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

1,3-dichloropropene

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(version of 14 June 2006 with minor editorial changes marked yellow)

SUMMARY

1,3-Dichloropropene is one of the 52 substances of the second stage of the review programme covered by Commission Regulation (EC) No 451/2000[1], as amended by Commission Regulation (EC) No 1490/2002[2]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Spain being the designated rapporteur Member State submitted the DAR on 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 originally consisted of Dow AgroScience B.V. and BASF Agro B.V. BASF sold the business of 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 final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 8 February 2006 leading to the conclusions as laid down in this report.

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 grew. The application rates are up to 283 kg 1,3-dichloropropene per hectare ("EF-1478") and up to 224 kg per hectare

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

("XRM-5048"), respectively. 1,3-dichloropropene can be used as nematicide, insecticide, fungicide and herbicide, depending on the dose rate used. In general, an application of 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 Greece, Italy and Spain 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 definition. 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 at least limited quality control measurements of the plant protection product are possible.

The toxicological risk assessment (and reference values) is considered to be inconclusive due to uncertainties in relation to the mutagenic and carcinogenic properties. 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 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”.
The weight of evidence indicates that 1,3-dichloropropene 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 is proposed.
1,3-dichloropropene 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. However, the mechanism of action for tumour formation has not been yet identified. Although, results indicate that 1,3- dichloropopene can be mutagenic, the relevance of these results to mammalian tumour formation is uncertain owing to the high concentrations or doses used. The issue was to be forwarded to the PPR panel. The classification as possible human carcinogenic Category 3, R40? is highlighted. No reproduction toxicity or neurotoxicity was observed. The metabolites 3-chloroallyl alcohol and 3-chloroacrylic acid are both toxic.
Dependent on the identity on the polychlorinated imp, it might be necessary to require new toxicological studies.

According to medical data, 1,3-dichloropropene should be classified as irritating to eyes (R36) and to irritating to respiratory system (R37). Furthermore, it is proposed to classify as R65 "Harmful, may cause lung damage if swallowed" due observed the adverse effects,
The provisional Acceptable Daily Intake (ADI) ADI is 0.0125 mg/kg bw/day, with the use of the safety factor of 200. The additional safety factor of 2 was added in order to have at least 1000 between the ADI and the dose level where tumours are evident. The provisional systemic Acceptable Operator Level (AOEL) is 0.1 mg/kg bw/day, safety factor 100.
As inhalation exposure is the main route of exposition and all data from operator exposure are expressed as atmospheric concentration (mg/m^3), an additional inhalatory human AOEC was assigned which is 0.066 ppm, equivalent to 0.30 mg/m^3 however should be considered as provisional. The ARfD is 0.2 mg/kg bw, with the safety factor of 100 added**.**
The 1,3-dichloropropene is applied to bare soil and consisted of two scenarios. The estimations are based on field measurements. However, the estimated operator exposure should be considered only as indicative due to the uncertainties in relation to the mutagenic and carcinogenic properties. For both uses drip irrigation and soil injection, PPE (gloves and coverall) and RPE (respiratory mask with filter for organic vapours) is needed in order not to exceed the AOEL (16% and 38%, respectively). The exposure for workers and bystanders should be negligible.

The degradation and metabolism of 1,3-D has been studied comparatively in fruit (tomatoes and citrus), root vegetables (sugar beets), and 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.
However, it is stressed that the available studies don't provide any information regarding the residue behaviour of the chlorinated impurities present in the technical material that are added to soil at a high level (up to *ca* 6 kg/ha) when applying 1,3-D at the intended rate. There is no information on possible persistency, uptake, accumulation or metabolic fate and residue level of those chlorinated impurities, whether of known or unknown type, and moreover data on their toxicological properties are not available. This lack of data gives rise to concern in respect of consumer safety, even though potential chronic and acute dietary exposure to residues of 1,3 D per se from tomatoes and peppers is well below (<1%) the ADI and ARfD, respectively.

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 1,3-dichloropropene exhibited very high to high mobility. (*EZ*)-3-chloroaryl 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 1,3-dichloropropene from the systems. 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 for the drip irrigation application in glasshouses. There is a data gap for acceptable concentration estimates from the outdoor uses, where the exposure from the drainage and runoff routes of entry need to be appropriately assessed. Member State experts' considered that potential deposition from the air to surface water should also be considered by the notifier when providing aquatic PEC from the outdoor uses notified.

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. However data requirements for further information regarding aspects of this monitoring have been identified. These identified deficiencies should be addressed before this monitoring work is used for regulatory decision making.

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. There is a data gap identified to provide information that these measured flux losses under American geoclimatic conditions are also pertinent to EU geoclimatic conditions. Member State experts' and the EFSA considered sufficient information has been provided to conclude that the 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.

Bridging studies are needed if new impurities are identified in the new five batch analysis which are not covered by the batches tested in the section on ecotoxicology. As the relevance of the impurity 1,2-dichloropropane was not discussed during the peer review process, the EFSA proposes the applicant to addresses the ecotoxicological relevance of this impurity. The levels of 1,2-dichloropropane in the ecotoxicological studies must be confirmed if considered relevant.

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 is identified for the outdoor uses. Data to address these risks is still awaited. 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 for the outdoor uses can only be concluded once the outstanding data requirements become 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. Algae and *Lemna gibba* are more sensitive to the metabolites (EZ)-3-chloroallyl alcohol and (EZ)-3-chloroacrylic acid than to the parent compound. Long term studies with the metabolite (EZ)-3-chloroacrylic acid on fish and *Daphnia magna* are requested as this metabolite has been identified and requires further consideration based on potential levels in ground and surface water. 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. The risk to aquatic organisms from the direct soil injection method of application indoors and outdoors, can only be concluded once the PEC in surface water become available (see 4.2.1 and 5.2). 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. The risk for bioconcentration in fish for 1,3-dichloropropene and metabolites (EZ)-3-chloroallyl alcohol and (EZ)-3-chloroacrylic acid is considered to be low.

An inhalation study with bees and a calculation of relevant PEC values to conduct the risk assessment for the inhalation toxicity to bees is requested as the active substance can be found in the air even at distances of 800 m from the treated field.

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. Given the observed effects on *Folsomia candida* the rapporteur Member State asked the applicant to further address the risk to non-target arthropods for the outdoor uses.

A high acute risk to earthworms was observed. The announced new field study in UK potato fields is still awaited to address several comments which were raised on the existing earthworm field study. The long term risk to earthworm from exposure to 7 day old treated soil can be regarded as low. The acute and long term risk to earthworms exposed to freshly treated soil can only be concluded once the outstanding field data become available. The rapporteur Member State considers that this data gap only applies to the outdoor uses.

Effects from 40.23% to 96.9% on soil microbial respiration and nitrogen transformation 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 to address this concern was discussed at the EPCO experts' meeting and the meeting identified the need for a new field study to address this risk which should also cover the concern for the effects from the soil metabolites. The rapporteur Member State considers that this data gap only applies to the outdoor uses.

Regarding the indoor uses, the EFSA would like to point out that earthworms, soil micro-organisms, *F. candida* and other soil non-target arthropods are likely to come into contact with 1,3-dichloropropene as the product is applied to full soil. This could affect the function of the soil indoors.

A potential risk to non-target plants was identified. The EPCO Expert's meeting decided that the risk should be more quantified and TER values at a few metres from the field should be calculated. The risk to non-target plants can only be concluded once this risk assessment becomes available.

It cannot be excluded that 1,3-D might be harmful if the waste water goes to sewage treatment plants.

Key words: (*EZ*)-1,3-dichloropropene, peer review, risk assessment, pesticide, nematicide, insecticide, fungicide, herbicide

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BACKGROUND

Commission Regulation (EC) No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No 1490/2002, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. 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 1,3-dichloropropene, hereafter referred to as the draft assessment report, 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 ~~main~~ applicant Task Force originally consisted of Dow AgroScience B.V. and BASF Agro B.V. BASF sold the business of 1,3-dichloropropene to Kanesho Soil Treatment BVBA on 17 December 2003 and therefore was replaced in the Task Force as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed in an evaluation meeting on 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.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 8 February 2006 leading to the conclusions as laid down in this report.

Following the consultation of experts a question in relation to the mechanism of the tumours observed in rat and mouse it 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 considers 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 are numerous data requirements and data gaps identified for 1,3-dichloropopene which should also be considered.

In accordance with Article 8(7) of the amended Regulation (EC) No 451/2000, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

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

- the comments received
- the resulting reporting table (rev. 1-1 of 10 December 2004)
- the consultation report

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

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 6 March 2006)

Given the importance of the draft assessment report including its addendum (compiled version of September 2005 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

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.

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, it has, depending on the dose rate, various secondary effects

(insecticidal, herbicidal, fungicidal) on a variety of organisms. In general, an application of 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 were, "Telone EC Drip" ("EF-1478"), an emulsifiable concentrate (EC), registered under different trade names in Greece, Italy and Spain 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).

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 grew. Application rates up to 283 kg 1,3-dichloropropene per hectare ("EF-1478") and up to 224 kg per hectare in ("XRM-5048"), have been presented for evaluation. 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 nematicide will be supported in the EU review programme.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of 1,3-dichloropropene as manufactured should not be less than 965 g/kg (at least 430 g/kg the of the *Z*- or *cis*-and 300 g/kg of the *E*- or *trans* isomer)[3], both isomers have been considered to contribute to the pesticidal activity. At the moment no FAO specification exists. It should be noted that applicant DOW AgroSciences has submitted data for more than one production site. However, due to a data gap, only one source (first one on page 11 of Vol. 1, level 1) was included in the risk assessment conducted.
Moreover, it should be noted that both applicants (Task Force) want to cover the technical material by a joint specification. Therefore, no assessment on the equivalence of the technical materials was conducted. However, due to the fact that not all impurities of the joint specification were analysed in the technical material, it cannot be concluded at the moment whether the Kanesho source is in compliance with the specification [see also "*List of studies to be generated, still ongoing or available but not peer reviewed*" and corrigendum (addendum 2) to volume 4, September 2005].

The technical material contains 1,2-dichloropropane, which has to regarded as relevant from a toxicological point of view (DAR, Volume 4, p 10). The maximum content in the technical material should not be higher than 0.1 g/kg. Whether or not 1,2 dichloropropane has to be regarded as relevant

[3] 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.

from an ecotoxicological point of view was not discussed within the EU peer review process (see chapter 5).
In addition also the relevance of other impurities is still under discussion (polychlorinated impurities). Beside from an ecotoxicological point of view ("data are only necessary, if new impurities are identified") further data are necessary and required in the other sections (see chapter 2, 3 and 4). Therefore, the applicant has to provide data to identify the unidentified polychlorinated impurities. Depending on the outcome and depending on the assessment of their relevance it could be necessary to require further data.
Based on this, the specification as a whole should be regarded as provisional.

Beside this, the assessment of the data package revealed no particular area of concern.

The content of 1,3-dichloropropene in the representative formulations is 936 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 1,3-dichloropropene and its physical and chemical properties are given in appendix 1.

The following data gaps relating to physical, chemical and technical properties of the 1,3-dichloropropene and the formulations were identified during the peer-review: surface tension of *cis*-1,3-dichloropropene; hydrolysis study for *cis*-1,3-dichloropropene; data on the oxidising properties of 1,3-dichloropropene and the formulations; data on the acidity of the formulation "EF-1478"; data on the accelerated storage stability of "XRM-5048".
It should also be noted that the shelf-life study shows that the formulation "EF-1478" meets the FAO criteria not for longer than 6 months (loss of 1,3-dichloropropene). Furthermore, the emulsion characteristics might be considered at Member State, due to the fact that the cream content was high after 8 weeks (measurements done at 8 weeks, 6, 12 and 24 months).
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 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. It should be noted that an analytical method for the determination of 1,2-dichloropropane in the technical material as well as in the formulation "EF-1478" is required.
Nevertheless, 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 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).

The discussion in the expert meeting on identity, physical and chemical properties (EPCO 25, May 2005) and analytical methods included the specification of the technical material, physical, chemical and technical properties of 1,3-dichloropropene and the formulations as well as the analytical methods.

Recently submitted studies, regarding the a hydrolysis study for the *cis*-1,3-dichloropropene, oxidising properties of the 1,3-dichloropropene and the formulations, information about the acidity of the "EF-1478" formulation as well as an accelerated storage stability study for the "XRM-5048" formulation were neither peer reviewed by other MS nor discussed in an EPCO expert meeting. These studies are assessed by the rapporteur Member State. The evaluation of the rapporteur Member State is given in the evaluation table (17226/EPCO/BVL/04, rev. 1-0; 21.09.2005) or in the respective addenda to the DAR (Annex B.2, B.5 and C). Also the missing clarification with respect to the validity of the analytical method for food of plant origin is given in the evaluation table.
In addition, rapporteur Member State has received new studies regarding the surface tension of *cis*-1,3-dichloropropene, an analytical method for the determination of 1,2-dichloropropene in the technical material as well as in the "EF-1478" formulation and experimental data (EEC A21) on the oxidising properties.

2. Mammalian toxicology

1,3-Dichloropopene (1,3-D) was discussed at EPCO experts' meeting for mammalian toxicology (EPCO 23) in May 2005. Based on the available information, it can be concluded that the toxicological data package only covers the Dow source. As it is not confirmed that the Kanesho source is in compliance with the joint specification covers, this could have implications for the toxicological studies in the dossier (see chapter 1).
In relation to the mechanism of the observed 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 considers 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
1,3-dichloropopene was discussed at the Working Group Evaluation meeting in February 2006 and the MSs agreed to highlight the uncertainties in the carcinogenic potential in addition to a statement that the risk assessment should be regarded as inconclusive.

2.1 ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

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 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, chloroallyl alcohol and 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 inhalatory LC_{50} is around 3 mg/L air. 1,3-D is irritant to skin but not to eyes. But, according to medical data 1,3-D should be classified as irritant to eyes too and to the respiratory system (see 2.9). Furthermore, it is a skin sensitizer (Buehler test).

Classification for acute toxicity is needed and the proposed risk phrases are: T; R24/25 "Toxic by dermal exposure and if swallowed", R20 "Harmful by inhalation", R36/38 "Irritant to eyes and skin", R43 "May cause sensitization by skin contact" and R37 "Irritating to respiratory system".

2.3 SHORT TERM TOXICITY

The short term effects of 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.

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 ≅ 80 mg/kg bw/day), and females, aggregates of mononuclear cells in submucosa of urinary bladder (27 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 rule out 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 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 experts´ meeting. Some studies show clear indications for DNA fragmentation *in vivo*, however, negative results are demonstrated in micronucleus, UDS and dominant lethal tests. Finally, it was agreed that the weight of evidence indicates 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.**

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) was discussed at the 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 the 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.

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. 102 mg/kg bw/day) for chronic toxicity and 20 ppm for oncogenicity.

Conclusion

The experts 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 has not been yet identified.

Although, results indicate that 1,3- dichloropopene can be mutagenic, the relevance of these results to mammalian tumour formation is uncertain owing to the high concentrations or doses used (see 2.4). The mechanistic studies, using GSH levels as endpoint, which showed that 1,3- dichloropopene 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 1,3-dichloropopene 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 are lacking. Furthermore, concerns are raised due to the structural resemblance to known carcinogens.

The classification as 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?** is highlighted in the list of endpoints and should therefore be considered as provisional, until the mechanism of formation of tumours is known. The final decision is made at ECB.

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 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 1,3 dichloropopene was studied in rats and rabbits by inhalation exposure. In rats, maternal toxicity as reduction in body weights, body weight gains and food consumption were 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 fetal 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 bw 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

Neurotoxicological studies were performed and they are reported under other toxicological studies in the DAR (see B.6.8).

2.8 FURTHER STUDIES

Metabolites

Toxicokinetics study demonstrated that 3-chloroallyl alcohol and 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-chloroallylalcohol and 3-choroacrylic acid administered by gavage was evaluated in rats. 3-chloroallylalcohol induced decreases in fetal body weights at maternal toxic doses (25 mg/kg bw/day), and 3-choroacrylic acid, increases in total resorptions and decreases in fetal 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-chloroallylalcohol 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 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 1,3 dichloropropene, has been evaluated by means of the Salmonella/mammalian microsome assay.
Both urine and disulfide metabolite of 1,3 dichloropropene were not mutagenic. N-acetylcysteine, sulfoxide/sulfone, thioglycolic acid and cysteine conjugates of 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 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 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.

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%.

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 suggests 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, 1,3-D should be classified as irritating to eyes (R36) and to irritating to respiratory system (R37). Furthermore, it is 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.**

2.10 ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) and ACUTE REFERENCE DOSE (ARfD)

The reference values should be considered as provisional due to the mutagenic and carcinogenic properties of 1,3-dichloropopene.

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 1,3-dichloropopene and the mechanism is not clarified as well as its possible relevance for humans, an adequate margin of safety must be 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 is 0.0125 mg/kg bw/day, with the use of the safety factor of 200.

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.

The AOEL is 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 is a margin of safety of 1000 in relation to the observed tumours in the mouse at 100 mg/kg bw/day.

The AOEL is rounded to 0.1 mg/kg bw/day, safety factor 100.

During the 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 the systemic AOEL of 0.1 mg/kg bw/day which would correspond of a dose of 0.1 ppm.

The rapporteur Member State presented the information in Addendum III (September, 2005) thus it is not been peer reviewed.

The human equivalent 1,3-dichlorpropene concentration can be extrapolated from the formula below expressed, considering that the default respiration rates used are 0.26 m^3/kg day for human adults and 0.96 m^3/kg day for rats. The rats were exposed 6 hr daily for 5 days a week (13-week study). Human and rats appeared to have the same respiratory absorption (80%) and that 1 ppm = 4.5 mg/m^3.

$$\text{ppm (human)} = \text{ppm (animal)} \times \frac{\text{animal respiration rate}}{\text{human respiration rate}} \times \frac{\text{hours exposed}}{24\ \text{hr}} \times \frac{\text{days exposed/week}}{7\ \text{days}}$$

ppm in human = 0.1 x 0.96/0.26 x 6/24 x 5/7 = 0.1 x3.69 x 0.25 x 0.71 = 0.066 ppm

Therefore, the rapporteur Member State proposes an can establish a human inhalatory AOEC of 0.066 ppm, equivalent to 0.30 mg/m^3, which will be used for risk assessment. EFSA notes that this is in the same range as the one proposed originally in the DAR, 0.22 mg/m^3.

ARfD

The rapporteur Member State had not proposed an ARfD. However, at the 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.

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

The exposure assessments should be considered as inconclusive in relation to the mutagenic and carcinogenic properties of 1,3-dichloropopene 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.

Drip irrigation

It can be applied via drip irrigation, used for greenhouses and through the irrigation system, what 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 amend it.

New calculations (due to revised AOEC) of the exposure is presented in the Addendum III (September, 2005) which has not been peer reviewed.

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

Soil injection

This procedure is usually made by professional applicators that use 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) new calculations of the exposure are presented (due to revised AOEC)

PPE is 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) is worn the exposure is reduced to approximately 21-38% of the AOEC.

Worker exposure

Generally, the worker re-entering soon after treatment have to adopt the 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.

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.

Bystander exposure

Drip irrigation

Bystanders may be exposed to average levels ranging from 0.6 to 1.4 mg/m^3, which are higher than proposed AOEL of 0.3 mg/m^3. However, 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.

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. The levels of 1,3-D measured in the air near application were within the value of estimated AOEC of 0.3 mg/m^3.

3. Residues

1,3-Dichloropropene (1,3-D) was discussed in the experts' meeting for residues in May 2005 (EPCO 24).

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

Metabolism studies in tomatoes, oranges, sugar beets 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-chloro allyl 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 1,3-D.

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 has 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 cover the indoor use in fruiting vegetable in an addendum (September 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 stressed that the submitted studies were designed to investigate the residue behaviour of 1,3-D on thus don't provide any information regarding the residue behaviour of the chlorinated impurities present in the technical material. Those chlorinated impurities, whether of known or unknown type, are added to soil at a high level (up to *ca* 6 kg/ha) when applying 1,3-D at the intended rate. Therefore the experts' meeting for residues agreed on that further information from the applicant is required on the relevance of such chlorinated impurities in terms of consumer exposure and consumer safety.

3.1.2. 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.
Again, attention is invited to the lack of data concerning the fate of chlorinated impurities applied together with 1,3-D at comparably high levels (see 3.1.1 above).

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

The assessment of consumer risk demonstrates that with an ADI of 0.025 mg/kg bw and an MRL of 0.01 mg/kg, the theoretical maximum daily intake (TMDI) of adults for 1,3-D is equivalent to 0.6% of the ADI. Hence, it was concluded unlikely that any European diet will lead to a chronic dietary risk for consumers.
The acute dietary risk assessment for 1,3-D is based on the UK model (PSD) to assess short-term dietary intake of pesticide residues. The NESTI for both, tomatoes and peppers are well below (<1%) the ARfD of 0.2 mg/kg for adults and children, respectively. Therefore, it can be assumed that the potential acute dietary exposure to 1,3-D residues in very unlikely to pose a risk to consumers.

However, it is stressed that due to the high application rate intended for the use of 1,3-D the amount of chlorinated impurities may be also very high (up to *ca* 6 kg, in a worst case even 7 kg chlorinated impurities/ha). Despite lacking data to characterise the hazard no information on residue behaviour and thus consumer exposure to such compounds is available. The experts' meeting for residues unanimously agreed that further information on chlorinated impurities is required to conclude on consumer safety. Therefore, the consumer risk assessment cannot be concluded in terms of the impact of chlorinated impurities, even though there is no concern on consumer exposure to 1,3-D residues only.

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

1,3-dichloropropene (1,3-D) was discussed at the EPCO experts' meeting for environmental fate and behaviour (EPCO 21) in April 2005.

It is important to note that the representative uses evaluated have very high application rates (170-283 kg a.s./ha). Therefore there is the potential for significant amounts of impurities to be added to the environment. Further clarification on the content, nature and potential hazard of the impurities in the material that will be applied is still required (see sections 1, 2 and 5). Once the final nature of the impurities in the active substance and their potential hazard has been clarified, it may be appropriate to request information on the fate and behaviour of some of these impurities in the environment?

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 3-chloroaryl alcohol, single first order DT_{50} calculated by non linear regression were estimated to be 0.1-0.6 days for 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 3-chloroacrylic acid these values calculated from the 4 experiments where 1,3-D was dosed and the 4 experiments where 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 have been 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 dated April 2005. For the direct soil injection uses (both open field and glasshouse) acceptable estimates of surface water concentrations are not available. The original dossier contained calculations that considered the runoff route of entry to surface water from the soil injection use in the field. The drainage route of entry was not assessed. The experts from the Member States discussed the assumptions used in the calculations relating to the runoff route of entry (water body size, field to water body ratio, % loss assumed (1% and 0.003% as measured in US field studies)) and considered they could not be supported. This is therefore a data gap. For more detail on the additional information the experts considered were required see section ‘List of studies to be generated’.

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 acive 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[4].

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 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

[4] 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.

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 this 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.

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 however inadequately documented. For France this aspect of the reporting was wholly inadequate. In the Spanish reports only % of total country sales in each region was summarised. The tonnage sales for each region were not reported. In the UK, the proportion of the total area of the potato crop treated for a region (county) was reported as was the area in a region growing potatoes. Tonnage sales were not reported. In Italy the reporting of the sales information was better as tonnage sales were reported at the Province level although again there was no direct evidence of the extent of use overlying the specific aquifers sampled. In order to use this monitoring data for regulatory purposes, better evidence of active substance use is required at the most detailed local level available pertinent to the groundwater catchments monitored. At the moment all that 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 and potatoes) are cultivated over a reasonable proportion of area of each groundwater catchment. The quantities of 1,3-D that was actually applied to the soil in which these crops were grown that overlay the aquifers that samples were taken from is less clear, as the available sales figures are for larger geographical areas than the monitored catchments.

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 it can be satisfactorily confirmed with documentary evidence at the appropriate spatial scale that 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 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 ingredient (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.

4.3. 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 $\mu g/m^3$ (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 which may not reflect European conditions. The experts from the Member States agreed therefore that the information in the addendum does not cover the issue of what concentrations might be under EU conditions and that information is still required.

5. Ecotoxicology

1,3-dichloropropene (1,3-D) was discussed at the EPCO experts' meeting for ecotoxicology (EPCO 22) in April 2005 in Braunschweig (Germany).

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 analysis which are not covered by the batches tested in the section on ecotoxicology.

1,2-dichloropropane is regarded as a relevant impurity from a toxicological point of view. During the peer review process the ecotoxicological relevance of this impurity was never discussed. An assessment is not possible due to lack of data. The EFSA considers 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.

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 is available. 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.

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.

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 result are too variable and not representative for Mediterranean conditions and considered that there is still a high risk to earthworms eating birds and hence kept the data requirement open.

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 is considered high and the short term risk can be considered as low. Since it cannot 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 consider the risk to insectivorous birds covered by the risk assessment for earthworm eating birds. The EFSA does 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 cannot be concluded for the outdoor uses of 1,3-D before the applicant provides a refinement of the risk assessment.

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 is still open.
The EFSA proposes 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.

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 PECair 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.

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 1,3-dichloropropene. Aquatic organisms are more sensitive to 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 substanceThe 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 PECtwa 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.

Studies on the toxicity of 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.

As the logPow is below 3 for 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.

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 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.

5.5. RISK TO EARTHWORMS

A study on the acute toxicity to earthworms from 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 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 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 PECtwa 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).

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 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 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.

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

A study on the effects of 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.

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.

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.

6. Residue definitions

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 identified data gaps need to be filled before this definition can be finalised.

Water

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

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

Air

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

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

Food of plant origin

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

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

Food of animal origin

Definitions for risk assessment: not required for representative uses

Definitions for monitoring: not required for representative uses

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

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.

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 (data gaps need to be filled before it is relied on for regulation).	Yes	Yes	See 5.2.
(*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.
(*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 (data gaps need to be filled before it is relied on for regulation).	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*.

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
(*EZ*)-1,3-dichloropropene	See 5.2.
(*EZ*)-3-chloroacrylic acid (when groundwater becomes surface water)	No conclusion possible due to outstanding data gap for PECsw-values. 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	No conclusion possible due to outstanding data gap for PECsw-values. Data available (fish, *D. magna*, algae, *L. gibba*). Similar to higher toxicity than parent.

Air

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

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

- Data to identify the unidentified polychlorinated impurities must be provided. Depending on the outcome and depending on the assessment of their relevance it could be necessary to require further data (information that included new risk assessments was submitted March 2006, not evaluated, data gap identified in the DAR and confirmed by the meetings of experts, relevant for applicant DOW AgroSciences, refer to chapters 1, 2, 3, 4 and 5).
- A new 5 batch analysis of the other manufacturing site (first one on page 11 of Vol. 1, level 1) (relevant for applicant DOW AgroSciences, study submitted to the rapporteur Member State in March 2006. The rapporteur Member State will conduct an assessment of the equivalence of the sources at a later stage; refer to chapter 1).
- The Kanesho source has to be analysed for certain impurities to verify that the technical material is in compliance with the joint specification (relevant for applicant Kanesho Soil Treatment, data gap identified in the expert meeting and confirmed by the rapporteur Member State in addendum 2 to Volume 4; refer to chapter 1).
- Data on the surface tension of *cis*-1,3-dichloropropene (study announced by applicant DOW AgroSciences for October 2005 and received but not evaluated by the rapporteur Member State, refer to chapter 1).
- An analytical method for the determination of 1,2-dichloropropane in the technical material and the "EF-1478" formulation (relevant for DOW AgroSciences, data gap identified in the DAR, study announced for October 2005 and received but not evaluated by the rapporteur Member State; refer to chapter 1).
- A hydrolysis study for *cis*-1,3-dichloropropene (study submitted and evaluated by the rapporteur Member State in addendum 3 to B.2, but neither peer reviewed by MS nor discussed in an expert meeting; refer to chapter 1).
- Data on the oxidising properties of 1,3-dichloropropene and the formulations "EF-1478" and "XRM-5048" (study submitted and evaluated by the rapporteur Member State in addendum 3 to B.2, but neither peer reviewed by MS nor discussed in an expert meeting, refer to chapter 1).
- Data on the acidity of the formulation "EF-1478" (study submitted and evaluated by the rapporteur Member State in the evaluation table rev. 2-1 (06.03.2006); refer to chapter 1).
- Data on the accelerated storage stability of "XRM-5048" (study submitted and evaluated by the rapporteur Member State in addendum 3 to B.2, but neither peer reviewed by MS nor discussed in an expert meeting; refer to chapter 1).
- Depending on the outcome of the discussion whether or not the polychlorinated impurities has to be regarded as relevant impurities further data could be required (e.g. analytical methods, shelf-life study, spectra; refer to chapter 1).
- Data on the potential variability in the impurity pattern (study submitted and evaluated by the rapporteur Member State in addendum 2 (corrigendum) to Annex C, but neither peer reviewed by MS nor discussed in an expert meeting, refer to chapter 1).

- Dependent on the identity on the polychlorinated imp, it might be necessary to require new toxicological studies (refer to point 2.8).
- For the direct soil injection method of application indoors and outdoors, applicant to submit PEC in surface water and the consequent risk assessment for aquatic organisms. The drainage route of entry must be assessed. The runoff route of entry must also be appropriately assessed. If the percentage runoff measured in US field studies is used in calculations, an appropriate justification identifying the appropriateness of the study to EU geoclimatic conditions would be required. These drainage and runoff assessments are required for (*EZ*)-1,3-dichloropropene and the soil residue (*EZ*)-3-chloroacrylic acid. The potential for wet and dry deposition of parent (*EZ*)-1,3-dichloropropene from the air should also be addressed (data submitted December 2005, not evaluated; refer to point 4.2.1. and 5.2).
- For the direct soil injection method of application outdoors, the applicant should provide acceptable PEC in air. (This information would be necessary to validate the estimates of wet and dry deposition input to aquatic systems, see requirement above). If flux losses from soil from US field trial sites are used in the estimation, the appropriateness of these flux losses to EU geoclimatic conditions must be satisfactorily demonstrated (data submitted December 2005 and January 2006, not evaluated; refer to point 4.3).
- If Member State risk managers would wish to use the targeted groundwater monitoring data to support regulatory decision making the applicant must submit documentary evidence at the appropriate spatial scale to confirm that there has been significant use of 1,3-dichloropropene over a prolonged period in the groundwater catchments included in the program of targeted groundwater monitoring. In addition for the monitoring carried out in France, appropriate documentation relating to cropping, soils, hydrogeology and climate in the monitored groundwater catchments would also be required (submission date unknown; refer to point 4.2.2).
- Bridging studies are needed if new impurities are identified in the new five batch analysis which are not covered by the batches tested in the section on ecotoxicology (relevant for all representative uses evaluated; statement submitted in March 2006; refer to point 5).
- Applicant to address 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. Data gap proposed by the EFSA (relevant for all representative uses evaluated; no submission date proposed by the applicant; refer to point 5).
- Applicant to submit a refinement of the acute risk to insectivorous and earthworm eating birds. (relevant for all field uses evaluated; data submitted in December 2005, not evaluated; refer to point 5.1)
- Applicant to submit a reproduction study with birds (relevant for all field uses evaluated; submission date proposed by the applicant: December 2005; refer to point 5.1).
- Applicant to submit a new residue study in plants (relevant for all field uses evaluated; data submitted in December 2005, not evaluated; refer to point 5.1).
- Applicant to submit a refined risk assessment for mammals (relevant for all field uses evaluated; data submitted in December 2005, not evaluated; refer to point 5.1).

- Applicant to submit long term studies on fish and *Daphnia magna* with the metabolite (EZ)-3-chloroacrylic acid (proposed by the rapporteur Member State in the addendum of September 2005, not peer reviewed) (relevant for all uses evaluated; notifier currently unaware of the requirement, no submission date proposed yet; refer to point 5.2).
- Applicant to submit the toxicity values for algae based on biomass for the available studies (relevant for all uses evaluated; data submitted in December 2005, not evaluated; refer to point 5.2).
- Applicant to submit an inhalation study with bees and a calculation of the relevant PEC values to conduct the risk assessment for the inhalation toxicity to bees (relevant for all uses evaluated; data submitted in December 2005, not evaluated; refer to point 5.3).
- Applicant to further address the risk to non-target arthropods (relevant for all outdoor uses evaluated; data submitted in December 2005, not evaluated; refer to point 5.4 and 5.6).
- Applicant to submit a study on the recovery potential of earthworms after application of the active substance The applicant has to add an argumentation on the use in southern Europe (relevant for all outdoor uses evaluated; data submitted in December 2005, not evaluated; refer to point 5.5).
- Applicant to submit a field study to address the risk to soil micro-organisms. The metabolites should also be covered by this study (relevant for all outdoor uses evaluated; data submitted in December 2005, not evaluated; refer to point 5.7).
- 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 (relevant for all outdoor uses evaluated; data submitted in December 2005, not evaluated; refer to point 5.8).
- Applicant to submit pesticidal screening data for (*EZ*)-3-chloroacrylic acid; Data gap proposed by the EFSA (relevant for all representative uses evaluated; no submission date proposed yet; refer to point 5.8).

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 grew. The application rates are up to 283 kg 1,3-dichloropropene per hectare ("EF-1478") and up to 224 kg per hectare ("XRM-5048"), respectively. 1,3-dichloropropene can be used as nematicide, insecticide, fungicide and herbicide, depending on the dose rate used. In general, an application of 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 Greece, Italy and Spain 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).

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Adequate methods are available to monitor all compounds given in the respective residue definition. 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 at least limited quality control measurements of the plant protection product are possible.

The toxicological risk assessment (and reference values) is considered to be inconclusive due to uncertainties in relation to the mutagenic and carcinogenic properties. 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 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".**
The weight of evidence indicates that 1,3-dichloropropene 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 is proposed.**
1,3-dichloropropene 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. However, the mechanism of action for tumour formation has not been yet identified. Although, results indicate that 1,3- dichloropopene can be mutagenic, the relevance of these results to mammalian tumour formation is uncertain owing to the high concentrations or doses used. **The issue was to be forwarded to the PPR panel. The classification as possible human carcinogenic Category 3, R40?** is highlighted. No reproduction toxicity or neurotoxicity was observed. The metabolites 3-chloroallyl alcohol and 3-chloroacrylic acid are both toxic.
Dependent on the identity on the polychlorinated impurities, it might be necessary to require new toxicological studies.

According to medical data, 1,3-dichloropropene should be classified as irritating to eyes (R36) and to irritating to respiratory system (R37). Furthermore, it is proposed to classify as R65 "Harmful, may cause lung damage if swallowed" due observed the adverse effects,
The provisional Acceptable Daily Intake (ADI) ADI is 0.0125 mg/kg bw/day, with the use of the safety factor of 200. The additional safety factor of 2 was added in order to have at least 1000 between the ADI and the dose level where tumours are evident. The provisional systemic Acceptable Operator Level (AOEL) is 0.1 mg/kg bw/day, safety factor 100.
As inhalation exposure is the main route of exposition and all data from operator exposure are expressed as atmospheric concentration (mg/m^3), an additional inhalatory human AOEC was assigned which is 0.066 ppm, equivalent to 0.30 mg/m^3 however should be considered as provisional. The ARfD is 0.2 mg/kg bw, with the safety factor of 100 added**.**
The 1,3-dichloropropene is applied to bare soil and consisted of two scenarios. The estimations are based on field measurements. However, the estimated operator exposure should be considered only as indicative due to the uncertainties in relation to the mutagenic and carcinogenic properties. For both uses drip irrigation and soil injection, **PPE (gloves and coverall) and RPE (respiratory mask with filter for organic vapours) is needed** in order not to exceed the AOEL (16% and 38%, respectively). The exposure for workers and bystanders should be negligible.

The degradation and metabolism of 1,3-D has been studied comparatively in fruit (tomatoes and citrus), root vegetables (sugar beets), and 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.
However, it is stressed that the available studies don't provide any information regarding the residue behaviour of the chlorinated impurities present in the technical material that are added to soil at a high level (up to *ca* 6 kg/ha) when applying 1,3-D at the intended rate. There is no information on possible persistency, uptake, accumulation or metabolic fate and residue level of those chlorinated impurities, whether of known or unknown type, and moreover data on their toxicological properties are not available. This lack of data gives rise to concern in respect of consumer safety, even though potential chronic and acute dietary exposure to residues of 1,3 D per se from tomatoes and peppers is well below (<1%) the ADI and ARfD, respectively.

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 are required for environmental risk assessment with the following notable exceptions: Flux losses of 1,3-D from soil

treated outdoors to the air compartment under EU geoclimatic conditions need to be reliably estimated and used as input to PEC air and subsequently PECsurface water as a result of deposition of 1,3-D from the air. For the outdoor and indoor direct injection uses, appropriate PEC in aquatic systems need to be calculated taking into account both the drainage and runoff routes of entry to surface water for 1,3-D and its identified soil metabolite (*EZ*)-3-chloroacrylic acid.

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.

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. However data requirements for further information regarding aspects of this monitoring have been identified. These identified deficiencies would need to be addressed before this monitoring work could be used to support a science based regulatory decision. If risk managers chose to use the monitoring work (following the provision of the missing information) 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, at the monitored abstraction points.

Bridging studies are needed if new impurities are identified in the new five batch analysis which are not covered by the batches tested in the section on ecotoxicology. As the relevance of the impurity 1,2-dichloropropane was not discussed during the peer review process, the EFSA proposes the applicant to addresses the ecotoxicological relevance of this impurity. The levels of 1,2-dichloropropane in the ecotoxicological studies must be confirmed if considered relevant.
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 is identified for the outdoor uses. Data to address these risks is still awaited. 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 for the outdoor uses can only be concluded once the outstanding data become 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. Algae and *Lemna gibba* are more sensitive to the metabolites *(EZ)-3-chloroallyl*

alcohol and (EZ)-3-chloroacrylic acid than to the parent compound. 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. 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. The risk to aquatic organisms from the direct soil injection method of application indoors and outdoors, can only be concluded once the PEC in surface water become available (see 4.2.1 and 5.2). 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. The risk for bioconcentration in fish for 1,3-dichloropropene and metabolites (EZ)-3-chloroallyl alcohol and (EZ)-3-chloroacrylic acid is considered to be low.

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 EPCO experts' meeting decided on the need for an inhalation study with bees and a calculation of relevant PEC values to conduct the risk assessment for the inhalation toxicity to bees.

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. Given the observed effects on *Folsomia candida* the rapporteur Member State asked the applicant to further address the risk to non-target arthropods for the outdoor uses.

A high acute risk to earthworms was observed. The EPCO experts' meeting agreed to await the announced new field study in UK potato fields to address several comments which were raised on the existing earthworm field study. The long term risk to earthworm from exposure to 7 day old treated soil can be regarded as low while the acute and long term risk to earthworms exposed to freshly treated soil can only be concluded once the outstanding field data become available. The rapporteur Member State considers that this data gap only applies to the outdoor uses.

Effects from 40.23% to 96.9% on soil microbial respiration and nitrogen transformation 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 to address this concern was discussed at the EPCO experts' meeting and the meeting identified the need for a new field study to address this risk. This new field study should also cover the concern for the effects from the soil metabolites. The rapporteur Member State considers that this data gap only applies to the outdoor uses.

Regarding the indoor uses, the EFSA would like to point out that earthworms, soil micro-organisms, *F. candida* and other soil non-target arthropods are likely to come into contact with 1,3-dichloropropene as the product is applied to full soil. This could affect the function of the soil indoors.

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. The EPCO Expert's meeting decided that the risk should be further quantified and TER values at a few metres from the field should be calculated. The EFSA is of the opinion that this assessment should be based on an

ER_{50} value. The risk to non-target plants can only be concluded once this risk assessment becomes available.
It cannot be excluded that 1,3-D might be harmful if the waste water goes to sewage treatment plants.

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

- Member States should consider that in cases where only a sum content of a group of certain impurities is given that the individual values are in compliance with the proposed specification (refer to chapter 1).
- The shelf-life study shows that the formulation "EF-1478" meets the FAO criteria not for longer than 6 months (loss of 1,3-dichloropropene). Furthermore, the emulsion characteristics might be considered, due to the fact that the cream content was high after 8 weeks (refer to chapter 1).
- 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.

Critical areas of concern

- At the moment no final specification for the technical material can be set (refer to chapter 1).
- As the representative uses evaluated have very high application rates (170-283 kg a.s./ha), there is the potential for significant amounts of polychlorinated impurities in the technical material (both identified and not identified) to be added to the environment. Further clarification on the content, nature and potential hazard of the impurities in the material that will be applied, is still required. Further information on their fate and behaviour in the environment and potential for uptake from soil by crops may be appropriate depending on what it is possible to conclude on their potential hazard.
- 1,3-dichloropropene is toxic via oral and dermal exposure, possibly mutagenic and carcinogenic (at high dose levels) and due to the uncertainties of the mechanism, the risk assessment should be regarded as inconclusive.
- 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.
- 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. Data to address these risks is still awaited. 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 for the outdoor uses can only be concluded once the outstanding data requirements become available.

- The risk to aquatic organisms from the use as a direct soil injection method of application indoors and outdoors can only be concluded once the PEC in surface water become available (see 4.2.1 and 5.2). 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.
- 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), an inhalation study with bees and a calculation of relevant PEC values to conduct the risk assessment for the inhalation toxicity to bees is required.
- Given the observed effects on *Folsomia candida* the risk to non-target arthropods for the outdoor uses should be further addressed. The risk to non-target arthropods for the outdoor uses can only be concluded once these data become available.
- A high acute risk to earthworms was observed in the laboratory. A study to address this risk for the outdoor uses is still awaited. The EFSA would like to point out that MS should be aware that the function of the soil indoors could be affected by the acute risk to earthworms.
- A high risk to soil micro-organisms was observed in the laboratory. A study to address this risk for the outdoor uses is still awaited. The EFSA would like to point out that MS should be aware that the function of the soil indoors could be affected by the risk to soil micro-organisms.
- A potential risk to non-target plants was identified. The risk should be further quantified and TER values at a few metres from the field should be known. The risk to non-target plants can only be concluded once this risk assessment becomes available.
- It cannot be excluded that 1,3-D might be harmful if the waste water goes to sewage treatment plants.

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

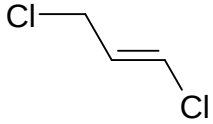
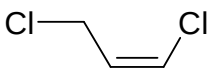
(Abbreviations used in this list are explained in appendix 2)

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

Active substance (ISO Common Name) ‡	*An ISO Common will not be 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 430 g/kg Minimum for *E* or *trans* 1,3-D 300 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	1,2-dichloropropane 0.1 g/kg (*The relevance of this impurities has only been confirmed from an toxicological point of view and not from an ecotoxicological point of view*)
Molecular formula ‡	$C_3H_4Cl_2$
Molecular mass ‡	110.97 g/mol
Structural formula ‡	 *E* or *trans*-isomer  *Z* or *cis*-isomer

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

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	***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.
Relative density (state purity) ‡	***cis*-isomer**: D^{23}_4 = 1.221 ***trans*-isomer**: D^{23}_4 = 1.23
Surface tension	***cis*-isomer**: No data available ***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

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

	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 POW) ‡ (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 $dm^3 \cdot mol^{-1} \cdot cm^{-1}$ 0.1 M aqueous HCl (202.7 nm): ε = 4409 $dm^3 \cdot mol^{-1} \cdot cm^{-1}$ 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

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

	the study. Only at very basic pH (pH = 13.0) absorbance above 250 nm is observed probably due to the formation of an hydrolysis product.
Photostability (DT50) ‡ (aqueous, sunlight, state pH)	**Technical product** (xenon arc lamp)**:** The calculated photolysis half-life for 1,3-D can be estimated for a typical mid-summer day of 14 hours of sunlight 14ºN latitude is on the order of 650 days if the difference between irradiated and dark control is significant. Photolysis is not a significant pathway for the environmental degradation of 1,3-D.
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡	Not required. No significant photo degradation.
Flammability ‡	**Technical compound.** Flash point 27.0 ºC. Therefore, 1,3 D should be classified as flammable compound.
Explosive properties ‡	**Technical compound:** Technical 1,3-dichloropropene is not explosive.

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

List of representative uses evaluated*

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hl min max	water L/ha min max	kg a.s./ha min max		
Tomatoes and Peppers	France (North zone)	1,3D Injection (DAS Telone 2000)	F	Nematodes	AL	1180 g/L	Soil injection	Preplant	1	-	-	-	187	-	2 – 3 weeks [3][4]
Tomatoes and Peppers	Italy (South zone)	1,3D Injection (DAS Telone II[1])	F	Nematodes	AL	1180 g/L	Soil injection	Preplants	1	-	-	-	224	-	28 days [3][4]
Tomatoes and Peppers	Italy (South zone)	1,3D Injection (DAS Telone II[1])	G	Nematodes	AL	1180 g/L	Soil injection	Preplants	1	-	-	-	224	-	28 days [3][4]
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	Preplant	1	-	-	-	170-283	-	2-4 weeks [3][4]

(1) KST Tradenames for 1,3-D Injection product are DD95, DD92, DD Soil fumigant, DD Soil Inyectable
(2) KST Tradename for 1,3-D Drip Irrigation EC is DD Emulsionable

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

[3] The risk assessment has revealed a data gap(s) in section 5.
[4] The risk assessment has revealed a risk (exceedance of relevant threshold) in section 5.

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

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

Appendix 1.2: Methods of Analysis

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

Technical as (principle of method)	**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. **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** ***Data gap:*** *There is no method for the analysis of the relevant impurity in EF 1478.*

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/MSD** 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 sensibity). **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

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

	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/MSD** 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/MSD** (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).

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

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 (Annex IIA, point 10)

with regard to physical/chemical data	R10 Flammable

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

Appendix 1.3: Impact on Human and Animal Health

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

Rate and extent of absorption ‡	Rapid and complete, based on urinary, faecal and CO2 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 CO2 (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 CO2 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 significant compounds ‡ (animals, plants and 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 ‡	333 mg/kg bw	**R24**

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

Rat LC_{50} inhalation ‡	2.70 mg/L (whole-body, vapour exposure)	**R20**
Skin irritation ‡	Irritant	**R38**
Eye irritation ‡	Irritant	**R36**
Skin sensitization ‡ (test method used and result)	Sensitizer (Buehler test)	**R43**
Respiratory system irritation	Irritant	**R37**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Stomach (rat, hyperkeratosis and basal cells hyperplasia), liver (mice and rat, hepatotoxicity), tongue (dog, mucosal inflammation), nasal cavity (rat and mice, inhalation exposure, hyperplasia of respiratory epithelium) and urinary bladder (mice, females). Hypochromic and microcytic anaemia in dogs.
Lowest relevant oral NOAEL / NOEL ‡	5 mg/kg/ bw/day (rat, 90 days) 2.5 mg/kg/ bw/day (dog, 1 year)
Lowest relevant dermal NOAEL / NOEL ‡	No data; none required
Lowest relevant inhalation NOAEL / NOEL ‡	10 ppm (0.046 mg/L) i.e. 9.72 mg/kg/day (rat, 13-weeks)

Genotoxicity ‡ (Annex IIA, point 5.4)

.....	Some studies show clear indications for DNA fragmentation *in vivo*, however, negative results are demonstrated in micronucleus, UDS and dominant lethal tests. **Mut. cat 3, R68**

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).
Lowest relevant NOAEL / NOEL ‡	2.5mg/kg /day (2-year dietary study in rats) 5ppm (4.43 mg/kg /day) (2-year inhalation study in mice)

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

Carcinogenicity ‡	Benign lung tumors at 60 ppm and submucosal mesenchymal tumors in the urinary bladder at 25 mg/kg bw/day (in mice). Hepatocellular adenoma in liver (in rats) at 25 mg/kg bw/day. Uncertainties of the mode of action of the substance causing the tumours resulted in a question proposed to be addressed to the PPR Panel **R40 ?**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	No adverse effects on reproduction identified following exposure by the inhalatory route
Lowest relevant reproductive NOAEL / NOEL ‡	Inhalation reproductive NOAEL: 90 ppm (0.4086 mg/L air)
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.
Lowest relevant developmental NOAEL / NOEL ‡	Inhalation developmental LOAEL of 20 ppm (0.09 mg/L air) in rats NOEL: 120 ppm (0.5448 mg/L air) both for rats and rabbits

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

.....	No data. None required.

Other toxicological studies ‡ (Annex IIA, point 5.8)

Toxicity of metabolites 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-days rat study).

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

	Tested for developmental toxicity in rats by gavage. Developmental critical effect: increase in total resorptions and decrease in fetal body weights at maternal toxic doses (65 mg/kg bw/day). No teratogenicity. Lowest developmental NOAEL: 25 mg/kg bw/day.
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. **R25** Rabbit dermal LD_{50} 316 mg/kg. **R24** No skin irritation Not sensitising (Buehler test) Tested for developmental toxicity in rats by gavage. Developmental critical effect: decreased fetal 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.
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.
Mechanistic 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

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

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.

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 *provisional*	0.0125 mg/kg bw/day	2-year long-term toxicity and carcinogenicity study in rats	200[5]
AOEL (systemic rat) *provisional*	0.1mg/kg bw/day	13-weeks inhalation study in rats supported by the 2-year mice study.	100
AOEL (inhalatory human) *provisional*	0.066 ppm or 0.30 mg/m^3	13-weeks inhalation study in rats supported by the 2-year mice study.	100
ARfD ‡ (acute reference dose)	0.2 mg/kg bw	2-weeks study in dogs	100

Dermal absorption (Annex IIIA, point 7.3)

Telone drip, Telone injection	Main route of exposure is via 1,3-D inhalation. However, if dermal absorption would occur, 100% default value should be used.

[5] The safety factor is increase by an additional factor of 2 due to the evidence of tumors and lack of information on the mechanism and in order to have a margin of 1000 to the effect level.

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

Acceptable exposure scenarios (including method of calculation)

The risk assessment (and reference values) is considered to be inconclusive due to uncertainties in relation to the mutagenic and carcinogenic properties.

Operator	Estimated exposure i.e. % of the AOEL for: Drip irrigation in green house (non professionals). **Without PPE:** **With PPE and RPE*:** Worst case 330% Worst case 16.5 % Soil injection (professional users) **Without PPE:** **With PPE and RPE*:** Worst case: 776 % Worst case 38%
Re-entry workers	Drip irrigation in green house (non professionals). Levels <5% AOEL or Non detectable Re-entry during application require of PPE and as well as RPE*, re-entry period: 21 days Soil injection (professional users) Worst case: 94% AOEL Activities performed before (sheet install, bed shaping) require PPE and respiratory mask for organic vapours. <10% AOEL, re-entry period: 14-26 days
Bystanders	Drip irrigation in green house (non professionals). Worst case 56.3% AOEL High risk (>100% AOEL) walking at 1 m and within 2 days after application in greenhouse Soil injection (professional users) Worst case: 33.3% AOEL

* Coverall, gloves and face mask with activated carbon filters.

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

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data

T, Xi	Toxic, irritating, carcinogenic cat. 3, mutagenic cat 3
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
R40?	Limited evidence of carcinogenic effect
R43	May cause sensitisation by skin contact
R65	Harmful, may cause lung damage if swallowed
R68	Possible risk of irreversible effects

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

Appendix 1.4: Residues

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

Plant groups covered	Fruiting vegetables (tomato); fruits (citrus); root & tuber vegetables (sugar beet); oilseeds (soybeans)
Rotational crops	Wheat , lettuce, carrots, radishes
Plant residue definition for monitoring	*Cis*- and *trans*- 1,3 Dichloropropene
Plant residue definition for risk assessment	*Cis*- and *trans*- 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

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

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

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			

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

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

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Pepper	Japan[1]	2: < 0.01 mg/kg		0.01	
Tomato	Japan[1]; USA[2]	8: < 0.01 mg/kg		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] Japan trials were performed in greenhouse; residues were below LOD (0.001 mg/kg) each isomer.

[2] 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

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

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

ADI	0.0125 mg/kg/day
TMDI (European Diet) (% ADI)	1.12%
IEDI (% ADI)	Not necessary
Factors included in IEDI	Not necessary
ARfD	0.2 mg/kg bw/d
Acute exposure (% ARfD)	Tomato: 0.05% adults, 0.21% toddlers Pepper: 0.04% adults, 0.12% toddlers

* Note: potential consumer risk due to chlorinated impurities was not assessed

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

Not required. Supervised residue trials showed no residue situation

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

Tomato, pepper	0.01* mg/kg

*) LOQ

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

Appendix 1.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil[6] (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[7] (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

[6] It refers to combined isomers
[7] 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).

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

Laboratory studies ‡ (range or median, with n value, with r^2 value) Note: In this case n value refers to the number of sampling points (not to the number of soils tested)	Parent: DT_{50lab} (20°C, 40% MHC aerobic): 9.3 d, (r^2=0.95; n=8) 3-chloroarylalcohol: DT_{50lab} (20°C, 40% MHC aerobic): 0.2 d; 0.1 d (r^2= 0.995) 3-chloroacrylic acid: DT_{50lab} (20°C, 40% MHC aerobic): 6.0 d (r^2=0.95; n=8); 0.7 (r^2= 0.97; n=7) Parent: DT_{90lab} (20°C 40% MHC aerobic): 30.9 d (r^2=0.95; n=8) 3-chloroarylalcohol: DT_{90lab} (20°C 40% MHC aerobic): 0.8 d; 0.4 d (r^2= 0.995) 3-chloroacrylic acid: DT_{90lab} (20°C 40% MHC aerobic): 19.9 d (r^2=0.95; n=8); 2.4 d (r^2= 0.97; n=7)
	Parent: DT_{50lab} (20°C, 20% MHC aerobic): 9.9 d, (r^2= 0.95; n=8) 3-chloroarylalcohol DT_{50lab} (20°C, 20% MHC aerobic): 0.5 d; 3-chloroacrylic acid: DT_{50lab} (20°C, 20% MHC aerobic): 12.2 d (r^2= 0.95; n=8); Parent: DT_{90lab} (20°C 20% MHC aerobic): 32.9 d, (r^2= 0.95; n=8) 3-chloroarylalcohol DT_{90lab} (20°C 20% MHC aerobic)::1.6 d; 3-chloroacrylic acid: DT_{90lab} (20°C 20% MHC aerobic): 40.5 d (r^2= 0.95; n=8); Parent: DT_{50lab} (20°C, 40% MHC aerobic): 15.5 d (r^2=0.98; n=9) 3-chloroarylalcohol DT_{50lab} (20°C, 40% MHC aerobic): 0.3 d; 0.5 d (r^2= 0.9996); 0.6 (r^2=0.9987) 3-chloroacrylic acid: DT_{50lab} (20°C, 40% MHC aerobic): 18.2 d (r^2=0.98; n=9); 2.0 d (r^2=0.95; n=10) Parent: DT_{90lab} (20°C 40% MHC aerobic): 51.4 d, (r^2=0.98; n=9) 3-chloroarylalcohol DT_{90lab} (20°C 40% MHC aerobic): 0.9 d; 1.9 (r^2=0.9987) 3-chloroacrylic acid: DT_{90lab} (20°C 40% MHC aerobic): 60.3 d (r^2=0.98; n=9); 6.7 d (r^2=0.95; n=10)

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

	Parent: DT_{50lab} (20°C, 40% MHC aerobic): 8.8 d (r^2=0.97; n=10) 3-chloroarylalcohol DT_{50lab} (20°C, 40% MHC aerobic): 0.1 d; 0.6 (r^2=0.9959) 3-chloroacrylic acid: DT_{50lab} (20°C, 40% MHC aerobic): 19.8 d (r^2=0.97; n=10); 3.4 d (r^2=0.97; n= 10) Parent: DT_{90lab} (20°C 40% MHC aerobic): 29.1d, (r^2=0.97; n=10) 3-chloroarylalcohol DT_{90lab} (20°C 40% MHC aerobic): 0.7 d- 1.9 (r^2=0.9959) 3-chloroacrylic acid: DT_{90lab} (20°C 40% MHC aerobic): 65.8 d (r^2=0.97; n=10); 11.2 d (r^2=0.97; n= 10)
	Parent: DT_{50lab} (20°C, 40% MHC aerobic): 10.7 d, (r^2=0.98; n=9) 3-chloroarylalcohol DT_{50lab} (20°C, 40% MHC aerobic):0.1 d; 0.5 d (r^2=0.9996) 3-chloroacrylic acid: DT_{50lab} (20°C, 40% MHC aerobic): 10.4 d, (r^2=0.98; n=9); 2.0 d (r^2=0.95; n= 10) Parent: DT_{90lab} (20°C 40% MHC aerobic): 35.6 d, (r^2=0.98; n=9) 3-chloroarylalcohol DT_{90lab} (20°C 40% MHC aerobic): 0.4 d; 1.6 d (r^2=0.9996) 3-chloroacrylic acid: DT_{90lab} (20°C 40% MHC aerobic): 34.6 d (r^2=0.98; n=9); 6.6 d (r^2=0.95; n= 10)
	Parent (aerobic 20ºC): Range: DT_{50}= 8.8-15.5 d, DT_{90}= 29.1-51.4 d ; Average normalised-10kPa: DT_{50} = 9.4 days (n=4; 20ºC) 3-chloroarylalcohol (aerobic 20ºC): Range: DT_{50}= 0.1. d to 0.6 d, DT_{90}= 0.4 to 1.9 d Overall Average normalised-10kPa: DT_{50} = 0.3 d 3-chloroacrylic acid (aerobic 20ºC): Range: DT_{50}= 0.7 d to 19.8d, DT_{90} = 19.9to 65.8d Overall Average normalised-10kPa: DT_{50} =7.4 d;

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

	Parent: DT_{50lab} (10°C, 40% MHC aerobic): 24.9 d (r^2= 0.97, n=12) 3-chloroarylalcohol DT_{50lab} (10°C, 40% MHC aerobic): 0.6 d 3-chloroacrylic acid: DT_{50lab} (10°C, 40% MHC aerobic): 30.0 d (r^2= 0.97, n=12)
	Parent: DT_{50lab} (20°C, anaerobic): 7.7 d (r^2=0.98)
Degradation in the saturated zone:	Parent was degraded in incubations with saturated sub soils, the pattern of decline was not first order.
Field studies (state location, range or median with n value)	Quincy, Florida, US Parent: Biphasic behaviour. Firstly a fast dissipation took place followed by a much slower degradation.
Soil accumulation and plateau concentration ‡	No data

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_d/K_f / K_{oc}	Active substance: K_{foc}= 18.6-83mL/g (mean=33.7mL/g, 7 soils). 1/n 0.92-1.05 (mean 1/n=1) 3-chloroacrylic acid K_{doc}= <1-17.5mL/g (mean=3.78mL/g, 9 soils). 3-chloroallyl alcohol K_{foc}= 5.3-11.9mL/g (mean=9.4mL/g, 9 soils). 1/n 0.72-0.98 (mean 1/n=0.88)
PH dependence (yes / no) (if yes type of dependence)	No dependence for parent and 3-chloroallyl alcohol. For 3-chloroacrylic acid slightly pH-dependence: when pH decreases Koc increases

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

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 Precipitation: 3 mL/min over 7 h Aged for (d): 30 d 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[8] ‡ 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.

[8] Analysis of 3-chloroacrylic acid was not carried out at any site. Irrigation was not made after application

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

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	DT_{50}= 15.5 days Kinetics: 1st order Representative worst case from lab studies.
Application rate	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)			377.33	-	-	-
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

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

Metabolite I (3-chloroacrylic acid)

Method of calculation	DT_{50}= 19.8 days Kinetics: 1st order Representative worst case from lab studies.
Application rate	Crop: Fruiting vegetables (tomatoes) % plant interception: pre-plant therefore no crop interception 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

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

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) ‡ (state pH and temperature)	pH 4: Active substance: Z- 1,3-D: 25ºC DT_{50} = 100 h E-1,3-D: 25 ºC DT_{50} = 118 h (r^2=). 3-chloroallyl alcohol: 75% initial dose at 16 h. 3-chloroacrylic acid stable 3-chloroallyl alcohol stable
	pH 7: Active substance: Z- 1,3-D: 25ºC DT_{50}= 64.5 h E-1,3-D: 25 ºC DT_{50}= 114 h (r^2=). 3-chloroallyl alcohol: 77.1% initial dose at 16 h. 3-chloroacrylic acid stable 3-chloroallyl alcohol stable
	pH 9: Active substance: 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 relevant metabolites ‡	No
Readily biodegradable (yes/no)	No for active substance.
Degradation in water/sediment - DT_{50} water ‡ - DT_{90} water ‡ - DT_{50} whole system ‡ - DT_{90} whole system ‡	 2.58 days 8.6 days Parent 4.9 days 3-chloroallyl alcohol 1.2 days 3-chloroacrylic acid 5.6 days 16.2 days
Mineralisation	38% TAR after 21 days
Non-extractable residues	16% TAR after 21 days
Distribution in water / sediment systems (active substance) ‡	Water: 2.2% TAR after 21 days Sediment: 0.6% TAR after 21 days Note: 63.35% TAR volatilised at 0 day

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

Distribution in water / sediment systems (metabolites) ‡	Metabolites higher than 10% TAR were not observed.

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

Parent

Method of calculation	First order kinetics.
Application rate	Injected: 224 Kg a.s./ha (south zone); Drip: 283 Kg a.s./HA (south zone).
Main routes of entry	Drip: Deposition[a] Injected: ***Data requirement***

Initial PEC$_{(sw)}$ (µg/L) (% of maximum application rate in water body)	Single application Actual Drip
	1.4 µg/L according to the bystander study

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.

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

Method of calculation and type of study (*e.g.* modelling, monitoring, 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,

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

	Porto Sevilla, Thiva Crop: tomatoes Arithmetic mean parent DT_{50lab} 9.4 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.2). Kdoc: parent, arithmetic mean 44.7mL/g, 1/n 1.0 Arithmetic mean 3-chloroallyl alcohol DT_{50lab} 0.3d (considering the overall mean of the DT_{50} 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 DT_{50lab} 7.4 d considering the overall mean of the DT_{50} 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	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

$PEC_{(gw)}$

Maximum concentration	Not calculated by FOCUS model shells, not required
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	1,3-dichloropropene up to 78µg/L 3-chloroacrylic acid up to 144µg/L 3-chloroallyl alcohol up to 0.089µg/L

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

Injected application

	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**

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

Drip application

Application rate	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

	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**

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

Direct photolysis in air ‡	No data

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

Photochemical oxidative degradation in air (DT_{50})	Experimentally measured Reaction with OH radicals at 2 10^6 radicals cm^{-3} DT_{50}= 7 hours for E-1,3-D DT_{50}= 12 hours for Z-1,3-D Reaction with O_3 radicals at 1 10^{12} molecules cm^{-3} DT_{50}= 12 days for E-1,3-D DT_{50}= 52 days for Z-1,3-D
Photochemical metabolites	Reaction with OH radicals[9] - formyl chloride: DT_{50} = 1.668 d - chloroacetaldehyde: DT_{50} = 1.686 d - Formica acid: 20.569 d Reaction with O_3[9] - chloroacetaldehyde: DT_{50} = 1.686 d - formyl chloride: DT_{50} = 1.668 d - chloroacetic acid, 13.605 d - Formica acid: 20.569 d - HCl, CO, CO_2 **Overall assessment:** Formyl chloride could react with water to form formic acid, CO and HCl Chloroacetaldehyde is expected to be oxide to chloroacetic acid, which is very soluble in water (850 g/L, according to ICPS safe sheet) According to UNEP many inorganic halogen species are water solubles (HCl) or will react in solution to form water soluble products. They are removed efficiently in the lower troposphere. According to UNEP the effects of very short live (VSL) halogen source gases on halogen loading in the stratosphere is likely to be limited to bromide and ione budget in the present-day atmosphere. Therefore the effect of 1,3-D and its atmospheric degradation products in the stratospheric ozone layer could be considered no relevant.
Volatilization ‡	**From soil**: **Location**: Imperial Valley, California US Study type: volatilisation monitoring Number of applications: 1 Application rate : 112 L/ha

[9] Photochemical oxidative reaction with OH radicals at 1.5 10^6 radicals cm^{-3} 12h. Values estimated by the rapporteur Member State using the software APOWIN (1.91)

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

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).

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

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).

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

	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
PEC$_{(air)}$	
Method of calculation	PEC$_{air}$ not needed for assessment
PEC$_{(a)}$	
Maximum concentration	PEC$_{air}$ not needed for assessment

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

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Soil: 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 submitted
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

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

	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.
Air (indicate location and type of study)	No data submitted, not required.

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	Potential for R53 as is 'not readily biodegradable'

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

Appendix 1.6: Effects on non-target Species

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

Acute toxicity to mammals ‡	Rat (oral) LD_{50} = 130 mg a.s./kg bw Rat (inhalation) LD_{50} = 2.7 mg a.s./L
Long term toxicity to mammals ‡	Mice, 2 years (oral) NOAEL = 2.5 mg a.s./kg_{bw}/d (f/m). Rabbit (inhalation) NOAEL = 0.0908 mg a.s./L (from reproduction study)
Acute toxicity to birds ‡	Technical and formulate: *Colinus virginianus* LD_{50} = 139.8 mg a.s./kg $_{bw}$ Metabolites: No data
Dietary toxicity to birds ‡	Technical and formulate: *Anas platyrhynchos* LC_{50} > 1264 mg a.s./kg $_{bw}$/d (6243 mg a.s./kg $_{food}$) NOEC: 213.5 mg a.s./kg $_{bw}$/d (1054 mg a.s./kg $_{food}$) Metabolites: No data
Reproductive toxicity to birds ‡	No data reported.

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

Application rate (kg a.s./ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
224	Fruiting vegetables (tomatoes)	Herbivorous bird	acute	*Awaiting data*	10
224	Fruiting vegetables (tomatoes)	Birds feeding earthworms	acute	1.6	10
224	Fruiting vegetables (tomatoes)	Insectivorous bird	acute	1.7	10
224	Fruiting vegetables (tomatoes)	Herbivorous bird	Short term	*Awaiting data*	10
224	Fruiting vegetables (tomatoes)	Birds feeding earthworms	Short term	>82	10
224	Fruiting vegetables (tomatoes)	Insectivorous bird	Short term	> 82	10
187	Fruiting vegetables (tomatoes)	Birds feeding earthworms	acute	2.03	
187	Fruiting vegetables (tomatoes)	Insectivorous bird	acute	2.15	10

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

Application rate (kg a.s./ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
187	Fruiting vegetables (tomatoes)	Birds feeding earthworms	Short term	>99	10
187	Fruiting vegetables (tomatoes)	Insectivorous bird	Short term	> 99	10
224	Fruiting vegetables (tomatoes)	Mammals	Acute oral (plants intake)	Awaiting data	10
224	Fruiting vegetables (tomatoes)	Mammals (uptake insects)	Acute	3.1	10
224	Fruiting vegetables (tomatoes)	Mammals (uptake earthworms)	Acute	1.4	10
224	Fruiting vegetables (tomatoes)	Mammals	Acute (inhalation)	510	10
224	Fruiting vegetables (tomatoes)	Mammals	Long term oral (plants intake)	Awaiting data	5
224	Fruiting vegetables (tomatoes)	Mammals (uptake insects/worms)	Long term (oral)	3.3	5
224	Fruiting vegetables (tomatoes)	Mammals	Long term (inhalation)	102	5
187	Fruiting vegetables (tomatoes)	Mammals (uptake insects)	Acute (oral)	3.8	10
187	Fruiting vegetables (tomatoes)	Mammals (uptake earthworms)	Acute (oral)	1.72	10
187	Fruiting vegetables (tomatoes)	Mammals (uptake insects/worms)	Long term (oral)	4.0	5

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

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Laboratory tests ‡				
Fish Sheepshead minnow *Cyprinodon variegates*	Technical (1,3-D 96 %)	Acute	96h LC_{50}	0.87

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

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Rainbow trout *Oncorynchus mykiss*	Technical (1,3-D 100 %)	Acute	96h LC_{50}	2.78
Oncorynchus mykiss	(*EZ*)-3-chloroallyl alcohol	Acute	96h LC_{50}	0.986
Oncorynchus mykiss	(*EZ*)-3-chloroacrylic acid	Acute	96h LC_{50}	69.5[1]
Fathead minnow *pimephales promelas*	Technical (1,3-D 96%)	Chronic (early life stage)	33d NOEC	0.032
Invertebrates *Daphnia magna*	Technical (1,3-D 100 %)	Acute	48h ED_{50}	3.58
Eastern oyster *Crassotrea virginica*	Technical (1,3-D 96%)	Acute	96h EC_{50}	0.64
Daphnia magna	(*EZ*)-3-chloroallyl alcohol	Acute	48h EC_{50}	2.30
Daphnia magna	(*EZ*)-3-chloroacrylic acid	Acute	48h EC_{50}	55.0
Daphnia magna	Technical (1,3-D 96%)	Chronic	21d NOEC	0.0701
Algae *Navicula Pelliculosa*	Technical (1,3-D 96%)	Acute	5 d ICr_{50}	2.35[2]
Skeletonema costatum	(*EZ*)-3-chloroallyl alcohol	Acute	5 d ICr_{50}	0.727[2]
Selenastrum capricornotum	(*EZ*)-3-chloroacrylic acid	Acute	4 d ICr_{50}	0.691
Plant *Lemna gibba*	Technical (1,3-D 96%)	Acute	14 d LC_{50}	14.56[2]
Lemna gibba	(*EZ*)-3-chloroallyl alcohol	Acute	14 d LC_{50}	0.454[2]
Lemna gibba	(*EZ*)-3-chloroacrylic acid	Acute	14 d LC_{50}	0.26

[1] Low quality data, confidential limits are too high due to the lack of intermeddle results on mortality effects.
[2] Results based on initial measured concentrations of 1,3-D

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

Microcosm or mesocosm tests No information has been submitted

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

Application rate (kg a.s./ha)	Crop	Organism	Time-scale	PEC	TER	Annex VI Trigger
224 (injection)	Tomato/Pepper	**Fish** *C. variegates*	Acute	-*	-*	100
		O. mykiss	Acute	-*	-*	"
224 (injection)	Tomato/Pepper	**Invertebrates** *Daphnia*	Acute	-*	-*	100
		Crassotea v.	Acute	-*	-*	"
224 (injection)	Tomato/Pepper	**Algae** *Navicula p.*	Acute	-*	-*	10
224 (injection)	Tomato/Pepper	**Plant** *Lemna gibba*	Acute	-*	-*	10
224 (injection)	Tomato/Pepper	**Fish** *P. promelas*	Chronic	-*	-*	10
224 (injection)	Tomato/Pepper	**Invertebrate** *Daphnia*	Chronic	-*	-*	10

* pending on an outstanding data requirement

Applic. rate (kg/ha) (Applic. Method)	Crop	Specie	Substance	Time-scale	PECsw (µg/L)	TER_A	Trigger value
283 (Drip irrigation)	Tomato/ Pepper	**Fish** Sheepshead minnow *(Cyprinodon variegates)*	1,3-D	Acute	1.4	621	100
283 (Drip irrigation)	Tomato/ Pepper	**Aquatic invertebrate** Eastern oyster *(Crassotea virginica)*	1,3-D	Acute	1.4	457	100

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

Applic. rate (kg/ha) (Applic. Method)	Crop	Specie	Substance	Time-scale	PECsw (µg/L)	TER_A	Trigger value
283 (Drip irrigation)	Tomato/ Pepper	**Algae** Freshwater diatom *(Skeletonema costatum)*	1,3-D	Acute	1.4	1678	10
283 (Drip irrig.)	Tomato/ Pepper	**Aquatic plant** Duckweed (*Lemna gibba*)	1,3-D	Acute	1.4	10400	10
283 (Drip irrig.)	Tomato/ Pepper	Rainbow trout *(Oncorhynchus mykiss)*	3-chloroprop -2-en-1-ol	Acute	1.16	850	100
283 (Drip irrig.)	Tomato/ Pepper	*Daphnia magna*	3-chloroprop -2-en-1-ol	Acute	1.16	1982	100
283 (Drip irrig.)	Tomato/ Pepper	Freshwater diatom *(Skeletonema costatum)*	3-chloroprop -2-en-1-ol	Acute	1.16	626	10
283 (Drip irrig.)	Tomato/ Pepper	Duckweed (*Lemna gibba*)	3-chloroprop -2-en-1-ol	Acute	1.16	391	10
283 (Drip irrig.)	Tomato/ Pepper	Rainbow trout *(Oncorhynchus mykiss)*	(*EZ*)-3-chloro-acrylic acid	Acute	1.34	51865	100
283 (Drip irrig.)	Tomato/ Pepper	*Daphnia magna*	(*EZ*)-3-chloro-acrylic acid	Acute	1.34	41044	100
283 (Drip irrig.)	Tomato/ Pepper	Freshwater diatom *(S. capricornutum)*	(*EZ*)-3-chloro-acrylic acid	Acute	1.34	515	10
283 (Drip irrig.)	Tomato/ Pepper	Duckweed (*Lemna gibba*)	(*EZ*)-3-chloro-acrylic acid	Acute	1.34	194	10
283 (Drip irrig.)	Tomato/ Pepper	**Fish** Fathead Minnow *(Pimephales promelas)*	1,3-D	Chronic	1.4	22	10
283 (Drip irrig.)	Tomato/ Pepper	**Aquatic invertebrate** *Daphnia magna*	1,3-D	Chronic	1.4	50	10

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

Applic. rate (kg/ha) (Applic. Method)	Crop	Specie	Substance	Time-scale	PECsw (µg/L)	TER_A	Trigger value
283 (Drip irrig.)	Tomato/ Pepper	Fathead Minnow (*P. promelas*)	(EZ)-3-chloroacrylic acid	Chronic	1.16	*Data reques-ted*	
283 (Drip irrig.)	Tomato/ Pepper	*Daphnia magna*	(*EZ*)-3-chloroacrylic acid	Chronic	1.16	*Data reques-ted*	

Bioconcentration

Bioconcentration factor (BCF) ‡	Not required Log Kow = 1.82 *cis* Log Kow = 2.10 *trans* and very quick dissipation
Annex VI Trigger for the bioconcentration factor	Not required.
Clearance time (CT_{50}) (CT_{90})	Not required.
Level of residues (%) in organisms after the 14 day depuration phase	Not required.

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

Acute oral toxicity ‡	Not necessary. The product is applied subsoil, preemergence
Acute contact toxicity ‡	Not necessary. The product is applied subsoil, preemergence
Acute inhalator toxicity ‡	*Data requested during EPCO meeting.*

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

Application rate (kg a.s./ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests No data submitted				

Field or semi-field tests No data submitted

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

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

Species	Stage	Test Substance	Dose (kg a.s./ha)	Endpoint	Effect	Annex VI Trigger
Extended laboratory tests ‡						
Folsomia candida	Adults	Telone	329	Mortality 1DAT	**78**	30%
Hypoaspis aculeifer	Adults	Telone	329	Mortality 1DAT	18	30%
Poecilus cupreus	Adults	Telone	329	Mortality 1DAT	3	30%
Pardosa spp	Adults	Telone	329	Mortality 1DAT	0	30%
Aleochara bilineata	Adults	Telone	329	Mortality 1DAT	24	30%

Field or semi-field tests

A field study 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 a interpretation of results.

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

Acute toxicity ‡	LC_{50} = 55.6 mg a.s./kg soil
Reproductive toxicity ‡	NOEC =770 mg a.s./kg soil (577 kg/ha) (from a 1 week aged study)

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

Application rate (kg Telone/ha)	Crop	Time-scale	PECs (mg/kg)		TER	Annex VI Trigger
224-283 (injection &drip)	Tomatoes/Peppers	Acute	5 cm 20 cm	377.33 74.66	0.15 0.74	10

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.

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

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

Nitrogen mineralisation ‡	Technical: Important effects (above 25%) at 0.77 and 3.85 g Telone II/kg soil up to 90 days (end of study).
Carbon mineralisation ‡	Technical: Important effects (above 25%) at 0.77 and 3.85 g Telone II/kg soil up to 90 days (end of study).
Field study	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.

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

Seedling emergence	NOEC 11.25 mg a.s./kg soil (tomato)
Vegetative vigour	NOEC 11.25 mg a.s./kg soil (onion)

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	R50/R53	Very toxic to aquatic organisms, may cause long-term adverse effect to the aquatic environment

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

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

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

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