/ha	Short-term	15.4	> 82	10
Insectivorous bird-224 kg as/ha	Short-term	15.4	> 82	10
Birds feeding earthworms-187 kg as/ha	Acute	68	2.03	10
Insectivorous bird-187 kg as/ha	Acute	65	2.15	10
Birds feeding earthworms-187 kg as/ha	Short-term	1.41	> 99	10
Insectivorous bird-187 kg as/ha	Short-term	12.7	> 99	10
Higher tier refinement – uptake via diet (Birds)				
Herbivorous bird-224 kg as/ha	Acute	<0.00152	> 91000*	10
Insectivorous bird-224 kg as/ha	Acute	1.58	88*	10
Birds eating earthworms-224 kg as/ha	Acute	0.44	320	10
Herbivorous bird-224 kg as/ha	Short-term	<0.00152	> 830000*	10
Insectivorous bird-224 kg as/ha	Short-term	1.58	> 790*	10
Birds eating earthworms-224 kg as/ha	Short-term	0.44	> 2800*	10
Herbivorous bird-224 kg as/ha	Long-term	<0.00152	> 23000*	5
Insectivorous bird- 224 kg as/ha	Long-term	1.58	23*	5
Birds eating earthworms-224 kg as/ha	Long-term	0.44	82*	5
Tier 1– uptake via drinking water (Birds)				
	Acute		Not relevant	10
Tier 1 – secondary poisoning (Birds)				
Earthworm-eating bird	Long-term		Not relevant	5
Fish-eating bird	Long-term		Not relevant	5
Tier 1– uptake via diet (Mammals)				
Insectivorous mammals-187 kg as/ha	Acute	39.36	2.8	10
Mammals (uptake insects/worms)-187 kg as/ha	Acute	34.21	4.0	10

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Herbivorous mammals- 224 kg as/ha	Acute		See refinement	10
Insectivorous mammals-224 kg as/ha	Acute	41.9	3.1	10
Mammals (uptake wormsworms)-224 kg as/ha	Acute	92.8	1.4	10
Mammals-224 kg as/ha	Acute inhalation	5293 µg a.s/m^3	510	10
Herbivorous mammals-224 kg as/ha	Long term oral		See refinement	5
Mammals (uptake insects/worms)-224 kg as/ha	Long-term	0.75	3.3	5
Mammals-224 kg as/ha	Long-term (inhalation)	5293 µg as/m^3	102	5
Mammals (uptake insects)-187 kg as/ha	Acute oral	34	3.8	10
Mammals (uptake earthworms)-187 kg as/ha	Acute oral	75.6	1.72	10
Mammals (uptake insects/worms)-187 kg as/ha	Long-term (oral)	0.62	4.0	5
Higher tier refinement – uptake via diet (Mammals)				
Herbivorous mammals- 224 kg as/ha	Acute oral	<0.00278	> 46700*	10
Insectivorous mammals-224 kg as/ha	Acute oral	0.96	135*	10
Mammals eating earthworms-224 kg as/ha	Acute oral	0.56	232*	
Herbivorous mammals- 224 kg as/ha	Long-term oral	<0.00278	> 1798*	5
Insectivorous mammals-224 kg as/ha	Long-term oral	0.96	5.2*	5
Mammals eating earthworms-224 kg as/ha	Long-term inhalation	0.56	8.9*	5
Tier 1– uptake via drinking water (Mammals)				
	Acute		Not relevant	10
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammals	Long-term		Not relevant	5
Fish-eating mammals	Long-term		Not relevant	5

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)- *TER refined values using specific residue data

[2] for cereals indicate if it is early or late crop stage

[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

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 (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Sheepshead minnow Cyprinodon variegates	Technical (1,3-D 96 %)	96 hr (flow-through)	Mortality, EC_{50}	0.87
Rainbow trout *Oncorynchus mykiss*	Technical (1,3-D 100 %)	96 hr (flow-through)	Mortality, EC_{50}	2.78
Fathead minnow *Pimephales promelas*	Technical (1,3-D 96%)	33d- Chronic (early life stage)	Growth NOEC	0.032
Fathead minnow Pimephales promelas	(*EZ*)-3-chloroacrylic acid	33d- Chronic (early life stage)	Growth NOEC	2.22
Oncorhynchus mykiss	(*EZ*)-3-chloroallyl alcohol	96 hr (flow-through)	Mortality, EC_{50}	0.986
Oncorhynchus mykiss	(*EZ*)-3-chloroacrylic acid	96 hr (flow-through)	Mortality, EC_{50}	69.5[3]
Aquatic invertebrate				
Daphnia magna	Technical (1,3-D 100 %)	48 h (static)	Mortality, EC_{50}	3.58
Eastern oyster *Crassotrea virginica*	Technical (1,3-D 96%)	48 h (static)	Mortality, EC_{50}	0.64
Daphnia magna	Technical (1,3-D 96%)	21 d (static)	Reproduction, NOEC	0.0701
Daphnia magna	(*EZ*)-3-chloroallyl alcohol	48 h (static)	Mortality, EC_{50}	2.30
Daphnia magna	(*EZ*)-3-chloroacrylic acid	48 h (static)	Mortality, EC_{50}	55.0
Daphnia magna	Technical (1,3-D 96%)	21 d (static)	Reproduction, NOEC	0.0701

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Daphnia magna	(*EZ*)-3-chloroacrylic acid	21 d (static)	Reproduction, NOEC	2.53
Sediment dwelling organisms				
Chironomus riparius	a.s.	28 d (static)	NOEC	Not data
Chironomus riparius	Metabolite 2	28 d (static)	NOEC	Not data
Algae				
Navicula Pelliculosa	Technical (1,3-D 96%)	120 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Cell density: EC_{50}	3.64 5.84 2.35[2]
Selenastrum capricornutum	Technical (1,3-D 96%)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	14.9 13.6
Anabaena flosaquae	Technical (1,3-D 96%)	120 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Cell density: EC_{50}	64.3 96.3 62.58
Skeletonenam costatum	Technical (1,3-D 96%)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	13.4 18.7
Skeletonema costatum	(*EZ*)-3-chloroallyl alcohol	120 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Cell density: EC_{50}	0.49 0.637 0.727[2]
Selenastrum capricornutum	(*EZ*)-3-chloroacrylic acid	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Cell density: EC_{50}	0.663 1.746 0.691
Higher plant				
Lemna gibba	Technical (1,3-D 96%)	14 d (static)	Cell density: EC_{50}	14.56[2]
Lemna gibba	(*EZ*)-3-chloroallyl alcohol	14 d (static)	Cell density: EC_{50}	0.454[2]
Lemna gibba	(*EZ*)-3-chloroacrylic acid	14 d (static)	Cell density: EC_{50}	0.26mm
Microcosm or mesocosm tests				
Indicate if not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.
[2] Results based on initial measured concentrations of 1,3-D,
[3] Low quality data, confidential limits are too high due to the lack of intermeddle results on mortality effects.

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

Maximum PEC_{sw} values and TER values for 1,3-D – application to tomatoes at 224 kg a.s./ha

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	Fish prolonged	Fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Aquatic plant	Microcosm/ Mesocosm
			C. variegates	***P. promelas***	***O. mykiss***	***Crassotea v.***	***Daphnia magna***	***Navicula pelliculosa***	***L. gibba***	
			LC_{50}	NOEC	ND	EC_{50}	NOEC	EC_{50}	EC_{50}	ND
			870 µg/L	32 µg/L*		640 µg/L	70.1 µg/L	2350µg/L	14560	
PECsw[1]	3.2		**271**	**10**		**200**	**22**	**733**	**4550**	
Annex VI Trigger			100	10	10	100	10	10	10	5

[1] PECsw calculations have been conducted with CHAIN-2D CODE model

Maximum PEC_{sw} values and TER values for 1,3-D – Indoor use at 283 kg a.s./ha by drip irrigation

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	Fish prolonged	Fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Aquatic plant	Microcosm/ Mesocosm
			C. variegates	***P. promelas***	***O. mykiss***	***Crassotea v.***	***Daphnia magna***	***Navicula pelliculosa***	***L. gibba***	
			LC_{50}	NOEC	ND	EC_{50}	NOEC	EC_{50}	E_bC_{50}	ND
			870 µg/L	32 µg/L		640 µg/L	70.1 µg/L	2350µg/L	14560	
PECsw[1]	1.4		**621**	**22**		**457**	**50**	**1678**	**3257**	
Annex VI Trigger			100	10	10	100	10	10	10	5

[1] PECsw calculations have been conducted with CHAIN-2D CODE model

Maximum PEC_{sw} values and TER values for 1,3-D metabolite 3-chloroallyl alcohol – application to tomatoes at 224 kg /ha

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	Fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Aquatic plant	Microcosm/ Mesocosm
			O. mykiss	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***Skelotonema costatum***	***L. gibba***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	E_yC_{50}	ND
			986		2300		492	454	
PECsw[1]	2.67		**369**		**860**		**184**	**170**	
Annex VI Trigger			100	10	100	10	10	10	5

[1] PECsw calculations have been conducted with CHAIN-2D CODE model

Maximum PEC_{sw} values and TER values for 1,3-D metabolite 3-chloroacrylic acid – application to tomatoes at 224 kg /ha

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	Fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Aquatic plant	Microcosm/ Mesocosm
			O. mykiss	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***Selenastrum capricornutum***	***L. gibba***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	E_yC_{50}	ND
			69500	2220	55000	2530	663	260	
PECsw[1]	3.077		**22587**	**721**	**17875**	**822**	**215**	**84**	
Annex VI Trigger			100	10	100	10	10	10	5

[1] PECsw calculations have been conducted with CHAIN-2D CODE model

Maximum PEC_{sw} values and TER values for 1,3-D metabolite 3-chloroallyl alcohol – Indoor use at 283 kg a.s./ha by drip irrigation

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	Fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Aquatic plant	Microcosm/ Mesocosm
			O. mykiss	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***Skelotonema costatum***	***L. gibba***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	E_yC_{50}	ND
			986		2300		492	454	
PECsw[1]	1.16		**850**		**1982**		**626**	**391**	
Annex VI Trigger			100	10	100	10	10	10	5

[1] PECsw calculations have been conducted with CHAIN-2D CODE model

Maximum PEC_{sw} values and TER values for 1,3-D metabolite 3-chloroacrylic acid – Indoor use at 283 kg a.s./ha by drip irrigation

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	Fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Aquatic plant	Microcosm/ Mesocosm
			O. mykiss	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***Selenastrum capricornutum***	***L. gibba***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	E_yC_{50}	ND
			69500	2220	55000	2530	663	260	
PECsw[1]	1.34		**51865**	**1913**	**41044**	**2181**	**515**	**194**	
Annex VI Trigger			100	10	100	10	10	10	5

[1] PECsw calculations have been conducted with CHAIN-2D CODE model

Buffer zones of 3 m are needed to protect aquatic organisms

	1,3-Dichloropropene
$logP_{O/W}$	Not required Log Kow = 1.82 *cis* Log Kow = 2.10 *trans* and very quick dissipation
Bioconcentration factor (BCF)[1] ‡	X*
Annex VI Trigger for the bioconcentration factor	
Clearance time (days) (CT_{50})	Not required
(CT_{90})	
Level and nature of residues (%) in organisms after the 14 day depuration phase	Not required

[1] only required if log $P_{O/W}$ >3.
* based on total ^{14}C or on specific compounds

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

Test substance	**Acute oral toxicity (LD_{50} µg/bee)**	**Acute contact toxicity (LD_{50} µg/bee)**	**Acute inhalator toxicity**
1,3-D technical substance	Not necessary. The product is applied subsoil, preemergence	Not necessary. The product is applied subsoil, preemergence	48-h inhalation LC_{50} =831 mg/m^3 NOEC inhalation = 115 mg/m^3 (0.5-6h)
Preparation[1]			
Metabolite 1			
Field or semi-field tests			
Indicate if not required			

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

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

Crop and application rate

Test substance	**Route**	**Hazard quotient**	**Annex VI Trigger**
1,3-D technical and formulate	Inhalation	$NOEC_{inhalation}$/maximum PEC_{air} = 115/5.793 = 19	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡		Mortality	
Aphidius rhopalosiphi ‡		Mortality	

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Crop and application rate

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
	Typhlodromus pyri				2
	Aphidius rhopalosiphi				2

[1] indicate distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (kg as/ha)	End point	% effect	Trigger value
Folsomia candida	Adults	Telone, LUFA treated soil aged, 22 days	329	Mortality 1DAT	**78**	50 %
Hypoaspis aculeifer	Adults	Telone, LUFA treated soil aged, 22 days	329	Mortality 1DAT	18	50 %
Poecilus cupreus	Adults	Telone, LUFA treated soil aged, 22 days	329	Mortality 1DAT	3	50 %
Pardosa spp	Adults	Telone, LUFA treated soil aged, 22 days	329	Mortality 1DAT	0	50 %
Aleochara bilineata	Adults	Telone, LUFA treated soil aged, 28 days	329	Mortality 1DAT	24	50%

Field or semi-field tests

A field study (Ellis, 2001) was presented but it has been considered observational since it did not have a truly randomised design and the interpretation of results could be potentially confounded by the position of control and treated plots. For all species the number of individuals is too low for attempting an interpretation of results.

A new field study conducted under realistic agronomic in S. Europe shows that not statistical significant effects were observed for macroarthoprods and microarthopods investigated in Telone II treated and untreated plots at any of the post-treatment sampling intervals for an application rate of 224 kg as/ha (soil injection). It was agreed in PRAPeR TC 16 (September 2009) that the new field study should only be used to refine the risk assessment for the intended use (tomatoes and soil injection) and only in case the statistical power of the field study could be confirmed.

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
	Telone 97 (99.3% 1,3-D)	Acute 14 days	LC_{50} = 55.6 mg a.s./kg soil
	Telone 97 (99.3% 1,3-D)	Chronic 8 weeks	NOEC =770 mg a.s./kg soil (577 kg/ha) (from a 1 week aged study)
Field studies[2]			
Field study The EPCO Expert's meeting agreed to await the announced new field study in UK potato fields to address the several comments which were raised on the existing study. A study conducted by Luhrs (2002) to evaluate the effects of 1,3-D on earthworm populations in the field was evaluated by the RMS and summarised in the DAR. The study was considered acceptable by the RMS and showed that earthworm abundance and biomass was substantially decreased 3.5 weeks after treatment with 1,3-D **at 363 kg/ha**. After 4.5 months, however, both earthworm abundance and biomass had recovered to values comparable to those of the "agricultural control". Overall, full recovery of the earthworm populations in 1,3-D treated plots was evident within 4.5 months following application with 1,3-D at 363 kg/ha. A study has been conducted to evaluate the effects of Telone II, applied at 190 L/ha (224 kg a.s./ha), on earthworms (and soil arthropods) in Southern Europe (Small, 2006). The effects on earthworms were transient, lasting less than 6 months, with no difference in earthworm abundance between treated and untreated plots detected at 6, 9 or 12 months post-treatment. It was agreed in PRAPeR TC 16 (September 2009) that the new field study should only be used to refine the risk assessment for the intended use (tomatoes and soil injection) and only in case the statistical power of the field study could be confirmed. Furthermore, the results of a field survey conducted in inhabiting field sites in three counties of Sicily (Italy), where fumigation/sterilisation may be required for the control of nematodes showed that small numbers of earthworms were found it during November 2005 and February 2006.			
Other soil macro-organisms			
Soil mite	1,3-D Technical‡		
	Preparation		
	Metabolite 1		
Collembola			
	a.s. ‡	Chronic	NOEC mg a.s./kg d.w.soil (mg a.s/ha)
	Preparation		
	Metabolite 1		
Soil micro-organisms			
Nitrogen mineralisation	1,3-D Technical ‡		Technical: Important effects (above 25%) at 0.77 and 3.85 g Telone II/kg soil up to 90 days (end of study).

Test organism	Test substance	Time scale	End point[1]
Carbon mineralisation	1,3-D Technical ‡		Technical: Important effects (above 25%) at 0.77 and 3.85 g Telone II/kg soil up to 90 days (end of study).
Field studies[2]			
A field treated with 363 kg/ha of Telone recovered the soil respiration rate (25% respect control) after 102 days from application; however nitrogen turnover recovered at above level after 184 days. A new study conducted in S Europe shows that a field treated with 190 L/ha (= 224 kg/ha injected to the soil) Telone II did not have any significant long lasting effects on soil respiration or nitrogen turnover. Recovery was showed within 4.5 months of treatment. Soil function was not significantly different to that of untreated soils (less than 25% deviation) after 4.5 months post-treatment. For collembolan see comments to field study by Small (2006) in the table above.			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

Crop and application rate

Test organism	Test substance	Time scale	Soil PEC[2]		TER	Trigger
Earthworms						
224-283 (injection &drip)	Technical 1,3-D and preparation‡	Acute	5 cm 20 cm	377.33 74.66	0.15 0.74	10
224 (injection)	Technical 1,3-D and preparation ‡	Acute	5 cm 20 cm	298.66 49.77	0.18 1.11	10
224 (injection)	Technical 1,3-D and preparation	Chronic Aged soil 1 week	5 cm 20 cm	298.66 49.77	2.6 15	5 5
224 (injection)	Technical 1,3-D and preparation	Chronic Aged soil 3 weeks	5 cm 20 cm	298.66 49.77	13 77	5 5
Other soil macro-organisms						
Soil mite	a.s. ‡					
	Preparation					
	Metabolite 1					
Collembola	a.s. ‡					
	Preparation					
	Metabolite 1					

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Most sensitive species	**Test substance**	**ER_{50} vegetative vigour**	**ER_{50} Seedling emergence**	**Exposure[1] (mg as/kg soil)**	**TER**	**Trigger**
tomato soybean	1,3-D technical substance	3.8 mg as/kg soil onion	7.4 mg as/kg soil Soy bean	1m 1.6 3m 0.006 5m <0.001	**4.6** 1233 >7400	5
	(EZ)-3-chloroallyl alcohol	> 1.6 mg as/kg soil	> 1.6 mg as/kg soil	1m 1.6 3m 0.006 5m <0.001	**1** 266 > 1600	5
	(EZ)-3-chloroacrylic acid	> 0.53 mg as/kg soil	> 0.53 mg as/kg soil	1m 1.6 3m 0.006 5m <0.001	**0.33** 88 530	5

1 Wang et al (2005) for the upper 30 cm soil profile

Mitigation measure

Buffer zones of 3 m are needed to protect non target plants

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	No reliable studies available
Pseudomonas sp	No reliable studies available

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

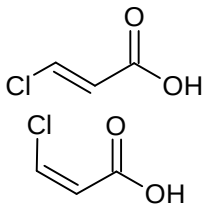
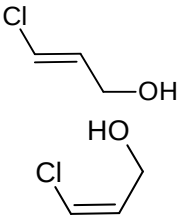
Compartment	
soil	1,3-Dichloropropene (Z+E isomers), 3-chloroallyl alcohol, 3-chloroacrylic acid
water	3-dichloropropene (Z+E isomers) 3-chloroallyl alcohol, 3-chloroacrylic acid.
sediment	None
groundwater	1,3 dichloropropene (Z+E isomers), 3-chloroallyl alcohol, 3-chloroacrylic acid.
Air	1,3-dichloropropene (Z+E isomers)

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	R50/R53 Very toxic to aquatic organisms, may cause long-term adverse effect to the aquatic environment

	RMS/peer review proposal
Preparation	R50/R53 Very toxic to aquatic organisms, may cause long-term adverse effect to the aquatic environment

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
(EZ)-3-chloroacrylic acid	(2*E*)-3-chloroprop-2-enoic acid (2*Z*)-3-chloroprop-2-enoic acid	
(EZ)-3-chloroallyl alcohol	(2*E*)-3-chloroprop-2-en-1-ol (2*Z*)-3-chloroprop-2-en-1-ol	

ABBREVIATIONS

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