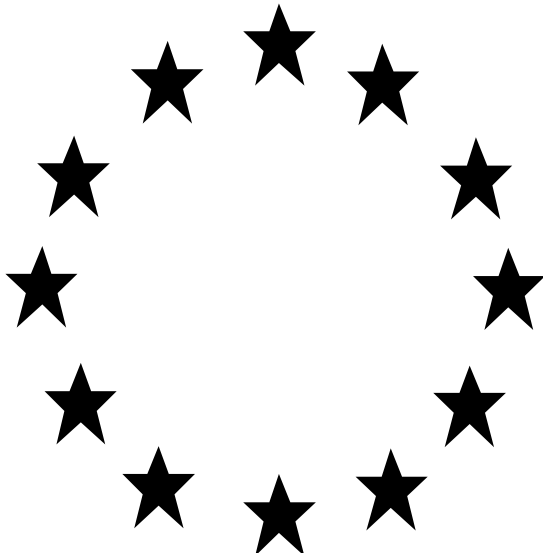

Final addendum to the

Additional Report

- public version -

Additional risk assessment provided by the rapporteur Member State Spain for the existing active substance

1,3-DICHLOROPROPENE

according to the Accelerated Resubmission Procedure laid down in Commission Regulation (EC) No. 33/2008

September 2009

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ANNEX B

1,3 DICHLOROPROPENE

ADDENDUM 4_REV_24_06_09

B - 2 : PHYSICAL AND CHEMICAL PROPERTIES

B.2 Physical and chemical properties

B.2.1 Physical and chemical properties of the active substance

Study	Guidelines and Method/GLP	Material/ Purity	Results	Conclusion/ Comments	Reference
B.2.1.11 Spectra of relevant impurities (IIA 2.5.2)	OPPTS 830.7050/OECD101 GLP: Yes	1,2-Dichloropropane AGR277102, 99% purity	See Addendum 2 B2 (March 2005)	This study has been already evaluated in Addendum 2 B2 and was considered acceptable	Humfleet B (Jan 2005) Report FAPC043741, Masterfile A59 IIA, 2.5.2
B.2.1.15 Hydrolysis rate at pH 4, 7 and 9 under sterile conditions in the absence of light (IIA 2.9.1)	OECD Guideline 111 GLP: Yes	cis-1,3-Dichloropropene AGR164303, 96.3% purity	See Addendum 3 B2 (September 2005)	This study has been already evaluated in Addendum 3 B2 (cited by Knowles, S., 2005) and was considered acceptable	Comb A.L (June 2005) Report GHE-P-11126, Masterfile A67 IIA, 2.9.1/01
B.2.1.24 Surface tension (IIA 2.14)	EEC Method A5 (Fisher Scientific Surface Tensiomat Model 21) GLP: Yes	cis-1,3-Dichloropropene TSN 100275, 98.9% purity	69.6 ± 0.4 mN/m at 20 °C (90% saturated solution) not surface active	Acceptable.	Sarff P (Sep 2005) Report NAFST-05-104, Masterfile MA93 IIA, 2.14/01
B.2.1.25 Oxidizing properties (technical active substance) (IIA 2.15)	EEC Method A21 GLP: Yes	Telone II TSN 104897, 95.9% purity	Not oxidising	Acceptable.	Comb AL. (July 2005) Report DOS433/052926, Masterfile MA91 IIA, 2.15/01
Other/special studies (IIA 2.18)	Physical properties of impurities of 1,3-Dichloropropene Technical				

Study	Guidelines and Method/GLP	Material/ Purity	Results	Conclusion/ Comments	Reference
B.2.1.26 Hydrolysis of 1,3-Dichloropropene impurities (IIA 2.18/01)	None GLP: Yes	2-chloro-1,5-hexadiene, 3-chloro-1,5-hexadiene, 2-chloro-2-methyl-pentane, 2-chloro-4-methylpentane, 2-chloro-2,3-dimethylbutane, cis and trans 1,3,3-trichloropropene, 1,2-dichloropropane, 1,3-dichloropropane and 1,2,2-trichloropropane (all impurities were >90% purity)	Key impurities that are in 1,3-Dichloropropene technical have shown that under typical environmental conditions, the compounds studied would not be likely to persist under environmental conditions (for detailed information see B.8.11)	Not acceptable. The samples were exposed to ambient laboratory light; therefore, the contribution of photodegradation in the study cannot be excluded. The validation of the analytical method is based on the comparison of the results found for 1,3-D with the hydrolysis results summarised in the list of endpoints. The intervals of concentrations used in the calibration lines are very wide (< 10 ppb 50, 100, and 200 ppb) No recoveries for the tested concentrations are included in the report. DT50 values reported in this study are not considered valid but the study gives information about the stability of the impurities and it can be concluded that the impurities of 1,3-D are not expected to persist in the environment. (see B.8.11)	Lamastra, L et al, (May 2008), Masterfile A78 IIA 2.18/01

B.2.2a Physical, chemical and technical properties of the plant protection product (Annex IIIA 2)

B.2.2.1a Physical, chemical and technical properties of the plant protection product 1,3-D, EF-1478

Product name: 1,3-D, EF-1478 containing 96% 1,3-D technical (Telone II); EC formulation

<table>
<tr><th>Study</th><th>Method</th><th>Results</th><th>Conclusion</th><th>Reference</th></tr>
<tr><td>B.2.2.5a
Oxidising properties
(IIIA 2.2.2a)</td><td>Theoretical justification</td><td>Not oxidizing
Based on individual components not being oxidising</td><td>Acceptable</td><td>Latham, A:, 2005
Derbi number 209027, Masterfile MA92

IIIA, 2.2.2/01</td></tr>
<tr><td>B.2.2.17a
Shelf life
(IIIA 2.7.5a)</td><td>GIFAP Monograph No. 17
Storage at ambient temperature for 2 years in steel drums

GLP: Yes</td><td>Results for initial and 2 years:
<table>
<tr><th></th><th>Before storage</th><th>After storage</th></tr>
<tr><td>Active content</td><td>963 g/kg</td><td>976 g/kg</td></tr>
<tr><td>appearance, colour</td><td colspan="2">No change</td></tr>
<tr><td>Water content</td><td>0.026%</td><td>0.019%</td></tr>
<tr><td>Acidity (HCl content)</td><td>30.4 ppm</td><td>30.4 ppm</td></tr>
<tr><td>pH (1% w/v.)</td><td>3.75</td><td>3.17</td></tr>
<tr><td>Persistent foam (after 12 min)</td><td><1ml</td><td>2ml</td></tr>
<tr><td>Emulsion properties</td><td>Rehomogenises easily after 24 hours and stays homogenous at 24 hrs + 30 minutes in both hard and soft waters</td><td>Re-homogenises easily after 24 hours. No significant separation at 24 hrs + 30 minutes in hard waters. Significant separation in standard soft water but easily re-homogenised.</td></tr>
</table>
No significant change in physical and chemical properties following accelerated storage except for the emulsion properties.</td><td>Acceptable

But the emulsion characteristics might be considered at Member State, due to the fact that the cream content was high after 8 weeks</td><td>A Latham, 2007
FOR-04-041, Masterfile MA88C

IIIA, 2.7.5/01</td></tr>
</table>

Study	Method	Results	Conclusion	Reference
		.Product is applied by a Drip application technique and so long term emulsion stability is not critical with this application technique.		

B.2.2.2b Physical, chemical and technical properties of the plant protection product 1,3-D-XRM 5048

Product name: 1,3-D-XRM 5048 (containing 965 g/kg pure 1,3-D), 1,3-D technical

Study	Method	Results	Conclusion	Reference
B.2.2.5b **Oxidising properties** **(IIIA 2.2.2b)**	EEC Method A21 GLP: Yes	Not oxidising	Acceptable	Comb AL. (July 2005) Report DOS433/052926, Masterfile MA91 IIIA, 2.2.2
B.2.2.15b **Stability after storage for 14 days at 54°C** **(IIIA 2.7.1b)**	CIPAC MT 46.1.3 GLP: Yes	See Addendum 3 B2	This study has been already evaluated in Addendum 3 B2 (cited by Knowles, S., 2005) and was considered acceptable	Amy Latham (2005) FOR-05-006, Latham A, May 2005, Masterfile MA89 IIIA, 2.7.1

B.2.3 References relied on.

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
(IIA 2.5.2)	Humfleet B	2005	MS, IR, NMR, and UV/vis spectral analysis of 1,2-Dichloropropane, AGR277102 Dow AgroSciences DAS Report No.: FAPC04371 (Masterfile Number): A59 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
(IIA 2.9.1/01)	Knowles S	2005	1,3-D (Cis Isomer): Determination of hydrolysis as a function of pH Huntingdon Life Sciences DAS Report No.: HLS DOS/445 (GHE-P11126) (Masterfile Number): A67 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
(IIA 2.15/01)	Comb A.L	Jul-05	Determination of oxidising properties for Telone II Huntingdon Life Sciences DAS Report No.: DOS433/05296 (Masterfile Number): MA91 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
(IIA 2.14/01)	Sarff P	2005	Determination of the Surface Tension of Cis 1,3-Dichloropropene ABC Laboratories DAS Report No.: nafst-05-14 (Masterfile Number): MA93 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIA 2.18/01 and B 8.4.1.1	Lamastra, L.; Ferrari, F.; Trevisan, M.; Capri, E.	2008	HYDROLYTIC STABILITY OF THE TELONE PROCESS IMPURITIES ICAA Catholic University of Piacenza DAS Report No.: GHE-P-11780 (Masterfile Number): A78 GLP/GEP (Y/N): N Published (Y/N): N	N	DAS

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
(IIIA 2.2.2/01, IIIA 2.2.2/02)	Latham A	2005	Oxidising properties waiver justification for EF-1478, Telone EC drip Dow AgroSciences DAS Report No.: Not applicable (Masterfile Number): MA92 GLP/GEP (Y/N): N Published (Y/N): N	Y	DAS
(IIIA 2.7.5/01)	A Latham	2007	Storage Stability and Packaging Corrosion Characteristics of EF-1478; Accelerated and 2 year Ambient Study –, 2 Year Final Dow AgroSciences DAS Report No.: FOR04-041 (Masterfile Number): MA88C GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIIA 2.2.2 (IIA 2.15/01)	Comb A.L	Jul-05	Determination of oxidising properties for Telone II Huntingdon Life Sciences DAS Report No.: DOS433/05296 (Masterfile Number): MA91 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIIA 2.7.1	A Latham	16-May-05	Accelerated storage stability of Telone II in glass for 2 weeks at 54 deg C Dow AgroSciences DAS Report No.: FOR05-006 (Masterfile Number): MA89 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS

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ANNEX B

1, 3 - DICHLOROPROPENE

Addendum 2_REV_24_06_09

B - 7 : RESIDUE DATA

This Adendum has been prepared under the responsability of:

Dr. García - Baudín, J. Mª. (Co-ordinator).

Dr. Alonso - Prados, J. L. (Co-ordinator).

Unidad de Productos Fitosanitarios, INIA., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FROM THE STUDIES SUBMITTED BY:

Task Force: Dow AgroScience & Kanesho Soil Treatment SPRL/BVBA

WITH THE ASSISTANCE OF THE FOLLOWING EXPERTS:

Residue data

Mr. Del Corro Toro, Miguel

Unidad de Productos Fitosanitarios I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FOREWORD

This addendum has been prepared after the publication of the non-inclusion for 1,3-Dichloropropene[1] soil fumigant in Annex I of 91/414/EEC and taking into account the information provided by the notifier to address the critical areas of concern and outstanding data requirements regarding the identity of the active substance, as specified in the EFSA conclusion report[2]. This Addendum is drawn up from this submitted information.

Critical areas of concern

- *As the representative uses evaluated have very high application rates (170-283 kg a.s./ha), there is the potential for significant amounts of poly chlorinated 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] Commission Decision 2007/619/EC
[2] EFSA Scientific Report (2006) 72, 1-99

B.7. Residue data.

With regard to the Residues Section, the EFSA Report main concern (EFSA Scientific Report – 2006. 72, 1-99) was that available studies do not 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 when applying 1,3-Dichloropropene (1,3-D) at the intended rate. This Addendum is drawn up from the new submitted information regarding to this concern by Dow AgroSciences and KST.

B.7.5 Identification of all critical GAPs.

The conditions leading to realistic worst-cases for residue levels in crops for supported uses are summarised in the following table, and are the same indicated in the main Monograph (DAR) for 1, 3-Dichloropropene:

Table 7.5-1: Critical Good Agricultural Practices for Supported Uses

Crop	Method of Applic.	Application rate Min/Max (kg as/ha)	No. of application	Growth stage at application	Pre-plant interval
Fruiting vegetables	Soil injection	187-224	1	Pre-plant	2-4 weeks
Fruiting vegetables	Drip irrigation	170-283	1	Pre-plant	2-4 weeks

B.7.6 Residues resulting from supervised trials.

Three additional residue studies were conducted and submitted to allow some further clarification on human health risk assessment.

Two of these three studies were carried out in order to provide some empirical evidence that the chlorinated impurities present in 1,3-D will behave similarly to 1,3-D and will not result in crop residues in harvest (see Tables 7.6-1 to 7.6-4). Parent 1,3-D and six chlorinated impurities were analysed in both studies. The chlorinated impurities analysed were the following ones: 1,2-Dichloropropane, 2-Chloro-1,5-Hexadiene, 2-Chloro-4-Methylpentane, 3-Chloro-2-Methylpentane, 1,3-Dichloropropane and 1,2,2-Trichloropropane. Parent cis-1,3-D and trans-1,3-D were analysed in these studies too.

In one of the studies (GHE-P-11766), eight trials were carried out in tomato and pepper according to the critical GAP for pre-plant soil injection applications. These trials were conducted outdoors in Italy and Spain in 2007 using the formulation called Telone II (see Tables 7.6-1 and 7.6-2). Not detectable residues were found in any of the trials for the parent compound and for the six mentioned impurities. Method of analysis CEMS-3339 (CEMS-3629, GHE-P-11736, Ref.OR35) was used in the study, with a limit of quantification of 0.01 mg/kg.

In the other study (GHE-P-11705), eight trials were carried out in tomato and pepper according to the critical GAP for pre-plant soil drip irrigation. These trials were conducted indoors in Italy and Spain in

2007 using the formulation called Telone EC (see Tables 7.6-3 and 7.6-4). Not detectable residues were found in any of the trials for the parent compound and for the six mentioned impurities. Method of analysis CEMS-3339 (CEMS-3629, GHE-P-11736, Ref.OR35) was used in the study, with a limit of quantification of 0.01 mg/kg.

The third study (GHE-P11176) was conducted in young tomato plants, but only the parent 1,3-Dichloropropene (total cis + trans) was analyzed. Four trials were carried out in tomato according to the critical GAP for pre-plant soil injection applications. These trials were conducted outdoors in Italy in 2005 using the formulation called Telone II (see Table 7.6-5). The samplings were conducted from 14 to 35 days after the soil treatment (0 to 21 days post planting), and not detectable residues were found in any of the trials for the parent compound. Residues of 1,3-D were measured according to the method described in Restec report 0503, with a limit of quantification of 0.01 mg/kg (0.005 mg/kg each of cis- and trans-).

Table 7.6-1: Residues of 1,3-D and impurities in tomato after pre-plant application by soil injection

Tomato (LYPES)			Application Details					Residue in whole fruits (mg/kg)				
Country	**Zone**	**Year**	**Form.**	**No.**	**Rate * (kg as/ha)**	**Rate (kg as/hL)**	**Spray vol. (L/ha)**	**PPI** ** **(days)**	***cis*-1,3-D**	***trans*-1,3-D**	**Impurities** ***	**Study no.**
Italy	S	2007	Telone II	1	208	N/A	N/A	81	ND	ND	ND	CEMS-3487A GHE-P-11766
Italy	S	2007	Telone II	1	208	N/A	N/A	70	ND	ND	ND	CEMS-3487B GHE-P-11766
Spain	S	2007	Telone II	1	205	N/A	N/A	106	ND	ND	ND	CEMS-3487C GHE-P-11766
Spain	S	2007	Telone II	1	253	N/A	N/A	72	ND	ND	ND	CEMS-3487D GHE-P-11766

S = Southern Zone ND = Not detected (<0.003 mg/kg)

* A certificate of analysis was submitted regarding the batch of Telone II used in the residue trials (test substance TSN 106191), and all the six impurities sought were found present in the applied formulation.

** PPI = post planting interval

***Impurities = 1,2-Dichloropropane, 2-Chloro-1,5-Hexadiene, 2-Chloro-4-Methylpentane, 3-Chloro-2-Methylpentane, 1,3-Dichloropropane, 1,2,2-Trichloropropane. ND refers to all the individual impurities.

Table 7.6-2: Residues of 1,3-D and impurities in pepper after pre-plant application by soil injection

Pepper (CPSAN)			Application Details					Residue in whole fruits (mg/kg)				
Country	**Zone**	**Year**	**Form.**	**No.**	**Rate * (kg as/ha)**	**Rate (kg as/hL)**	**Spray vol. (L/ha)**	**PPI** ** **(days)**	***cis*-1,3-D**	***trans*-1,3-D**	**Impurities** ***	**Study no.**
Italy	S	2007	Telone II	1	213	N/A	N/A	91	ND	ND	ND	CEMS-3487E GHE-P-11766
Italy	S	2007	Telone II	1	219	N/A	N/A	80	ND	ND	ND	CEMS-3487F GHE-P-11766
Spain	S	2007	Telone II	1	214	N/A	N/A	84	ND	ND	ND	CEMS-3487G GHE-P-11766
Spain	S	2007	Telone II	1	253	N/A	N/A	73	ND	ND	ND	CEMS-3487H GHE-P-11766

S = Southern Zone ND = Not detected (<0.003 mg/kg)

* A certificate of analysis was submitted regarding the batch of Telone II used in the residue trials (test substance TSN 106191), and all the six impurities sought were found present in the applied formulation.

** PPI = post planting interval

*** Impurities = 1,2-Dichloropropane, 2-Chloro-1,5-Hexadiene, 2-Chloro-4-Methylpentane, 3-Chloro-2-Methylpentane, 1,3-Dichloropropane, 1,2,2-Trichloropropane. ND refers to all the individual impurities.

Table 7.6-3: Residues of 1,3-D and impurities in tomato after pre-plant application by soil drip irrigation

Tomato (LYPES)			Application Details					Residue in whole fruits (mg/kg)				
Country	**Zone**	**Year**	**Form.**	**No.**	**Rate * (kg as/ha)**	**Rate (kg as/hL)**	**Spray vol. (L/ha)**	**PPI** ** **(days)**	***cis*-1,3-D**	***trans*-1,3-D**	**Impurities** ***	**Study no.**
Italy	S	2007	Telone EC	1	283	N/A	N/A	73	ND	ND	ND	CEMS-3486A GHE-P-11705
Italy	S	2007	Telone EC	1	283	N/A	N/A	82	ND	ND	ND	CEMS-3486B GHE-P-11705
Spain	S	2007	Telone EC	1	281	N/A	N/A	83	ND	ND	ND	CEMS-3486C GHE-P-11705
Spain	S	2007	Telone EC	1	283	N/A	N/A	98	ND	ND	ND	CEMS-3486D GHE-P-11705

S = Southern Zone ND = Not detected (<0.003 mg/kg)

* Regarding the batch used in the residue trials for Telone EC (test substance TSN106192), the impurity content was not quantified directly, although it could be assumed to be similar to the batch of Telone II, since Telone EC was produced from the batch of Telone II (TSN 106191).

** PPI = post planting interval

*** Impurities = 1,2-Dichloropropane, 2-Chloro-1,5-Hexadiene, 2-Chloro-4-Methylpentane, 3-Chloro-2-Methylpentane, 1,3-Dichloropropane, 1,2,2-Trichloropropane. ND refers to all the individual impurities.

Table 7.6-4: Residues of 1,3-D and impurities in pepper after pre-plant application by soil drip irrigation

Pepper (CPSAN)			Application Details					Residue in whole fruits (mg/kg)				
Country	**Zone**	**Year**	**Form.**	**No.**	**Rate (kg as/ha)**	**Rate (kg as/hL)**	**Spray vol. (L/ha)**	**PPI* (days)**	***cis*-1,3-D**	***trans*-1,3-D**	**Impurities ******	**Study no.**
Italy	S	2007	Telone EC	1	283	N/A	N/A	91	ND	ND	ND	CEMS-3486E GHE-P-11705
Italy	S	2007	Telone EC	1	283	N/A	N/A	99	ND	ND	ND	CEMS-3486F GHE-P-11705
Spain	S	2007	Telone EC	1	281	N/A	N/A	83	ND	ND	ND	CEMS-3486G GHE-P-11705
Spain	S	2007	Telone EC	1	283	N/A	N/A	78	ND	ND	ND	CEMS-3486H GHE-P-11705

S = Southern Zone ND = Not detected (<0.003 mg/kg)

* Regarding the batch used in the residue trials for Telone EC (test substance TSN106192), the impurity content was not quantified directly, although it could be assumed to be similar to the batch of Telone II, since Telone EC was produced from the batch of Telone II (TSN 106191).

** PPI = post planting interval

*** Impurities = 1,2-Dichloropropane, 2-Chloro-1,5-Hexadiene, 2-Chloro-4-Methylpentane, 3-Chloro-2-Methylpentane, 1,3-Dichloropropane, 1,2,2-Trichloropropane. ND refers to the all the individual impurities.

Table 7.6-5: Residues of 1,3-D in tomato plants after pre-plant application by soil injection

Tomato (LYPES)			Application Details					Residue in whole plants without roots (mg/kg)		
Country	**Zone**	**Year**	**Form.**	**No.**	**Rate (kg as/ha)**	**Rate (kg as/hL)**	**Spray vol. (Lha)**	**DAT (PPI) (days)***	***Cis* + *trans* 1,3-D**	**Study no.**
Italy	S	2005	Telone II	1	224	N/A	N/A	14 (0) 15 (1) 17 (3) 21 (7) 24 (10) 28 (14) 35 (21)	ND ND ND ND ND ND ND	CEMS-2710A (GHE-P-11176)
Italy	S	2005	Telone II	1	224	N/A	N/A	14 (0) 15 (1) 17 (3) 21 (7) 24 (10) 28 (14) 35 (21)	ND ND ND ND ND ND ND	CEMS-2710B (GHE-P-11176)

Tomato (LYPES)			Application Details					Residue in whole plants without roots (mg/kg)		
Country	**Zone**	**Year**	**Form.**	**No.**	**Rate (kg as/ha)**	**Rate (kg as/hL)**	**Spray vol. (Lha)**	**DAT (PPI) (days)***	***Cis* + *trans* 1,3-D**	**Study no.**
Italy	S	2005	Telone II	1	224	N/A	N/A	14 (0) 15 (1) 17 (3) 21 (7) 24 (10) 28 (14) 35 (21)	ND ND ND ND ND ND ND	CEMS-2710C (GHE-P-11176)
Italy	S	2005	Telone II	1	224	N/A	N/A	14 (0) 15 (1) 17 (3) 21 (7) 24 (10) 28 (14) 35 (21)	ND ND ND ND ND ND ND	CEMS-2710D (GHE-P-11176)

S = Southern Zone ND = Not detected (<0.002 mg/kg) * DAT = days after treatment (PPI = post planting interval)

B.7.15 Estimation of the potential and actual exposure through diet and other means.

It must be taken into account that 1,3-D is applied to soil (via soil injection or drip irrigation) at least 14 days before planting and the minimum PHI is 10 weeks for fruiting vegetables. In fact, no residues of 1,3-D have been detected in any crop over 30-year period. As seen in the submitted residue trials shown in Table 7.6-5, even young plants analysed within 21 days of planting (35 days from treatment) did not show any detectable residues of parental 1,3-D. Moreover, since commercially applied 1,3-D has a minimum purity of 96.5% and contains individual impurities at 0.01 to 0.6%, the maximum level of any impurity applied to soil is about 200 times lower than application rates of 1,3-D that give no residues.

Although determination of a crop residue for an impurity in a technical material is not a data requirement in Directive 91/414/EEC, two of the three additional submitted studies provide information about six key chlorinated impurities present in 1,3-D technical.

The six impurities which were looked for and not found present in any of the sixteen residue trials included in the two submitted studies are the following ones: 1,2-Dichloropropane, [redacted]e. These six impurities were found present in the submitted 1,3-D technical profile of representative batches (see Summary of analysis of representative batches: Dow Site Stade, Germany; Site Rheinberg, Germany; Site Tabaux, France).

There are other impurities above 1 g/kg (0.1% w/w) in the submitted 1,3-D technical profile of representative batches. However, all of them are in a similar range of content in the studied representative batches of 1,3-D technical, from 1 g/kg to a maximum of 6 g/kg.

Moreover, according to Addendum IV.B-6 (March 2009), calculation of contributions of impurities to the mammalian toxicity of 1,3-Dichloropropene products (Manual of development and use of FAO and WHO specifications for pesticides, Feb.2006) concluded that impurities which may occur in 1,3-Dichloropropene do not contribute to the potential toxicity of these products. All the impurities present above 1 g/kg in any of the two submitted 1,3-D technical profiles of batches were considered in this calculation, and not any impurity was found to be relevant, since the greatest contribution of an individual impurity was estimated to be 0.26% (MTIhaz= 1.0026) for 1,3-dichloropropane. Furthermore, contribution to the mammalian toxicity of 1,3-Dichloropropene of other impurities found in the studied profile of batches below 1 g/kg was calculated too, and none of them was found to be relevant. The calculated potential contribution of all impurities, if present at their maximum allowable concentration, would be proximately 0.85% (MThaz=1.0085).

Therefore, it was concluded that the impurities which can occur in 1,3-Dichloropropene products de not contribute to the potential toxicity of the product.

Moreover, most of them are polychlorinated hydrocarbons of a similar chemical class to 1,3-D (e.g., propenes, propanes, butanes, pentanes). In addition, as 1,3-D is refined by a distillation process, the impurities have in general similar volatility and physico-chemical properties. Therefore, uptake and residue formation in crops would not be significantly different to that of 1,3-D.

Exceptions to this similar volatility or physico-chemical structure were the impurities [redacted] (both declared at concentration below 1 g/kg). Calculation of contributions of impurities to the mammalian toxicity of 1,3-Dichloropropene products showed none of them was found to be relevant too (Addendum IV.B-6; March 2009).

[redacted] was considered as non toxicologically relevant according to the information reported by notifier and assessed in the Addendum IV.B-6. March 2009. An estimation of rat oral LD50 value of [redacted] of 337,6 mg/kg using the commercially available, statistically-based, QSAR computer model TOPKAT™. So that, [redacted] should be considered as not toxicologically relevant

In summary, based on the fact that 1,3-D and its impurities are applied to soil at least 14 days before planting and 70 days before harvest, 1,3-D and its six analysed impurities do not leave crop residues, and the contribution of all the studied impurities to the mammalian toxicity of 1,3-Dichloropropene products showed none of them was found to be relevant, residues of 1,3-D and its impurities used for the intended uses should not represent a risk to health of consumers.

References by Annex Point

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
IIA 6.3 and IIIA 10.1.4/01	N W Rawle	2005	Residues of 1,3-Dichloropropene in transplanted tomato plants at intervals following a single application of TELONE II (XRM-5048), Italy – 2005 CEMAS DAS Report No.: ghe-p-11176 (Masterfile Number): NB69 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIA 6.3	Devine H C	2008	Residues o 1,3-Dichloropropene and 6 impurities in tomatoes and peppers (outdoor) at harvest following a single application of XRM-5048 (Telone II)- Southern Europe- 2007 CEMAS DAS Report No.: GHE-P-11776 (Masterfile Number): NB70 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIA 6.3	Eversfield SG	2008	Residues o 1,3-Dichloropropene and 6 impurities in tomatoes and peppers (INDOOR) at harvest following a single application of ef-1478 (Telone EC)- Southern Europe- 2007 CEMAS DAS Report No.: GHE-P-11705 (Masterfile Number): NB71 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS

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ANNEX B

1,3-DICHLOROPROPENE

ADDENDEUM 3_REV_24_06_09

B - 8 : ENVIRONMENTAL FATE AND BEHAVIOUR

THIS ADDENDUM WAS PREPARED UNDER THE RESPONSIBILITY OF:

Mr. García - Baudín, J. Mª. Ph. D. (Co-ordinator).

Mr. Alonso - Prados, J. L. Ph D. (Scientific Co-ordinator).

Unidad de Productos Fitosanitarios I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FROM THE DOSSIERS SUBMITTED BY:

Task Force: Dow AgroScience & Kanesho Soil Treatment SPRL/BVBA

WITH THE ASSISTANCE OF THE FOLLOWING EXPERTS:

Environmental fate and behaviour

Ms. Alonso-Prados, Elena

Unidad de Productos Fitosanitarios I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FOREWORD

This addendum has been prepared after the publication of the non-inclusion for 1,3-Dichloropropene[2] soil fumigant in Annex I of 91/414/EEC and taking into account the information provided by the notifier to address the critical areas of concern and outstanding data requirements regarding the identity of the active substance, as specified in the EFSA conclusion report[2] :

Critical areas of concern

- *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.*

List of studies to be generated, still ongoing or available but not peer reviewed

- *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 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).*

B.8 Environmental fate and Behaviour.

B.8.6.2 Estimation of concentrations in surface water.

During the Peer Review a data gap was identified regarding to PEC in surface water for the direct soil injection method of application (indoors and outdoor). According to the EFSA Scientific Report (2006), the drainage route of entry must be assessed and the runoff route of entry must also be appropriately assessed. These drainage and runoff assessments are required for (EZ)-1,3-dichloropropene and the soil residue (EZ)-3-chloroacrylic acid.

An experimental runoff study conducted in US was evaluated in the original DAR. 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.

The potential for wet and dry deposition of parent (EZ)-1,3-dichloropropene from the air should also be addressed

To address these issues, data have been submitted to evaluate the open field use and drainage, deposition by air and run-off to surface water. The US site used to determine the percentage runoff was evaluated relative to EU conditions and FOCUS run-off scenarios.

A separate modelling study has generated data to evaluate the lateral flow movement of 1,3-D in soil. As 1,3-D is not use in tile drained fields, lateral flow modelling is used to evaluate the “drainage” potential and movement to a 30 depth water body. Run-off has been considered for 1,3-D open field use even though the product is injected into the soil and thereby creating a negligible run-off risk.

[2] Commission Decision 2007/619/EC
[2] EFSA Scientific Report (2006) 72, 1-99

B.8.6.2.1 Drainage /lateral flow

a) Shank use. Field conditions

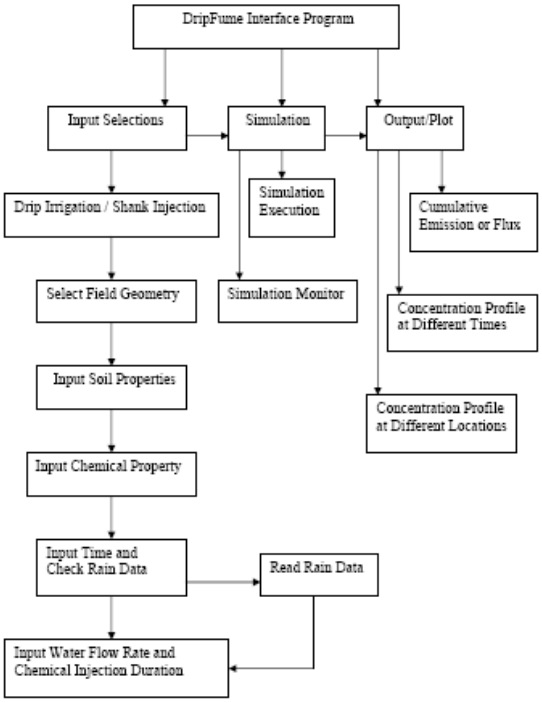
a.1) Description of DripFume model

Report: Knuteson, J.A and Wang, D. (2001) Report Nº: GH-C 5358 (Masterfile:MK 42) Annex point/reference IIIA 9.2.3/02

DripFume is a Windows-based graphical user interface program developed in MS Visual Basic (VB) to use a two dimensional multi-phase finite element pesticide transport model to simulate distribution and emission of volatile fumigant chemicals when applied through drip irrigation or shank injection. The pesticide model was modified from a generic two-dimensional finite element code CHAIN 2D (Simunek and van Genuchten, 1994)[3]. Briefly, a governing equation is used for computing fumigant transport in unsaturated subsurface soil in both solution and gaseous phases. The model assumes nonequilibrium interaction between the solution and adsorbed concentrations, and equilibrium interaction between the solution and gaseous concentrations. A linear relationship was used for chemical partition between the three phases. Degradation was considered in the solution and adsorbed phases, but not in the air, using a first-order decay having the same rate constant.

DripFume provides an intuitive user interface by linking databases of soil and chemical properties to generate input files for the pesticide model, initiate model execution and monitor the simulation progress, and post-process the model output to graphical displays for easier interpretation (Figure 8.6.2.1-1).

Figure 8.6.2.1-1: Flow chart of the DripFume interface program.



Input selection:

a) Application method Two choices are available a) drip irrigation, b) shank injection. The next step in the program deals with selection related to field configuration that include bed shape, application depth, and soil layering.

Under drip irrigation four field configurations can be selected: a flat surface, 40 inch bed (101.6 cm); 42-inch bed (106.7 cm) or 80 inch bed (203.2 cm), One drip line is located directly below the 40 inch and 40 inch bed centre. Two drip lines are used, one located at 12 inch (30.5 cm) to the left and one at 12 inch (30.5 cm) to the right from the bed centre.

Drip lines can be located at six possible depths: 1-inch (2.54 cm), 3 inch (7.62 cm), 6 inch (15.24 cm), 8 inch (20.3 cm), and 18 inch (45.7 cm)

[3] Simunek, J. van Genuchten, M Th., 1994. The CHAIN-2D code for simulating the two dimensional movement of water, heat, and multiple solutes in variability saturated porous media. Version 1.1 Research report Nº 136 US Salinity Laboratory, USDA-ARS, Riverside, CA.

Under shank injection, two field configurations can be selected: 40 inch bed (101.6 cm) or flat surface. The flat field is to simulate the more conventional pre-plant soil fumigation with shank knives located at 25 cm spacing. Injection can be mad directly below the bed center at 12 inch (30.5 cm) and 18 inch (45.7 cm).

b) soil hydraulic parameters: One soil type can be selected for each simulation run. Arithmetic means of hydraulic properties (residual, saturation water contents, hydraulic conductivity under saturationand α and n parameters used in describing the water retention and hydraulic conductivity functions) of all 12 soil series (clay, silt, silty, clay,, caly loam, silt clay loam, sandy,clay, sandy clay loam, silt loam, loam sandy loam loamy sand and sand) were obtained from literature data sets (Carsel and Parrish, 1988)[4].

Users of the program also have the choice of selecting the duration of fumigant injection, total drip irrigation duration, and the duration of simulation to examine subsurface fumigation distribution patterns and surface emission losses. Other input options include selecting either one soil type or a two-layered soil profile, either with or without film cover, and with or without rain or sprinkler irrigation.

Output options in the post-processing of DripFume include data and graphs of cumulative volatilization loss, volatilization flux density, concentration profile by time for a selected location or by location for selected lapsed times after fumigant application.

RMS comment. During the Peer Review there was a concern about the applicability of the FOCUS SW with chemicals with vapour pressure >100 Pa (comment 4(11) in reporting table and data requirement 4.2 in the evaluation table and EPCO 21 report).

DripFume is based on CHAIN2_D, this model was used to simulate the fate and transport of 1,3-D by lateral flow and derive PECsw (see section a.2) below. The characteristics of DripFume were published in *Computers and electronics in Agriculture* 56 (2): 111-119 (2007) and more details can be found in the following link:
http://mbao.org/2006/06PowerPoints/MBAO%20PDFs/Preplant/2%20-%20Fumigant%20Modeling%20&%20Analysis/Wang.pdf

a.2) Predicted environmental concentration calculation (lateral transport) with CHAIN_2D

Report: Wang, D., Knowles, S., Knuteson, J (2005) Report Nº: GHE-P-11175 (Masterfile: K83) Annex point/reference IIIA 9.2.3/03

The pesticide model: Chain_2D code was selected for simulating 1,3-D fate and lateral transport in the soil because this mechanistic model has capability of simultaneously simulating the transport of heat, water, and vapor and solute phase chemicals in soils. The governing equation for describing 1,3-D transport in both gaseous and liquid phases in the soil can be written as

$$\frac{\partial \theta C_L}{\partial t} + \frac{\partial \rho C_S}{\partial t} + \frac{\partial a_s C_g}{\partial t} = \theta D_L \frac{\partial}{\partial x}\left[\frac{\partial C_L}{\partial z}\right] + a_s D_g \frac{\partial}{\partial x}\left[\frac{\partial C_g}{\partial z}\right] - \frac{\partial q C_L}{\partial z} - \mu_L \theta C_L - \mu_S \rho C_S \quad [1]$$

where CL, Cs, and Cg are 1,3-D concentrations in the soil in liquid (M L^{-3}), solid (M M^{-1}), and gaseous (M L^{-3}) phases, respectively; θ is soil volumetric water content (L^3 L^{-3}); ρ is soil bulk density (M L^{-3});α_s is soil air content (L^3 L^{-3}); D_L and D_g are respectively 1,3-D effective diffusion coefficients in liquid and gaseous phases (L^2 T^{-1}); q is volumetric liquid flux density (L T^{-1}); μ_L and μs are first-order degradation rate constants for 1,3-D in liquid and solid phases (T^{-1}); t is time (T); and x and z are lateral and vertical distances (L). The soil water content (θ) and liquid flux density (q) was computed with the Richards' equation:

$$\frac{\partial \theta}{\partial t} = \frac{\partial}{\partial x}\left[K(h)\frac{\partial h}{\partial x}\right] - \frac{\partial K(h)}{\partial x} \quad [2]$$

[4] Carsel R.., Parrish, R.S., 1988. Developing joint probability distribution of soil water retention characteristics. Water. Resour. Res: 24-. 755-769

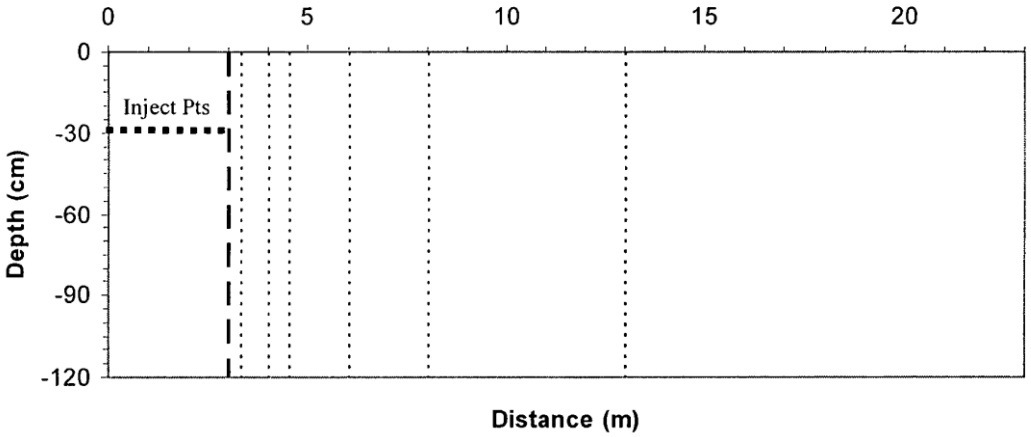
where K(h) is soil hydraulic conductivity (L T^{-1}) under water potential h (L). The liquid flux density (q) also determines the rate of 1,3-D convective transport in the liquid or solution phase. The model assumes non-equilibrium interaction between the solution and adsorbed concentrations, and equilibrium interaction between the solution and gaseous concentrations. A linear relationship was used for 1,3-D partition between the three phases. Degradation of 1,3-D was considered in the solution and adsorbed phases, but not in the air, using a first order decay having the same rate constant (table 8.6.2.1.1-3). The model considers temperature dependence of transport parameters, therefore, soil temperature is computed at each time step based on the rate of heat transfer in the soil. Heat transfer in the soil is accounted as conduction and convection coupled with liquid flux, but neglecting the relatively insignificant diffusive heat movement through water vapour. Therefore, a one-dimensional heat transport equation can be described as:

$$C(\theta)\frac{\partial T_S}{\partial t} = \frac{\partial}{\partial x}\left[\lambda(\theta)\frac{\partial T_S}{\partial x}\right] - C_w q\frac{\partial T_S}{\partial x} \qquad [3]$$

where Ts is soil temperature (K); C(θ) and Cw are the volumetric heat capacity for soil and water (MT^2 L^{-1} K^{-1}), respectively; and λ(θ) is the apparent thermal conductivity of the soil (ML T^{-3} K^{-1}).

Simulation domain for lateral transport: The two simulation domain included 3 m of treated field adjacent to 20 m of untreated soil (23 m wide) and to a depth of 1.2 m (figure 8.6.2.1-2). A representative application unit toolbar was 3 m wide with shanks spaced at 30 cm along its width. The model simulated 11 shanks spaced 30 cm apart with the first shank at zero distance and the last shank at 3 m (figure 8.6.2.1.1-2). 1,3-D was injected at a depth of 30 cm at 230 kg a.i. 1,3-D/ha as sum of cis- and trans- isomers at 50:50 ratio. Transport of the chemical through the soil surface to the atmosphere and below 1.2m was simulated but not considered as contributing to lateral transport, e.g no atmospheric redeposition or subsurface upward input to the off filed locations.

Figure 8.6.2.1-2: Simulation domain



The cumulative flux over the lifetime of the simulation was an estimate of the total mass of 1,3-D (in both liquid and vapour phases) that passed through the vertical flux plane selected at several sections off the fumigated field. Each vertical section required a new grid file with different nodal code at the vertical plane . The model calculated the movement of 1,3-D due to diffusion in the vapour phase and convection in the liquid phase in the unsaturated field soil. Transport was mediated by soil solid phase sorption processes.

Boundary conditions

The initial 1,3-D concentration in the soil profile is controlled by the amount and method of the application. For shank injection, instantaneous sources at 11 shank locations are added in the two dimensional domain and can be described as:

$$C_{L,g}(x, z, 0) = C_o(x_i, z_i)$$

$$C_{L,g}(x, z, 0) = 0 \ (x \neq x_i, z \neq z_i)$$

Where C_0 is the initial 1,3-D concentration at the source (ML^{-3}) and xi and zi specify the source or shank location in the soil profile. Because 1,3-D was injected at 30 cm depth, zi= 30 cm and x= 0, 30, 60, 90, 120, 150, 180, 210, 240, 270, 300 cm

Weather characteristics: The treated field was fumigated with a typical open field shank injection under two temperature conditions typical of northern (15 ºC in average) and southern (30 ºC in average) zones in the European Union (EU). Surface environmental boundary conditions were created based on long-term weather information deom Etain, France and Almería, Spain.

Table 8.6.2.1-1: Weather input parameters used in the model for northern EU and southern EU

Parameters	Etain, France	Almería, Spain
Surface mean temperature (ºC)	15	30
Temperature amplitude at soil surface (ºC)	5	5
Mean precipitation (cm 30-d^{-1})	4.2863	1.0000
Precipitation frequency (d^{-1})	0.1333	0.0667
Maximum precipitation intensity (cm d^{-1})	9	4
ET while no raining (cm d^{-1})	0.05	0.0678
ET while raining (cm d^{-1})	0.01	0.01

The surface was also considered as a bare soil , and 1,3-D volatilization was allowed. A constant diffusion layer thickness of 0.5 cm above the soil surface was used throughout the simulation

Soil hydraulic properties: To represent a near realistic yet worst case situation, the Cuckney sand texture (90% sand, 6% silt, 4 % clay) was used to determine the soil transport properties using a neural network pedotransfer function (Rosetta).

Table 8.6.2.1-2: Soil hydraulic parameters

Residual water content θ_r (cm^3 cm^{-3})	0.0370
Saturation water content θ_s (cm^3 cm^{-3})	0.4124
α (cm^{-1})	0.0552
N	2.2262
Hydraulc conductivity, K_s (cm d^{-1})	697.84

Chemical properties for each isomer of 1,3-D are given in table 8.6.2.1-3

Table 8.6.2.1-3: Input parameters used in the model for the two isomers of 1,3-D

Parameter	cis-1,3-D	Trans- 1,3-D
Diffusion coefficient Dg (cm^2 d^{-1})[1]	7199	7182
Adsorption coefficient Kd (cm^3 g^{-1})[2]	0.3	0.3
Hnery's constant [3]	0.056	0.037
DT50 soil (d)[4]	15	15
DT 50 water (d)[4]	15	15
DT50 air (d)	∞	∞
Activation energy (J mol^{-1})		
Diffusion coefficient Dg [1]	4511	4511
Adsorption coefficient Kd [2]	0	0
Hnery's constant [3]	43207	43207
DT50 soil [4]	43551	43551
DT 50 water [4]	43551	43551

1 Wang et al (1997) J. Environ. Qual. 26: 1072-1079;
2 Wolt et al (1993) Acta Hortic. 334:361-371
3 Leistra (1970) J. Agricultural and Food Chemistry 18: 1124-1126
4 van Dijk (1980) Pestic.Sci 11:625-632

The gaseous phase diffusion (Dg), the mofied henry's constant (Kh) and the DT50 in soil and water are temperature dependant. To account for temperature effect on 1,3-D transport and volatilization, a generic equation similar to the Arrhenius equation is used in model simulation:

$$\beta(T_a) = \beta_r^{rT} \exp\left[\frac{T_r - T_a}{R\, T_r T_a} E_a^{\beta}\right]$$

Where: β (Ta) describes a temperature dependant parameter; β_r^{rT} is the reference value for parameter β at a reference temperature (T_r) $E_a^{\beta_r}$ is the activation enrgy for parameter β (J mol^{-1}), Ta is the apparent soil or air temperature (K); Tr is the reference temperature (K) and Rthe universal constant (8.314 J mol^{-1} K^{-1}) . The liquid to solid phase adsorption coefficient was independent of temperature change.

With time zero being the time of fumigant application, the total run time for each simulation scenario was limited to 120 d since additional off field transport had become insignificant

Computation of PEC . The liquid phase concentration of total 1,3-D (vapour and liquid) arrived in a ditch 100-cm wide by 120 cm deep with a a water layer of 30 cm. To determine totat 1,3-D discharging to the ditch, six flux planes were selected at 0.3, 1, 1.5, 3, 5 and 10 m from the field (doted lines in the figure 8.6.2.1-2).

The model computed total 1,3-D mass in both solution and vapour phases, passed the flux plane for a unit length in the third dimension . The total mass was further converted to PEC (ug/L) by dividing the total 1,3-D mass with the total volume of water per unit of length of the ditch . The two dimensional simulation domain was a cross section (or a slab of) the soil profile including the fumigated and no fumigated fields (20 m from the field edge) in the direction perpendicular to the fumigation shank passes. The length unit used in this two-dimensional simulation was cm so the unit length for the ditch was 1cm in the third dimension of shank passes or the ditch. Therefore, the total volume of water for unit of length of the ditch was a constant to 100cm x 30cmx 1cm= $300cm^3$

The total 1,3-D concentration (the sum of liquid, vapour and adsorbed 1,3-D on solid phase in a unit of soil volume) in the upper 30 cm soil profile was estimated for each off-fieldcalculation distance at 5 cm increment to 30 cm depth. An average PEC in the 30 cm depth was also computed for each off – field section

Findings:

Total 1,3-D concentration in ditch water : The predicted cumulative (summed) total 1,3-D concentrations in ditch water (PECsw) decreased rapidly with distance from the treated field boundary. The concentration, cumulative up to 120 days after application, decreased to very small values (< 0.5µg/L) at all distances more than 3 m from the field edge when average temperature was 15 ºC (table 8.6.2.1-4). The concentration, cumulative up to 120 days after application, decreasd to < 0.3 µg/L at all distances beyond 1.5 m from the field edge when average temperature was 30 ºC (table 8.6.2.1-5).

Table 8.6.2.1-4: Predicted cumulative 1,3-D concentrations (µg/L) in ditch water at 0.1, 1, 5, 14, 28, and 120 days after injection at selected locations from the field edge, T = 15 ºC.

Time	Distance from Field Edge				
(day)	0.3 m	1 m	3 m	5 m	10 m
0.1	0.0	0.0	0.000	0.000	0.000
1	3.7	0.0	0.000	0.000	0.000
5	640.0	1.7	0.000	0.000	0.000
14	1366.7	24.9	0.000	0.000	0.000
28	2386.7	138.3	0.001	0.000	0.000
120	**2763.3**	**250.0**	**0.466**	**0.006**	**0.000**

Table 8.6.2.1.1-5: Predicted cumulative 1,3-D concentrations (µg/L) in ditch water at 0.1, 1, 5, 14, 28, and 120 days after injection at selected locations from the field edge, T = 30 ºC.

Time	Distance from Field Edge				
(day)	0.3 m	1 m	3 m	5 m	10 m
0.1	0.000	0.000	0.000	0.000	0.000
1	9.357	0.001	0.000	0.000	0.000
5	34.300	1.567	0.000	0.000	0.000
14	86.333	3.373	0.000	0.000	0.000
28	89.333	4.060	0.000	0.000	0.000
120	**90.667**	**4.060**	**0.000**	**0.000**	**0.000**

Total 1,3-D concentration in the soil

The predicted instantaneous (every 5 cm increment) and 30-cm average total 1,3-D soil concentrations (sum of liquid, vapor, and absorbed phases) also decreased rapidly with distance from the treated field boundary. At 15 ºC, the 30-cm average total 1,3-D soil concentration reduced to < 0.001 mg/kg at locations 3 m beyond the field edge at 28 days after application. At 30 ºC, the average 1,3-D concentration reduced to < 0.010 mg/kg at 3 m and < 0.001 mg/kg at 5 m beyond the treated field boundary.

Table 8.6.2.1.1-6: Average total 1,3-D concentrations (mg/kg-soil) in the top 30-cm soil at 0.1, 1, 5, 14, and 28 days after injection at selected locations from the field edge, T = 15 ºC.

Time	Distance from Field Edge				
(day)	0.1 m	1 m	3 m	5 m	10 m
0.1	**121.0**	0.000	0.000	0.000	0.000
1	191.0	0.000	0.000	0.000	0.000
5	61.50	0.477	0.000	0.000	0.000
14	14.60	**1.410**	0.000	0.000	0.000
28	4.060	0.960	0.001	0.000	0.000

Table 8.6.2.1.1-7: Average total 1,3-D concentrations (mg/kg-soil) in the top 30-cm soil at 0.1, 1, 5, 14, and 28 days after injection at selected locations from the field edge, T = 30 ºC.

Time	Distance from Field Edge				
(day)	0.1 m	1 m	3 m	5 m	10 m
0.1	**221.0**	0.000	0.000	0.000	0.000
1	106.0	0.052	0.000	0.000	0.000
5	15.10	**1.600**	0.000	0.000	0.000
14	2.320	0.783	0.006	0.000	0.000
28	0.348	0.174	0.010	0.000	0.000

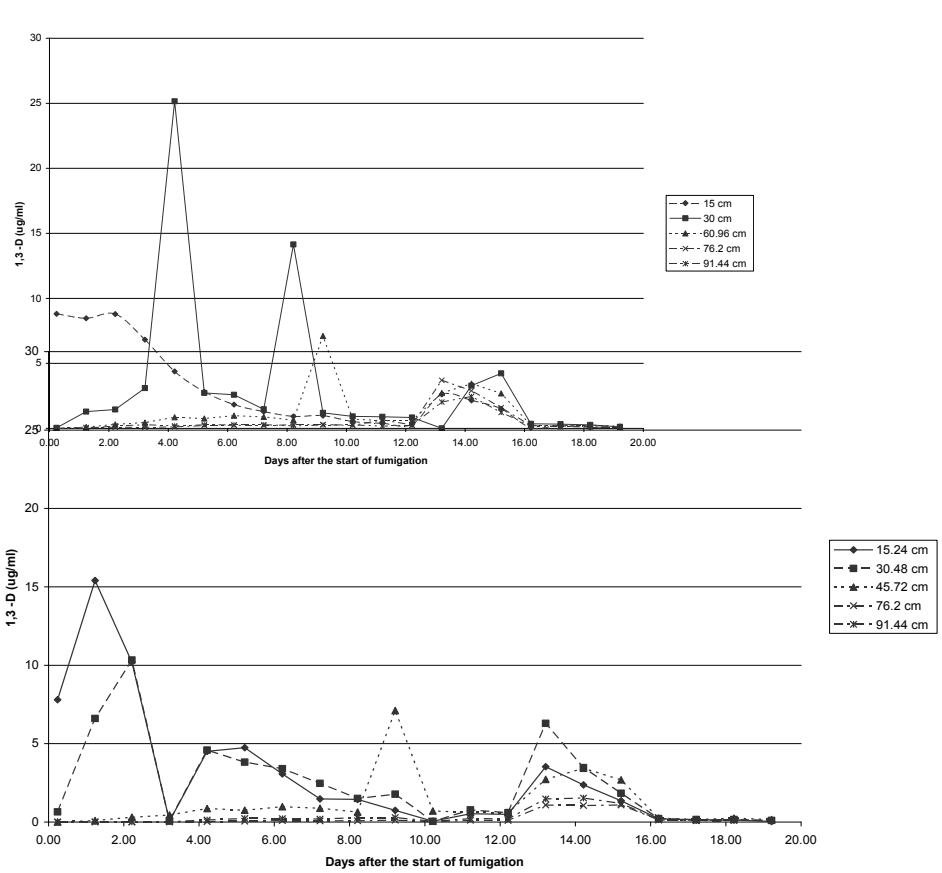
b) Drip irrigation. Experimental evidences of limited lateral transport o 1,3-D.

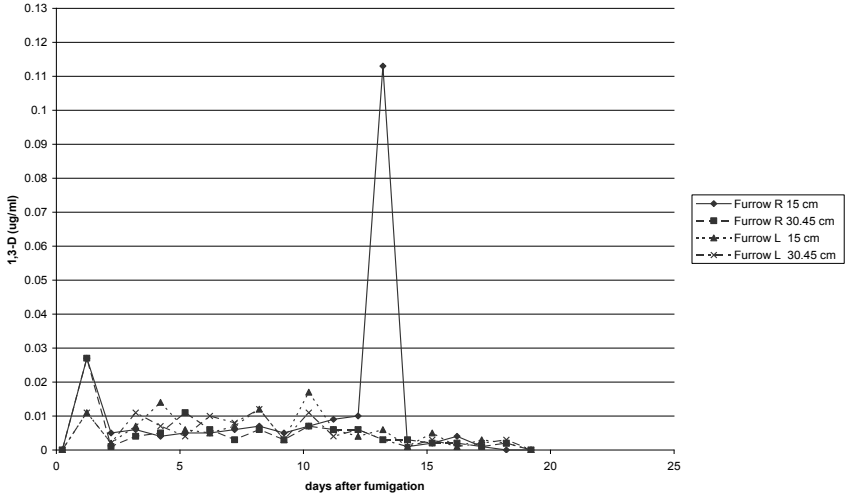
Report: Knutenson and Dolder (2000). Dow AgroSciences, Report Nº GH-C 5075 (Masterfile MK33) Annex point/reference IIIA 9.2.3/04

This report is summarised in section B.8.7.2. in the (updated) addendum I to annex B.8 (March 2005). This study was designed to look at the volatile loss of 1,3-D and chloropicrin from strawberry bed which were the product was applied using drip irrigation to soil beds covered with a virtually impermeable film. Although the study was not set up to specifically investigate lateral movement of 1,3-D in soil, concentrations of 1,3-D were measured in the open field furrows between the treated beds.

Details on 1,3-D soil data are given in the figure 8.6.2.1-3

Figure 8.6.2.1-3: 1,3-D Soil gas in the Beds (left) and in the furrows (right)





The initial gravimetric soil water content near the two TDR stations locations showed that soil was at or near field capacity prior to the start of the application irrigation. The post-application soil water content exceeded that which could be held by the soil. The excess water was available for gravitational drainage and unsaturated flow to drier regions of the soil. The volumetric soil water content of the soil beds was collected by TDR. There waas an inmediated rise of water content in the upper horizons, followed by a period of drainage . Lower horizons received the excess water and subsequently drained, or retained the water inputs.

1,3-dichloropropene did not move in soil very far horizontally away from the treated area. The soil gas concentrations were one to two orders of magnitude less than 1,3-D soil gas concentration found in the bed. This is also consistent with an increasing body of research which shows that in 'raised bed' fumigations, negligible lateral movement of fumigant is indicated. For details see : Gao and Trout , Journal of Env Quality (36): 110-119 (for shank application); van Wesenbeeck et. al., Journal of Env Quality 36: 613-620 (for drip application).

B.8.6.2.2 Runoff

Report: Knowles, S. (2005b). Dow AgroSciences, Report Nº N/A (Masterfile K88). Annex point/reference AIII 9.2.3/01

The runoff of 1,3-D was measured from a site located in Blacksburg, Virginia, USA (GH-C 5046, Masterfile K52 (evaluated in the original DAR section 8.10 study IIA 7.4/09). Three replicate plots were injected with Telone II at a rate of 300 kg/ha to a depth of 30cm. A simulated rainfall event was timed to coincide with the estimated peak 1,3-D flux to the atmosphere. Natural rainfall and runoff occurred prior to the simulated rainfall event with a combined rainfall of 127 mm (98mm simulated). 71% of the rainfall became runoff which is indicative of the vulnerable nature of this site to runoff. The US study was conducted on a hydrologic group C soil with an average 5% slope to ensure potential runoff. Comparison with the FOCUS runoff scenarios which are representative of EU agricultural regions, indicates the US study is an extreme worst case example. See Table 8.6.1-1 summarising FOCUS scenarios, rainfall, soil group, slope amd maximum daily runoff.

Table 8.6.2.2-1: Summary of US versus FOCUS scenarios

Study	Annual Rainfall (mm)	Hydrologic Soil Group	Slope (%)	Maximum runoff (mm/day)
US 1,3-D	-	C	5	90
R1	817-909	C	3	8
R2	970-1906	B/C	5	30
R3	724-970	C	5	25
R4	812-816	C	5	40

In the DAR Section B.8.6.2.2, a range of run-off values were considered to evaluate the surface water predicted environmental concentrations with various run-off percent loadings from 0.001 - 1 %. For a 0.003% of runoff the PECsw was **2.24 ug/l.**

B.8.6.2.3 Deposition

Report: Knowles, S. (2005b). Dow AgroSciences, Report Nº N/A (Masterfile K88). Annex point/reference AIII 9.2.3/01

The deposition from the vapour phase can be considered from the air concentration data that was collected for field monitoring studies. 1,3-D have been measured in open field treatments in a total of 7 locations in the US. These sites are located in Imperial Valley (California), Salinas Valley (California), Yerington (Nevada), Moses Lake (Washington), Hookerton (North Carolina), Harquahala Valley (Arizona), Rio Grande Valley (Texas), report references GH-C 2751 (MK02), DECO-HEH-2.1-1-182 (102) (MK03), GH-C 3089 (MK13), GH-C 4864 (MK30). Correlation of pedo-climatic conditions for field locations used in 1,3-D air monitoring studies was conducted and showed that the studies conducted in Salinas Valley, Yerrington, Moses Lake and Hookerton are considered relevant to EU conditions for the purposes of these 1,3-D air concentration measurements above Telone treated fields (see point 8.7.2.1 for details).

Air concentrations were measured at various heights and distances away from treated fields for up to 14 days after treatment. The typical range for peak air concentrations at edge of field after treatment is in the range 300 - 500 µg/m3. The maximum peak air concentration recorded from all of the 7 locations was 3415 µg/m3 at 25m from the edge of field (within this 14 day period peak 3415 µg/m3 at 24-36 hours and 36.76 µg/m3 at timepoint 36-48 hours). The maximum peak air concentration recorded at 0m from the edge of field was 2212 µg/m3 at 8-12 hours after

application. Most of the air concentrations were significantly lower than these values with concentrations decreasing over time. The 14 day time-weighted average concentrations are in the range 1-10 µg/m3.

Therefore the typical 1,3-D peak air concentration was 500 µg/m3 (=0.5 µg/L of air). Given the high volatility of 1,3-D (vapour pressure 3 – 4.8 kPa) the percentage of this mass entering a nearby 1 litre of water will be low. Considering an extreme worst case, even if 100% of the 1,3-D mass from 1 litre if air deposited into 1 litre of water, the PECsw would be 0.5 µg/L. This concentration is below the level of ecotoxicological concern. From Henry's Law and Fugacity models, the percentage of airborne 1,3-D entering surface water from deposition is expected to be extremely low and demonstrating the above value of 0.5 µg/L to be an extreme worst case and an overestimation of the PECsw from air deposition

B.8.6.2.4 Proposed Predicted Estimated Concentrations in surface water for 1,3-D and its metabolites

Initial PECsw for metabolites taking into account route of entry in direct injection were calculated. Conservative values using only molar weight corrections (and not formation fractions) have been calculated

Table 8.6.2.4-1: Max PECsw derived for 1,3-D and its metabolites (µg/L).

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

1 cumulative concentration at 3 m (northern conditions)

The applicant concludes there is a extremely low risk of 1,3-D reaching surface water bodies in close proximity to treated open fields above a concentration of ecotoxicological concern. However, in consideration for the concerns expressed regarding possible deposition, lateral flow and run-off, the use of buffer zones between treated open fields and viable surface water bodies could be considered. Based on current data distances of 3-5 m could be introduced to mitigate any potential surface water contamination concerns.

RMS comments:

As a fumigant, 1,3-D will have a significant portion in the vapour phase, and its fate and transport in a porous media would simultaneously occur in both the gaseous and liquid phases. Temperature is found to affect the transport parameters (see Leistra 1970 for details). Adsorption and desorption with the solid phase or soil particles would make the transport process more transient.

In order to evaluate the transport of 1,3-D by lateral flow notifer proposes a calculation with the model CHAIN_2D.This mechanistic model simulates the transport of heat, water and vapour solute phase chemicals in soil.

With comparison purposes, RMS has attempted to calculate a FOCUS SW. Due to 1,3-D physic-chemical properties (high vapour pressure and Henry's law constant) standard FOCUS parameters (molar enthalpy for evaporation and dissolution, diffusion coefficient in water and air and activation energy) cannot be used in these particular case. All these parameters except molar enthalpies are available in (Wang, Knuteson and Yates (2000)[5] and Wang He and Knuteson, (2007)[6]. Molar enthalpy for evaporation is available in US EPA (2001)[7] and Molar enthalpy for dissolution can be calculated from Sander (1999a, b)[8, 9]. A summary of the parameters are given in the table 8.6.2.4-2

[5] J. Environ.Qual. 29: 639-644 (2000)

[6] Computers and electronics in Agriculture 56 (2): 111-119 (2007).

[7] U.S. Environmnetal Protection Agency, (2001) " FACT SHEET: Correcting the Henry's Law constant for soil temperature available at http://www.epa.gov/oswer/riskassessment/airmodel/pdf/factsheet.pdf

[8] Sanders, 1999a. "Compilation of Henry's Law Constants for Inorganic and Organic Species of Potential Importance in Environmental Chemistry (Version 3)," available at www.henrys-law.org

Table 8.6.2.4-2: Phys-chem properties for 1,3-d used in FOCUS SW

	cis- 1,3-d	*trans*-1,3-D
Molar mass (g/mol)	110.97	110.97
Saturated vapour pressure (Pa) at 25 ºC	4850	2982
Molar enthalpy of vaporisation at 25 ºC (J /mol)[5]	33319	33319
Solubility in water (mg/l) at 25 ºC	2180	2320
Molar enthalpy of dissolution at 25 ºC (J/mol)[6,7]	32439	32439
Diffusion coefficient in water (m^2/d)[1011]	9.5E-5	9.5E-5
Diffusion coefficient in air (m^2/d)[9]	0.72	0.72
Koc (L/g)	33.7	33.7
1/n	1	1
Ref concentration in liquid (g/m^3) (FOCUS default)	1	1
Factor for the uptake by plant roots[a]	0.0	0.0
Wash off factor from crop[a]	0.0	0.0
DT50 water (d) at 25ºC	1000	1000
DT50 soil (d) at 20ºC	15.6	15.6
DT50 sediment (d)	4.9	4.9
Activation energy (J/mol)[3]	43551	43551
Q10	1.87	1.87
MACRO Exponent (1/k) (lnQ10/10)	0.063	0.063

a 1,3-D is applied before the transplanting;

Only scenarios D were run. All attempts to run scenarios R failed since the known bug in SWASH 1.1 is kept in SWASH 2.1 (see readme.doc in swash). Assuming an isomer ratio of 1:1, the application rate for each isomer was of 112 kg /ha and 93.5 kg/ha for southern and northern Europe, respectively. The last day of application window was set 15 d before transplanting (table 8.6.2.4-3).

Table 8.6.2.4-3: Application windows selected for FOCUS SW

	Emergence date	Start of the application window (Julian day)	End of the application window (Julian day)
Southern EU			
D6	10 April (100)	24 Feb. (55)	26 march (85)
Northern EU			
D3	25 April (115)	11 March (70)	10 April (100)
D4	23 April (113)	9 March (68)	8 April (98)

The results are shown in Table 8.6.2.4-4

Table 8.6.2.4-4: FOCUS SW calculations for 1,3-D

CHAIN_2D	**FOCUS SW**

[9] Surveys in Geophysics 20:1-31
[10] Yates and Gan (1998) J. Agric. Food Chem. 46 (2): 755-761
[11] http://mbao.org/2006/06PowerPoints/MBAO%20PDFs/Preplant/2%20-%20Fumigant%20Modeling%20&%20Analysis/Wang.pdf

Cumulative 1,3-D PECsw Global maximum (µg/L)		Crop	Scenario	Surface water body	cis -1,3-D		trans-1,3-D		Sum	
					PECsw Global maximum (µg/L)	PECsed Global maximum (µg/Kg)	PECsw Global maximum (µg/L)	PECsed Global maximum (µg/Kg)	PECsw Global maximum (µg/L)	PECsed Global maximum (µg/Kg)
1 m	3 m	**Southern EU**								
4.06	**-**	Fruiting vegetables	D6	Ditch	3.095	0.805	3.186	0.83	6.281	1.635
		Northern EU								
250	**0.466**	Bulb Vegetables (surrogate)	D3	Ditch	0.293	0.227	0.311	0.219	0.604	0.446
			D4	Stream	88.773	32.416	87.532	32.142	176.305	64.558
			D4	Pond	2.396	0.799	2.449	0.821	4.845	1.62

It should be taken into account that MACRO does not consider volatilization in the calculations (FOCUS, 2001 p. 203). FOCUS SW GD states that 'clearly the model cannot be used for high volatile compounds'. Therefore, caution should be taken in the interpretation of these results since the drainage loadings can be overestimated (especially in FOCUS stream, where the loadings of upstream catchment are considered).

It is worth mentioning that according to phys-chem properties cis 1,3-D is more volatile than trans 1,3-D. It is shown in Global PECsw of scenarios D6, D3 and D4 (ponds) but not in D4 (stream).

Attending the global sum of PECsw 1,3-D, the following conclusions can be made:

- Under southern conditions: concentrations estimated by FOCUS are slightly higher that the ones estimated by CHAIN_2D.
- Under northern conditions: the concentration estimated by CHAIN_2D at 1m is higher than the worst case estimated by FOCUS SW. PECsw calculated by CHAIN_2D is 1.15- fold the worst FOCUS PECsw when corrected for an application rate of 230 kg a.s/ha .

Taking these results into account, RMS concluded that calculations made by CHAIN_2D are relevant for risk assessment.

Regarding to runoff, applicant compared the hydrological characteristics of the soil of the runoff study conducted in California and the soils used in FOCUS scenarios. Comparison with the FOCUS runoff scenarios, indicates the US study is an extreme worst case example. The location of the study can be considered relevant for EU geoclimatic conditions of southern Europe.

Finally, to cover the entry by air deposition applicant considered 100% of typical 1,3-D peak air concentration (500 µg/m^3)was deposited into 1 litre of water. This is considered a worst case taking into account Henry's Law constant for 1,3-D

A buffer zone of 3- 5 m was proposed by the notifier as a mitigation measure to aquatic systems.

B.8.7 Fate and behaviour in air.

B. 8.7.2 Volatilization monitoring studies

B.8.7.2.1 Correlations of geo-climatic characteristics of US field studies to European conditions

Background: The flux losses from the soil have been measured in seven field studies in the USA.

1) Imperial Valley, California, (GH-C 2751, MK02)
2) Salinas Valley, California, (GH-C 2751, MK02)
3) Yerington, Nevada, (DECO-HEH 2.1-1-182, MK03)
4) Moses Lake, Washington, (GH-C 3089, MK13)
5) Hookerton, North Carolina, (GH-C 3089, MK13)
6) Harquahala Valley, Arizona, (GH-C 3089, MK13)
7) Rio Grande City, Texas, (GH-C 4864, MK30)

These studies were summarised and evaluated in the original DAR. During the Peer Review a data gap was identified to provide information that these measured flux losses under American geoclimatic conditions are also pertinent to EU geoclimatic conditions. In response to this request a correlation between the climatic conditions from the 1,3-D studies in the USA and the conditions that exist in the EU Zones was submitted. It is presented and evaluated below.

Report: Steve Knowles (2005a). Report Nº: N/A (Masterfile reference K82.). Annex point IIA 7.4/09, III 9.3/01

To characterise how these sites correlate to European locations, soil temperature regimes (based on ranges of average annual, summer and winter soil temperatures) and soil moisture regimes (based on the duration of dry, moist or wet soil conditions within specified depths) have been compared. These two systems form an integral part of the USDA system for the classification of soils and the regimes can be used to compare the pedo-climates of soils throughout the world. Based on this classification scheme the sites have been classified as follows:

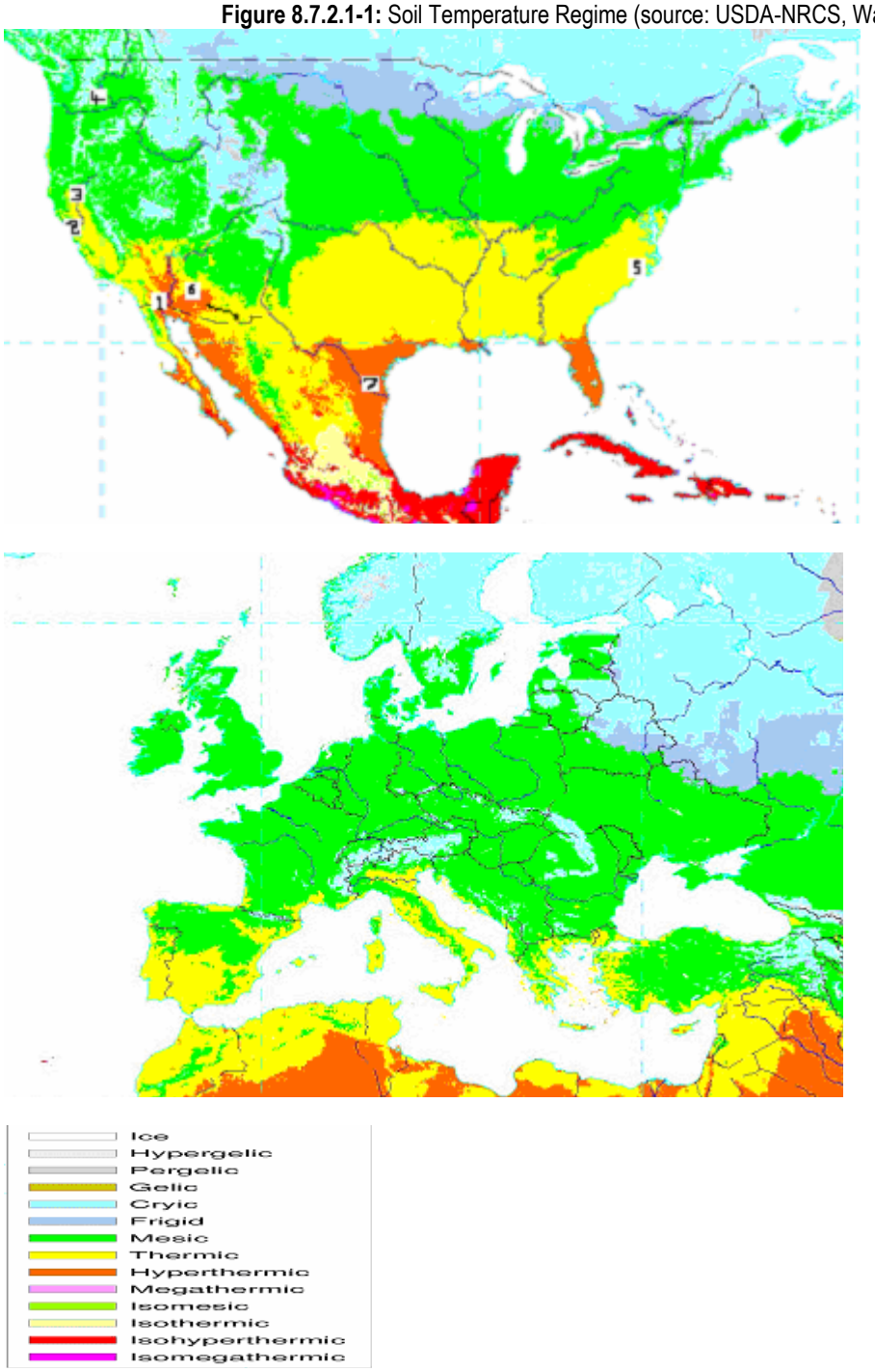
Table 8.7.2.1-1: Soil temperature and moisture regimes of air monitoring studies evaluated in the original DAR

Study Code	Annex point/reference (original DAR)	DAS Report Nº	Study location	soil temperature regimes/ soil moisture regimes
1	IIA 7.2.2/02	(GH-C 2751, MK02)	Imperial Valley, California	Hyperthermic/Aridic
2	**IIA 7.2.2/02**	**(GH-C 2751, MK02)**	**Salinas Valley, California**	Thermic/Xeric
3	**IIA 7.2.2/03**	**(DECO-HEH 2.1-1-182, MK03)**	**Yerington, Nevada**	Thermic-Mesic/Aridic
4	**IIA 7.2.2/04**	**(GH-C 3089, MK13)**	**Moses Lake, Washington**	Mesic/Udic
5	**IIA 7.2.2/04**	**(GH-C 3089, MK13)**	**Hookerton, North Carolina**	Thermic/Udic
6	IIA 7.2.2/04	(GH-C 3089, MK13)	Harquahala Valley, Arizona	Hyperthermic/Aridic
7	IIA 7.2.2/05	(GH-C 4864, MK30)	Rio Grande City, Texas	Hyperthermic/Aridic

In the maps below soil temperature regimes (figure 8.7.2.1-1) and soil moisture regimes (figure 8.7.2.1-2) from US and EU are shown. Numbers in maps corresponds to the study code in table 8.7.2.1-1.

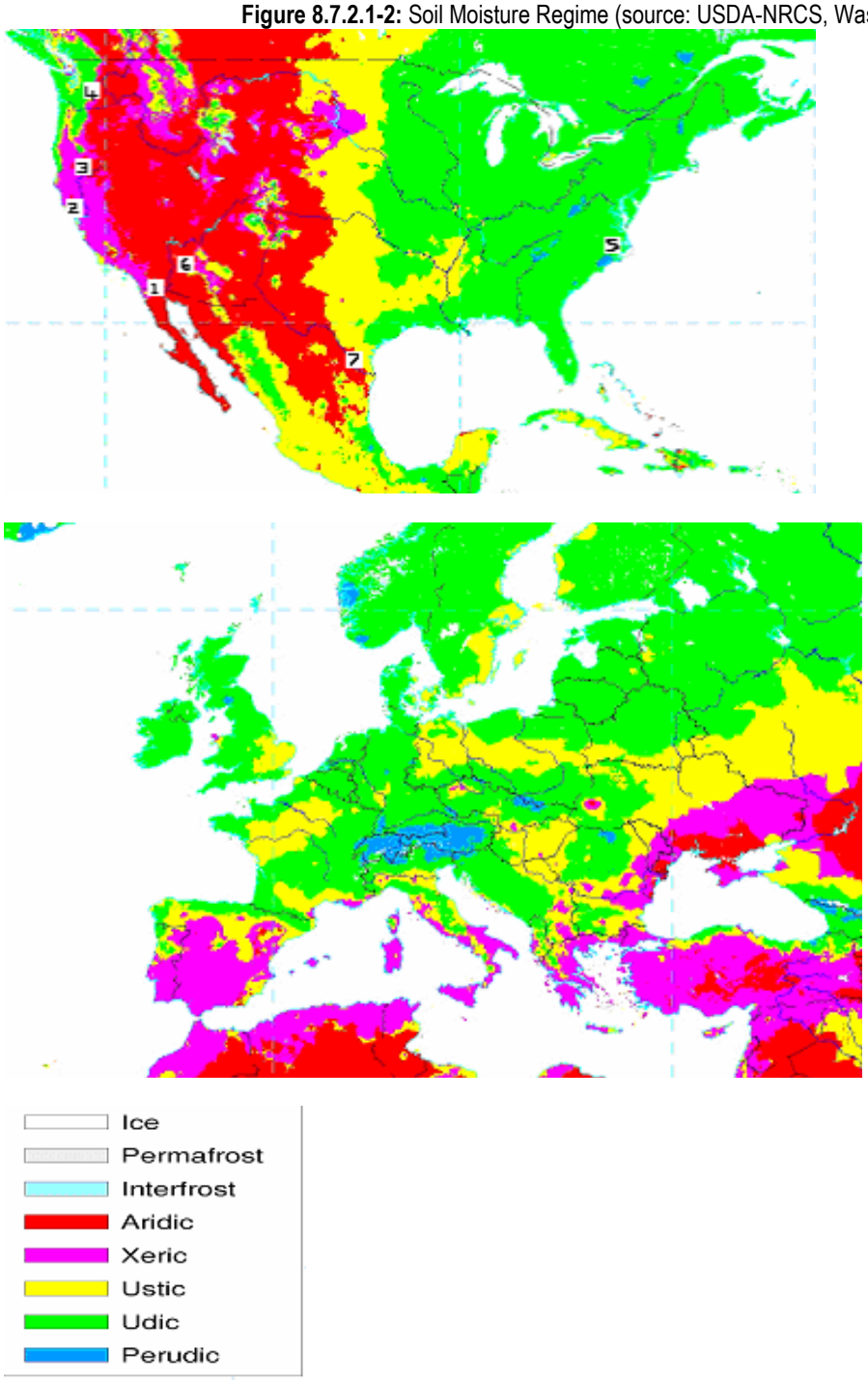
According to figure 8.7.2.1-1, Mesic soil temperature regimes extend across Northern Europe while Thermic soil regimes extend across southern Europe

Figure 8.7.2.1-1: Soil Temperature Regime (source: USDA-NRCS, Washington)



The Udic soil moisture regime occurs in northern Portugal, northern and central Spain, southern France, central France and eastern UK. The Xeric soil moisture regime occurs in Portugal, southern and central Spain, southern Italy, Sardinia, Sicily and much of Greece. The Aridic soil moisture regime occurs in small areas of Central and Southern Spain (figure 8.7.2.1-2).

Figure 8.7.2.1-2: Soil Moisture Regime (source: USDA-NRCS, Washington)



The combined soil temperature and soil moisture regimes restrict the area of correlation of the US and EU pedo-climates are shown in bold in table 8.7.2.1-1 As conclusion the studies conducted in Salinas Valley, Yerrington, Moses Lake and Hookerton are considered relevant to EU conditions for the purposes of these 1,3-D air concentration measurements above Telone treated fields

Assessment: The information submitted is considered relevant for risk assessment.

The risk assessment for birds and honeybees (inhalation) is based on the worst concentration in air observed, that is the monitoring study conducted in Arizona. The temperature and moisture regimes of the soil from this location were not correlated to European locations (Hyperthermic/Aridic). Nevertheless, this can be considered as a worst case. Negligible risk was identified for birds and honeybees (inhalation). No further information is necessary.

B.8.10 Monitoring Data

B.8.10.1 Groundwater

B.8.10.1.1 Monitoring conducted in Greece

Report: Knowles & Panagopoulos (2008). Report number: GHE-P-11707 (Masterfiel number: MK59). Annex point /reference IIA 7.4/01 IIIA 9.2.1/01

Report: Kennedy (2008), Report number: GHE-P-11693 (Masterfiel number: MK58) Annex point/reference II 7.4/02 IIIA 9.2.1/02

Selection of main regions for monitoring

Four regions in mainland Greece and Crete with a high Telone® were identified for groundwater monitoring of 1,3-D and related compounds. The areas were selected based on:

1.- percentage of total 1,3-D applied in Greece
2.- geographical distribution
3.- prevailing climatic conditions
4.- geological conditions
5.- multitude of treated cultivations and fumigation practices.

The four areas were: Chrysoupoli basin, Trifilia basin in Poloponnese , Timbaki and Ierapetra basins on the island of Crete.

Chrysoupoli basin is located in northern Greece . It is a large estuarine basin, it has a typical delta shape and the catchment is well over 500 km^2. The basin is bounded by Northern Agean Sea to the south, karstified carbonate rocks (Rhodope) to the north and by neogene hills to the east and west. It slopes gently to the south at an average slope of 0.01 %. Altitudes within the basin vary from sea level to about 100 m (Figure 8.10.1.1-1). The origin of Chrysoupoli basin is the sedimentary deposits of the Nestos River, one of the main rivers in Greece, which enters the country on its northern boundary with Bulgaria and discharges to the Northern Agean Sea.

Figure 8.10.1.1-1: Location map of the Chrysoupoli basin

Source: http://maps.google.es/maps?hl=es&q=chrisoupoli&um=1&ie=UTF-8&sa=N&tab=wl

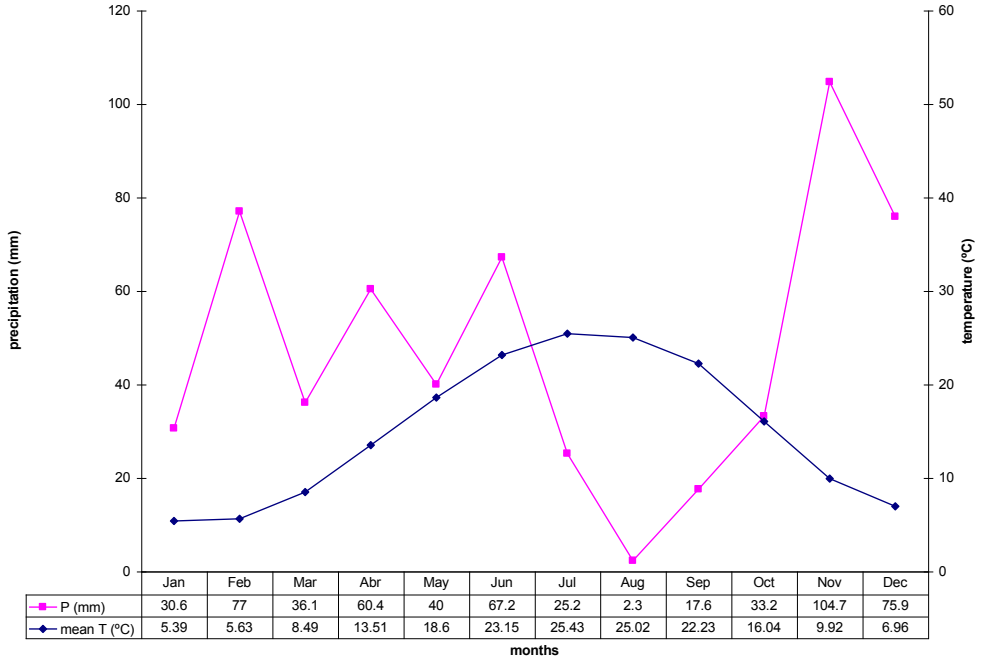
The main crops in the basin are potatoes, sugar beet, corn and wheat. Vegetables, asparagus, cotton and grapevines also exist and are mainly cultivated in the east part of the Nestos river.

1,3-Dichloropropene is used on sugar beet cultivated under field conditions in early winter .1,3-D sales were of **27 tones/year in 2003 and 2004 in Chrysoupoli basin** . Cultivated land in the entire basin sums up to 3200 ha, out of which 172 ha a 136 ha were treated in 2003 and 2004, respectively. Within the selected area of the basin 107 and 96 ha were treated in 2003 and 2004, respectively. Data on the fields treated with 1,3-D was supplied by the sugar industry. A progressive drop in the use of the product has been observed associated to the dramatic sugar beet production reduction as consequence of closing down the main sugar productions industries in Greece

Regional drinking water demand is covered by karstic springs located upstream of the Nestos river . Only Keramoti (Κεραμωτή) covers water demands from boreholes from regional groundwater resources. This is the part where this study concentrates (Figure 8.10.1.1-1).

The basin is characterised by relatively warm summers and cold winters Minimum temperature reaches up to – 4.47 ºC in January. Maximum temperature corresponds to July (36.05 ºC). Wet periods coincide with the winter-spring months and the direst periods with the warmer summer months (mean annual precipitation= 593.7 mm)

Figure 8.10.1.1-2: distribution of the mean monthly precipitation and temperatures . A10 year series from the meteorological station in Genisea (30 km to E)



	Jan	Feb	Mar	Abr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
P (mm)	30.6	77	36.1	60.4	40	67.2	25.2	2.3	17.6	33.2	104.7	75.9
mean T (°C)	5.39	5.63	8.49	13.51	18.6	23.15	25.43	25.02	22.23	16.04	9.92	6.96

This climatic pattern shows an increment of irrigation needs over the summer period. These needs are covered by the exploitation of as surface water as groundwater resources. West of the Nestos river, irrigation is managed by the Local Irrigation Organistation (TOEV) of Chryssohori. Water is transported by collective irrigation canals and pressurized networks.

Essentially, there are two aquifers in the area of study:

a) a confined to semi-confined system compromising a sequence of aquifer strata located at depths greater than 70 m. Local lateral lithological transitions exist . This is considered an aquifer of high potential and artesianisim is apparent towards the southern part of the system. It forms the main target for groundwater resources explotation in the region.

b) An unconfined aquifer developed up to 60 m depth. The thickness varies between 40-60 m. The upper parts of this aquifer are of reduced potential because of the prevalence of clay to marl rich sediments. It is a high productive aquifer (120-200 m^3/h) and the average depth to water level varies between 0 and 7 m.

During the period of low waters a variation of the pheatric level between 23 m to 1 m isobserved. The flow direction is radial from north the south (towards the sea). Hydraulic gradient is higher in the northern parts of the basin, where the main recharge zone exists and reduces progressively towards the end point of the aquifer system. The recent and historical courses of the Nestos river act as zones of preferential groundwater flow.

Trifilia Basin is located in Western Greece, it is included in the water district of West Peloponnese. It is a typical neotectonic basin. It is bounded by Ionan Sea to the west, by the mountainous range of Kiparissia (Κυπαρισσία) to the east. To the south and the north, the basin is not specifically bounded and is linked to Pilos and Zharo basins, respectively. The study area has an extent of 200 km^2. Altitudes vary between sea level to well over 200 m. The mean slope is 7.5% westwards (Figure 8.10.1.1-3)

Figure 8.10.1.1-3: Location map of the Trifilia basin

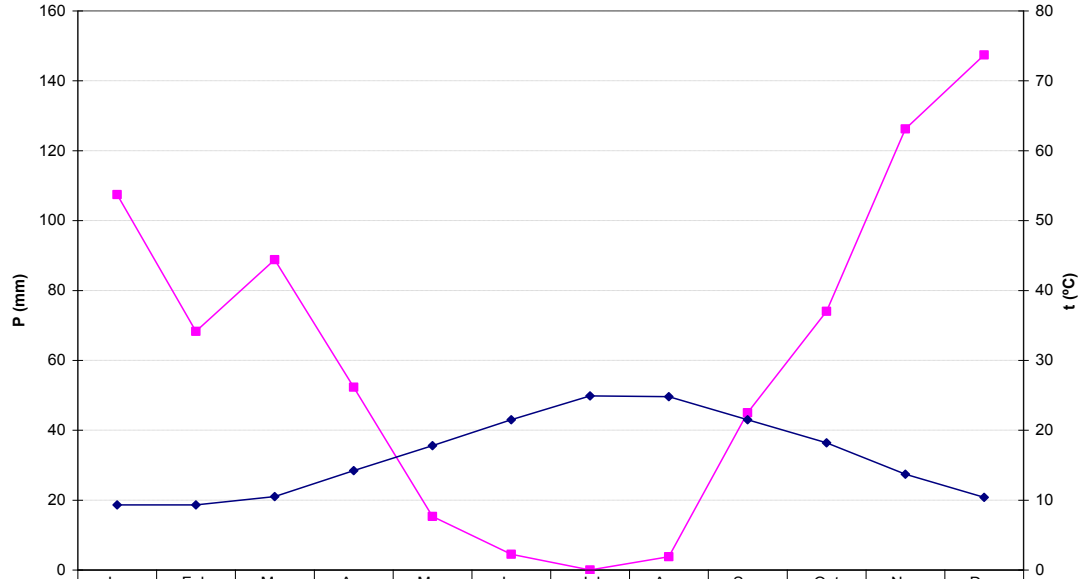
Source: http://maps.google.es/maps?hl=es&ie=UTF8&ll=37.042024,22.137451&spn=1.017224,2.801514&t=p&z=9

Trifilia basin is considered one of the most productive regions in Greece. The main crops are olives, grapes and vegetables (under field and greenhouse conditions) . The agriculture activity is concentrated in coastal part of the basin. 1,3-D is applied in green houses cultivation (mainly vegetables) and the dominant application period is summer (end of June to end of August) . 1,3-D sales exhibit a progressive increase since 1999 (sales= 9 tones/year), to 2006 **(17.4 tones/year).**

About 200 ha of green houses exist in the area, out of which 80-100 ha are being treated with 1,3-D.
No specific records exist on the fields treated with the product. Taking into account the instructions of agriculturalists and distributors, they are distributed in discrete zones (Marathopolis, Filiatra,Elea).

Trifilia basin is influenced by the Adriatic Sea weather fronts, which are associated with high precipitation heights compared to eastern Greece. The basin is characterised by mild winters and warm summers. Precipitation pattern shows a main peak of precipitation in winter with secondary peaks in spring and autumn (Figure 8.10.1.1-4). Taking into account the distribution of mean precipitations and temperatures with time, it is clear that irrigation demands are high during summer

Figure 8.10.1.1-4: distribution of the mean monthly precipitation (11-year period from Filiatra station) and temperatures (12 – year period from Gargaliani station).



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
P (mm)	107.4	68.3	88.8	52.3	15.3	4.5	0	3.8	45	74	126.2	147.4
t (°C)	9.3	9.3	10.5	14.2	17.8	21.5	24.9	24.8	21.5	18.2	13.7	10.4

Four aquifers are identified in the basin: a karstic aquifer; a fine grained pleistocene aquifer; a confined aquifer system; and, a coarse grained Pleistocene unconfined aquifer. A general N-S direction characterises the development of the four units .

The study focuses on the coarse grained Pleistocene aquifer. Predominant flow direction is from inland towards the sea at an E-W direction along the southern part of the aquifer and SE-NW direction along the nothern part of the aquifer Recharge in this aquifer occurs in the form of direct inflitration from precipitation and percolation along the torrents. It may also receive limited recharge in the form of lateral crossflow from the upstream karstic aquifer. Water levels vary from 80 m to 0m towards the coast . Exceptions are the areas of Terpsithea and Marathos, where negative water levels are recorded (-2.7 m and –1.5 m, respectively). Annual fluctuation is low and it does not exceed 0.4 m (average). Production rates range between 2-30 m^3/h.

Nowadays the aquifer is only used for irrigation and when the supply from deeper confined aquifer or transfer from the karstic aquifer is not possible, always it is provided no extensive pollution is recorded. Some farmers still use their wells occasionally for drinking purposes. Currently, water supplies are covered by the drilling of groundwater from the karsitc system which exists along the eastern margin of the study basin. Practically, application does not exist on the terrain where the karstic aquifer develops and the boreholes for dosmestic supplies are sited.

No organised irrigation body exists. Because of water scarcity, drip irrigation is practically the only system used across the entire basin

Tymbaki Basin. It is located in the southern part of island of Crete .The basin is tectonically controlled and filled by Pleistocene and alluvial deposits. It is bounded by pre-neogene sediments to the north and south, which act as no flow hydraulic boundaries; the Libyan Sea to the west and the upstream extension of the alluvial aquifer to the east. Tymbaki is run by the torrent of Faneromi and Geropotamos River and forms the end part of the larger basin of Messara , which extends to the east (Figure 8.10-4). The extent of the region is well over 50 km^2 .Altitudes vary from sea level to about 100 m and the core of the basin lies at a mean altitude of 25 m. The basin slopes gently towards the Libyan Sea at an average slop of 2%.

A large percentage of total greenhouse cultivations Greece is located in this basin (47% together Ierapetra basin). The main crops are vegetables, flowers (canations), melons and water-melons and olives. 1,3-D is applied in green houses cultivation Sales of 1,3-D exhibit progressive increase since systematic application begun in 1999 (5 tones/year) being of **33 tons/year in 2006.**

About 400 ha of greenhouses are spread throughout the basin, out of which 60-80 ha are being systematically treated with 1,3-D. No specific records exist on the fields treated with the product. Taking into account the instructions of

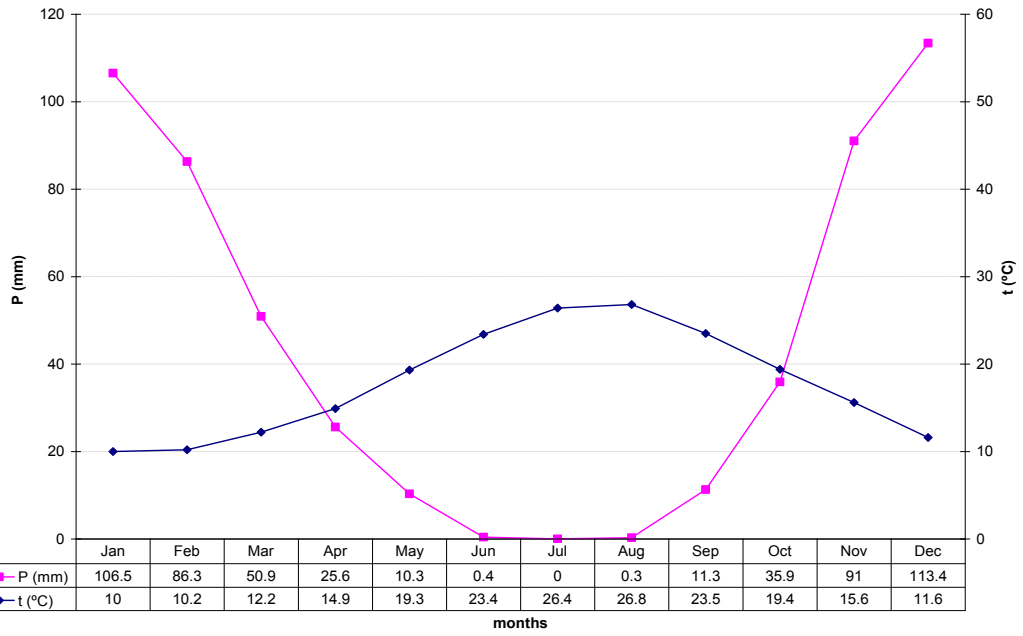
agriculturalists and distributors, 2 specific application zones were identified in the basin. Secondary areas, including isolated green houses, were 1,3-D is applied were also identified.

Figure 8.10.1.1-5: Location map of the Tymbaki basin

Source: http://maps.google.es/maps?hl=es&ie=UTF8&t=p&ll=35.158091,24.713745&spn=1.041911,2.801514&z=9

The basin is characterised by mild winters and warm summers. Precipitation pattern is typical of southern Greece. Summers are practically dry with no or limited precipitation. Most of the precipitation is concentrated in winter season. Temperature pattern exhibits high values over summer time and low values during winter.

Figure 8.10.1.1-6: distribution of the mean monthly precipitation (32-year period from Lagolio station) and temperatures (26 – year period from Pompia station).



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
P (mm)	106.5	86.3	50.9	25.6	10.3	0.4	0	0.3	11.3	35.9	91	113.4
t (°C)	10	10.2	12.2	14.9	19.3	23.4	26.4	26.8	23.5	19.4	15.6	11.6

A series of semi-confined to confined aquifers, superimposed by unconfined aquifer, develop in the basin . The thickness of this aquifer system varies from more than 20 m to the west and thin out towards the edges of the basin, to 60-80 m. Productivity is reasonable high reaching up to 120-150 m^3/h .

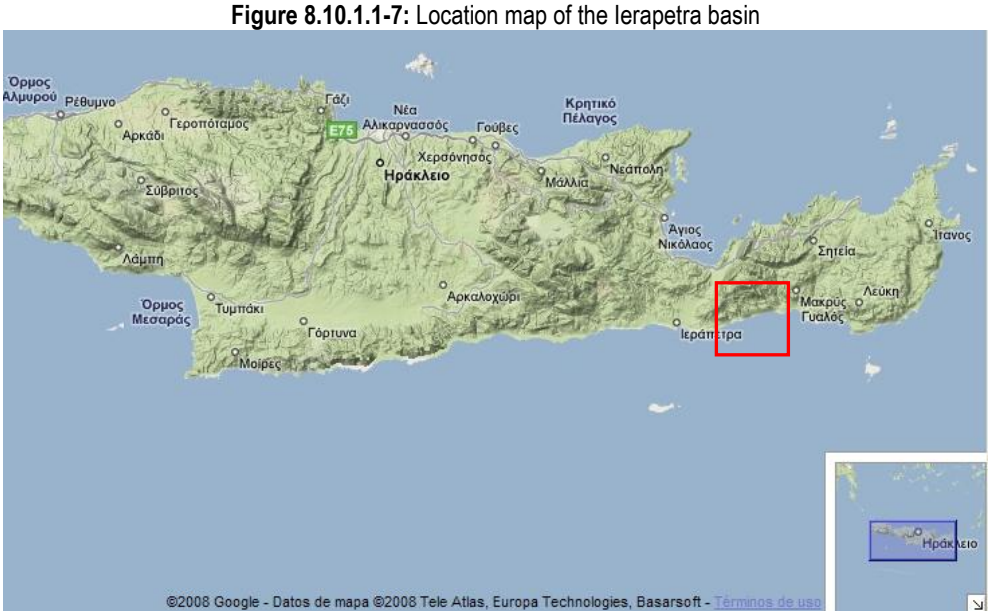
A general groundwater flow direction from east to west (inland towards the coast) is shown. A major recharge mound at the northern part of the basin and an extensive depression cone spread at the central parts of the basin. This is attributed to the intensive exploration over the summer irrigation period.

Recharge occurs in the form of direct infiltration from precipitation and along the courses of the main torrents (i.e The Geropotamos River).

Water levels vary from 0.5 m to 70 m (coastal to hilly zones) and no significant inter-annual variations have been documented. Nitrates concentrations and salinity are acceptable increasing towards the coastal parts. Salinity intrusion does exist along the northern boundary. This phenomenon is attributed to the geological structure and more specifically to a fault that strikes from the coast to an NE direction, parallel to the edge of the basin

Ierapetra basin: The study area is located in the island of Crete, on the southern coast along the eastern part of the island. It is bounded by the Lybian Sea to the south and Neogene and pre-neogene sequences to he north, west and the east (Figure 8.10.1.1-7). Total extent of the basin is about 30 km^2. Altitudes vary from sea level to about 70-80 m. The slope is about 4% (to the south).

Figure 8.10.1.1-7: Location map of the Ierapetra basin

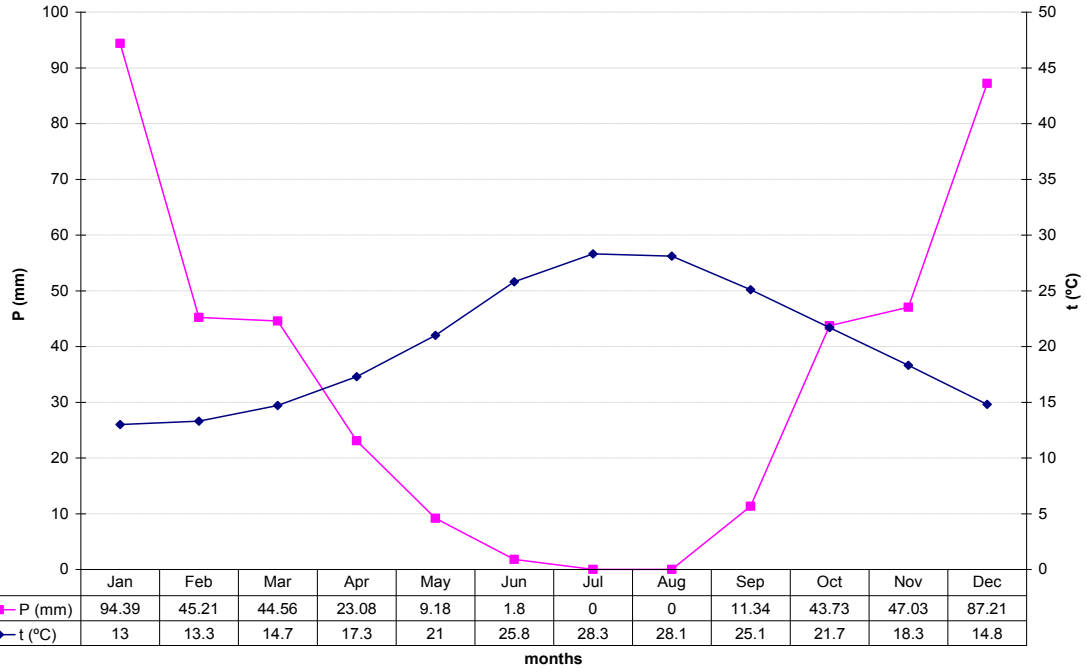


Source: http://maps.google.es/maps?hl=es&ie=UTF8&ll=34.973751,25.496521&spn=0.990253,2.801514&t=p&z=9

The largest percentage of the total green house cultivations in Greece is located in this basin. Main cultivations are vegetables, melons water-melons. 1,3-D sales in Ierapetra exhibitasignificant increase since 1999 (15 tones/year) to 2006 **(64 tones/year).** A total of 1500 ha of green houses exits in the basin No specific records exist on the fields treated with the product. Taking into account the instructions of agriculturalists and distributors, 2 specific application zones were identified in the basin at east and west of the Ierapetra town, being the last the most important one

The climate is characterized by very mild to warm winters and very warm to hot summers. Precipitation pattern shows that summer is completely dry and most precipitation occurs during the winter months (Figure 8.10.1.1-8)

Figure 8.10.1.1-8: distribution of the mean monthly precipitation and temperatures (15 –year period from Ierapetra station).



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
P (mm)	94.39	45.21	44.56	23.08	9.18	1.8	0	0	11.34	43.73	47.03	87.21
t (°C)	13	13.3	14.7	17.3	21	25.8	28.3	28.1	25.1	21.7	18.3	14.8

Two distinct aquifers may be distinguished in the area:

a) a system of successive confined aquifers without interconnections among them. This system is located within the Neogene sediments which crop out at the margin of the basin. They are characterized by high transmissivitites, but low storage capacity and unfavourable rechagew conditions. The effective production rates is less than 10 m^3/h. The average thickness of this system is about 100 m

b) An alluvial unconfined aquifer which has an average thickness of 30 m and low production rates. This is associated to the thickness the low recharge it receives and lithological composition (clay to marl rich sediments). The prevailing flow direction is from north to the south .Recharge is mainly due to direct infiltration.

Bramianos dam is probably the largest hydrological feature of the basin. It was constructed to cover irrigation needs of the basin. Most of the volumes collected come from the karstic spring of Malavra, in the northern coast of the island. Irrigation is managed by the Local Irrigation Organisation of Ierapetra.

Since irrigation supplies are predominately covered by surface water from the dam groundwater levels have recovered back to the levels noted in the 60-70. Domestic supplies are provided by boreholes in the basin of Mirtos.

Design of the monitoring network

Taking into account available well inventories, a selection of sampling points (16 sampling pints/site) was made based on the following criteria:

1) proximity to the 1,3-D application zone
2) reasonable coverage of the study basin
3) representative coverage of major hydrodynamic mechanisms
4) focus on the same aquifer system
5) existence of reasonable amount of information on well construction
6) use of monitoring points for production of drinking water

A set of maps and other supportive material was created for each basin (hydrolithological map of the basin; Piezometric map of the basin; 1,3-D application map of each area of study; inventory well map)

A new selection (up 5 sampling points /site) was made by ranking each candidate monitoring point. 14 criteria were considered and 5 classes/ criterion were used The criteria were related with distance from application, characteristics of wells and operational and property status. Up to 5 points were selected per site except for Irepetra site where 4 four wells were selected. Details of the wells sampled are given in table 8.10-1.

Table 8.10-1: Characteristics of the well sampled

Basin[1]	Well code	Description	Well coordantes (H.G.R.S 87)[2]		
			X	Y	Z
Chrysoupoli (4.1%)	B11KAV002	n down stream of treated area lepth: 144 m creening: only > 25 m nt use: drinking water r: Confined of well: Housed borehole peration al discharge 200 m³/h ent crop None	561728	4524951	7
	B11KAV003	n down stream of treated area water level: < 0.75m 83) lepth: 140 m creening: only > 25 m nt use: drinking water r: Confined of well: Housed borehole peration al discharge 200 m³/h ent crop none	559403	4524967	8
	B11KAV004	m in margin of main zone water level: < 20 m lepth: unknown creening: unknown nt use: drinking water r: Confined of well: Housed borehole peration al discharge 180 m³/h ent crop none	559658	4527616	10
	B11KAV0015	n downstream water level: 1 m lepth: 142 m creening: continuos nt use: irrigation r: Multiple of well: Housed borehole peration al discharge 180 m³/h ent crop: cotton, corn, asparagus	560565	4526495	9

Basin[1]	Well code	Description	Well coordantes (H.G.R.S 87)[2]		
			X	Y	Z
	B11KAV0016	m Margin of main zone water level: 4.1 m (1990) lepth: 152 m creening: only > 25 m nt use: irrigation er: Confined of well: Housed borehole peration nal discharge 180 m³/h ent crop: cotton, corn, asparagus	560307	4527766	11
Trifilia (14.5%)	B01MES009	Core of main zone water level: U/N lepth: 24 m nt use: irrigation er: Unconfined of well: Open air borehole nal discharge 5 m³/h peration ent crop: olives, some fruit trees, vegetables in greenhouses.	284771	4104204	25
	B01MES010	Margin of main zone water level: 38 m lepth: 60 m nt use: irrigation er: Unconfined of well: Open air borehole nal discharge 30 m³/h peration ent crop: olives fruit trees,	286671	4104283	80
	B01MES012	Well inventory form not included in the report			
	B01MES014	Upstream limit of 1,3-d application zone water level: U/N lepth: 83 m nt use: irrigation er: multiple of well: Open air borehole nal discharge 100 m³/h peration ent crop: vegetables (greenhouses)	285747	4111183	82
	B01MES015	Margin of the main zone water level: U/N lepth: 20 m nt use: irrigation er: unconfined of well: Open air borehole nal discharge 10 m³/h peration ent crop: vegetables (greenhouses)	285718	4115397	72

Basin[1]	Well code	Description	Well coordantes (H.G.R.S 87)[2]		
			X	Y	Z
Tymbaki (27.5%)	B13HER007	ore of the main zone water level: 15 m (2005) epth: 30 m nt use: irrigation r: unconfined of well: Housed borehole al discharge 20-25 m³/h peration ent crop: vegetables (greenhouses)	567662	3882455	8
	B13HER009	Upstream limit of the main zone with nerby application product water level: 77 m (1969) epth: 150 m nt use: irrigation/private use as drinking water r: multiple of well: housed borehole al discharge 40-45 m³/h peration ent crop: vegetables (greenhouses)	569276	3883914	72
	B13HER012	downstream of core zone water level: 22-26 m (2005) epth: 150 m nt use: irrigation/potable water r: unconfined of well: housed borehole al discharge 130 m³/h peration ent crop: vegetables (greenhouses)	571445	3880774	20
	B13HER013	ownstream of core zone water level: U/N epth: 18 m nt use: irrigation r: unconfined of well: housed borehole al discharge 20 m³/h peration ent crop: vegetables (greenhouses)	568316	3881426	3
	B13HER015	core of the main zone water level: 37. 3 (1973) epth: 106.5m nt use: irrigation r: multiple of well: housed borehole al discharge 15 m³/h peration ent crop: vegetables (greenhouses)-olives	570916	3881696	9

Basin[1]	Well code	Description	Well coordantes (H.G.R.S 87)[2]		
			X	Y	Z
Ierapetra (53.3%)	B13LAS002	core of the main zone er: multiple water level: 18 (2005) epth: 106.5m nt use: irrigation of well: housed borehole al discharge 70 m³/h peration ent crop: greenhouses	656837	3876107	35
	B13LAS005	margin of the main zone er: multiple water level: 30 m (2005) epth: 57.31 m nt use: irrigation of well: housed borehole al discharge 12-15 m³/h peration djacent crop: greenhouses-olive	657527	3876313	24
	B13LAS006	margin of the main zone er: multiple water level: 15 m (2005) epth: 103 m nt use: irrigation of well:air borehole al discharge 30 m³/h peration djacent crop: greenhouses	650929	3975776	56
	B13LAS015	upstream limit of the main zone er: multiple water level: 10-16 m (1995) epth: 103 m nt use: irrigation/potable water of well: housed borehole al discharge U/N peration ent crop: greenhouses	654132	3876780	37

1 the number in brackets corresponds to the % of sales of 1,3-D in 2006 in Greece
2 Hellenic geodetic Reference system 1987

Water sampling.
Each well was sampled a minimum of four times per year (8 sampling times).

	Sampling date
T1	Jan 06
T2	Apr 06
T3	Jul 06
T4	Oct 06
T5	Jan 07
T6	Apr 07
T7	Jul 07
T8	Oct 07

All 8 sampling sessions were performed simultaneously in the four basins between 10th and 20th of the respective months scheduled.

For analysis of 1,3-D and its related compounds, 40 ml amber glass vials for VOC sampling were used. 5 vials were collected from each monitoring site and every sampling period. Each well/borehole was purged prior to the collection of the sample. Purging time varied depending on the characteristics of each site and the specific hydrological conditions. Vials were filled up to the top, until meniscus was formed and then carefully capped and examined for possible air-bubbles trapped. After labelling, vials from the same site were stored in a thermally insulated container with wrapped blue ice boxes A temperature data logger programmed at 30 min intervals monitored variations in temperature during transport to analytical laboratory. Prior to shipment ice boxes were replaced by fresh ones.

Normal dispatch time from field to laboratory was scheduled to be 48 h. Average temperature of samples over the entire sampling campaign ranged from 10.6 ºC to 14.06 ºC. Ina few cases recorded temperatures at delivery time were high.

Samples were analysed 14 days (1,3-D) or 21 days (related compounds) of receipt at analytical laboratory. Water samples

Additional samples were collected for analysis of major ions and occasionally for heavy metals, NO_2 , NH_4 and P. Furthermore, pH, Twater and conductivity were measured in situ

Methods of analysis

1,3-Dichloropropene

For the T1 to T3 sample timings (January-July 2006)

Residues of *cis* and *trans*-1,3-D were partitioned from the water into hexane and quantified by gas chromatography with electron capture detection. The LOQ were 0.1 µg/l for each isomer of 1,3-D **(Method ACR 81.4).**

This method was evaluated in the original DAR and considered valid during the EU Peer Review

For the T4 to T8 sample timings (Oct 2006-Oct 2007)

The method was changed to include the analysis of process impurities (1,2-dichloropropane, 2-chloro-1,5-haxadiene, 2-chloro-4-methykpentane, 3-chloror-2-methylpentane, 1,3-dichloropropane, 1,2,2-trichloropropane). Additional process impurities were initially included in the method development but were found to be unstable in water (see section 8.11 for details)

Water samples (10 mL) were pipetted into a 22-mL headspace vial. Sufficient sodium chloride was added to saturate the solution. The vial was immediately septum capped. The target analytes were transferred into the headspace (gas phase) by warming and agitating the vial in a headspace oven. The headspace in the vial was swept into a sample loop and then onto the GC inlet. The analytes were detected using capillary gas chromatography with mass-selective detection. Quantitation was by the external standard method using calibration solutions prepared concurrently with the samples. The LOD was evaluated at 0.02 µg/L.

Metabolites

3-chloroallyl alcohol (3-CAAL)

Residues of *cis* and *trans* 3-chloroallyl alcohol (3-CAAL) were extracted with methyl-t-butyl ether (MTBE). The MTBE was dried and purified by passing over anhydrous magnesium sulphate and a silica gel solid phase extraction (SPE) column. hexane was added and the sample was concentrated by evaporation. 3-CAAL residues in hexane were derivatised with isobutyl chloroformate in the presence of pyridine to their corresponding cis and trans 3-chloroallyl isobutyl carbonates (CAIBC) which was determined by GC-MS The LOQ was 0.1 µg/l for each isomer of 3-CAAL **(Method GRM 94.15)**

This method was evaluated in the original DAR and considered valid during the EU Peer Review

3-chloroacrylic acid (3-CAAC)

Residues of cis and trans 3-chloroacrylic acid (3-CAAC) were concentrated on an ion-exchange solid phase extraction (SPE) column. The 3-CAAC was eluted from the column in 0.1 N hydrochloric acid, which was then further acidified, saturated with sodium chloride and the 3-CAAC residues partitioned into MTBE. The MTBE was passed through a silica gel SPE column to remove water and particulates. Iso-octane was then added and the methyl-N-(t-butyldimethylsilyl)-trifluoroacetamide (MTBSTFA) to their corresponding t-butyldimethylsilyl esters and analysed by GC_MS The LOQ was 0.05µg/l for each isomer of the 3-CAAC **(method GRM 94.14)**

This method was evaluated in the original DAR and considered valid during the EU Peer Review

Calibration lines were only documented for *cis* and *trans* isomers of 1,3-D, 3-chloraryl-alcohol and 3-chloroacrylic-acid and for 1,2dichloropropane (r>0.99)

Results:

1) **Chrysopoli Basin**: No residues of 1,3-D, its metabolites and the basic impurities in Telone were traced in any of the analysed samples from this basin, throughout hte entire sampling campaign.

Hydrochemical quality of sampled varied slightly from period to period and also from site to site. Nitrate concentrations were very low. This absence was attributed mainly to two reasons: 1) abstracted water consists of a mixture from the unconfined and the underlying confined aquifer system and 2) screen intervals in the selected wells are located at depths essentially remote the shallow from the deeper aquifers.

2) **Trifilia Basin:** Hydrochemical characteristics of sampled water varied significantly with time, showing the sensitivity and fragility of the system to climatic conditions and the pressure imposed by abstraction for irrigation. A variation was also seen in the different zones sampled within the basin, which suggests that the study had focused on sampling locations that cover a spectrum of variation in the recharge and evolution mechanisms of the aquifer system.

NH_4 and NO_3 concentrations are quite high and suggest considerable groundwater pollution from agricultural activities. Despite this, no residues of 1,3-D, its metabolites and the basic impurities in telone were traced in any of the analysed samples from this basin, throughout the entire sampling campaign.

3) **Ierapetra basin:** Hydrochemical quality of sampled water varied slightly from period to period and also from site to site. Overall, however it may be suggested that the origin of studied groundwater is the same aquifer system. Nitrate concentrations are very low to non existent. This may explained by 1) abstracted water consisted of a mixture from both the unconfined and unconfined aquifer systems 2) screen intervals in the selected wells are located at depths remote the shallow from the deeper aquifers.

No residues of 1,3-D and related compounds were traced in any of the analysed samples from this basin.

4) **Tymbaki basin:** There was a variation of hydro-chemical parameters with time, showing an increasing trend in some parameters as the conductivity. This trend suggests a groundwater quality deterioration as results of a series of hydrological years during which the recharge volumes may have been reduced. A clear variation is also shown among the 5 sampled sites. This suggests a correct selection of sampling sites from the recharge zone to the end down zone in order to monitor the hydrodynamic evolution of the system.

Nitrate concentrations are high and do suggests considerable groundwater pollution from agricultural activities. NO_3 increased towards the downstream end point part of the aquifer system where groundwater levels are considerably shallower. This pollution level clearly suggests the existence of active flow for pollutants to reach the saturated zone.

Nevertheless, no residues of 1,3-D and related compounds were traced in any of the analysed samples with the exception of 1,2-dichloropropane.

1,2-Dichloropropane was found in well B13HER007 from October 2006 to the end of the study. 1,2.dichloropropane residue showed a decay over periods T4 to T6 inclusive. Over period T7 residues increases and on T8 a decay evolution was seen again. So release to the environment occurs in a specific period of time (probably July and/or August).

Table 8.10.1.1-1: Concentrations found in well B13HER007

Sampling	Sampling month	1,2-dichloropropane
T4	Oct 06	**0.21**
T5	Jan 07	0.19
T6	Apr 07	0.11
T7	Jul 07	**0.25**
T8	Oct 07	0.19

As only the 1,2-D impurity was seen in one of the sampling regions (Timbaki well B13HER007) with none of the other process impurities seen (including closely related 1,3-dichloro-propane and 1,2,2-trichloropropane both of which are present at higher levels in the 1,3-D technical product), a non-1,3-D source of 1,2-D was suggested for the presence of this impurity around the Timbaki well.

The vicinity of well B13HER007 was examined in details to the identification of potential point pollution (with no agricultural origin) sources and then assessed. 6 potential point pollution sources were identified; they were spread on a NW-SE direction and a distance which varied between 95 and 826 m. Moreover, in the vicinity of the well several signs of mismanagement of plant protection products and fertiliser containers were recorded.

An extended monitoring well network was implemented from April 2007 to October 2007 around the target well B13HER007. The characteristics of the wells are given below. They were located along two virtual axes: perpendicular to the identified main potential sources (W13HER022, W13HER020, B13HER019, B13HER017, W13HER025, W13HER021) and parallel to it (W13HER023, B13HER018, W13HER024). Thus, hypothetical permanent of 1,2-D plume would be detected and sufficiently mapped

Piezometric maps in the vicinity of target well B13·HER007 were designed. These maps were based on the limited availability data from sampling points, therefore, they only served as indicative of the dynamic of the aquifer. They let to know the presence of a depression cone in the focal part of the study. However, the variations in the depth of the ground water level were not substantial and were fully justified from the continuous groundwater abstractions for irrigation purposes.

18 samples were collected: 9 groundwater samples; 5 swab samples from dust or water leaks at the the well heads; 4 soil samples from 3 soil depths at the vicinity of the target well B13HER007 80,0-25 cm, 25-50 cm). Swab and soil samples results are qualitative than quantitative.

Swab samples were collected from the water leaks of the pump at the well head and the floor dust within the shed of the well B13HER007. Also, from the soil surface and/or the floor dust of the cemented well head base at W13HER020, W13HEr024, B13HER019. These sites were deemed most susceptible to pollution because of the construction characteristics of the wells, the soil slope around them and the poor management of empty PPP containers.

Swab samples: in all 5 swab samples collected a small concentration was determined only over the period T6 and there were not traces in the next two periods. The positive determination in water leaks of the well head B13HER007 may be due to groundwater polluted with 1,2-D (see below)

The other 4 swab samples essentially traced concentrations of 1,2-D on the cemented base .This could be the result of either mishandling of agrochemicals containing 1,2-D either during the storage, or during the preparation of a mixture. Another possibility could be msmanagement of empty containers. Airborne droplets of compounds containing 1,2-D during field treatment may also the origin of the pollutant in swab samples.

Soil samples: no residues of 1,3-D were found at different depths. Samples were collected underneath the main water filter divice installed in well B13HER007. This particular point receives all leaks from the irrigation system which is apparently also used for application of PPP . Hence, this was deemed the most possible location of traces of 1,2-D in soil. A fourth sample was collected from a location adjacent to the target well where farmer stores empty 1,3-D drums until permanent disposal away from the fields.

Groundwater samples: all 9 groundwater monitoring points tapped the same aquifer system and more specifically the upstream part of the end point zone. This is supported by the fact that electrical conductivity pH and hydro-chemical characteristics did not show abrupt differences in any of the samples examined. The elevated conductivity and high concentrations of NO_3 and Cl, Na and K indicated that the zone is influenced by sea water intrusion and it is vulnerable to pollution of probably agricultural origin

Samples collected from additional monitoring points did not yield any positive results except in three sites (B13HER017; W13HER022; W13HER025). B13HER017 and W13HER022 showed similar concentrations than B13HER007 at sampling periods T6 . W13HER025 showed the highest concentration (0.21 ug/l). In T7, no concentration was detected in W13HER025 and the highest concentration was detected in B13HER007 (0.25 ug/l). Contrary, the highest concentrations were detected in B13HER017 and W13HER02 in sampling period T8

Table 8.10.1.1-2: Concentrations found in wells B13HER017, W13HER022 and W13HER025

Sampling	Sampling month	B13HER017 (U/N)[1]	W13HER022 (18.9 m)[1]	W13HER025 (6.5 m)[1]
T6	Apr 07	0.11	0.12	**0.21**
T7	Jul 07	0..16	0.17	ND
T8	Oct 07	**0.34**	**0.28**	< 0.1

1 depth of the water table at T6 period

The highest concentrations in T6 period were found in the shallowest well (W13HER025; 6.5m). whereas the lowest concentration is recorded at well with greater water table depths. Depth of the water table decreased from inland towards the coast. These findings might suggested that pollutant flow path through the unsaturated zone was much shorter than the decay time under aerobic conditions. This hypothesis was true whenever:

1. unsaturated zone had similar composition and geometry along the entire study area.
2. the aquifer matrix was homogenous
3. similar influx of pollutant influx along the entire area
4. groundwater flow did not influence to a substantial degree pollution transport

Should this be the case, concentrations of 1,2-D should have been detected in every groundwater monitoring point with a depth of water table less than 18. 9 m. However, residues were not detected in three wells with water table depths between 12.6 m and 19. 3 m (W13HER024, B13HER024, B13HER019, W13HER020).

Other reason to explain the result might be the degree of protection of well heads. However, it did not justify the no presence of traces of the pollutant in adjacent wells

Therefore, it was suggested that although depth to water table seems to be a crucial parameter to the transport of 1,2-D through the unsaturated zone , it is not a definitive one. Findings in groundwater showed a rather spurious pattern that could be attributed to either a very localised accidental (still repeated) pollution incidents through leaching from the gravel pack or the casin wells, and/or local strong heterogeneities of the aquifer stratigraphy that results in preferential flow paths of the pollutant, and/or leaching of the pollutant from the fields through the unsaturated zone

RMS comments: The study is considered valid.

B.8.10.1.2 Evidence of 1,3-D Use in the areas of monitoring

Report: Dawson, J. (2006). Report Nº:N/A (Masterfile: K86). Annex point/reference IIA 7.4/03 IIIA9.2.1/03

Major suppliers of 1,3-dichloropropene in UK, France, Spain Italy and Greece within the local catchments of the monitoring groundwater programme were selected. The key information captured highlights the use of 1,3-D estimated annual application in these catchments, the local crop types that the products are being used to

protect, and the approximate number of years for which 1,3-D has been used in the area (table 8.10.2-1) Data show that not only is 1,3-D use within the local areas being monitored but also that the products have been used for many years (in some cases up >35 years). Therefore, Current and historical use of 1,3-D products in the monitoring areas has been demonstrated.

Table 8.10.1.2-1:

Country	Distributor	Amount per year	Region	Locality	Application Proximity to Wells	Years Used	Relevant Well Monitored (code)
ITALY	Galanti	250000 l/y	Lazio	Sabaudia	Selva Piana	10	SAB02
	SIS	0.16%	Lazio	na	Aprilia		CAR, CAM02, GIA03
	SIS	0.13%	Lazio	Latina	Sabaudia		SAB02
	SIS	0.06%	Lazio	Latina	Fondi		FON07
	SIS	9.2%	Veneto	Verona			BIN, DAV
	SIS	0.2%	Veneto	Rovigo			OCC02,ROF09, ROF10
	Geofin	409800 l/y	Veneto	Verona	Ca' di David	12-45	DAV
	Geofin		Veneto	Verona	Binelunghe	12-45	BIN
	Geofin		Veneto	Isola della Scala	Borgodoltra	12-45	ISS
	Geofin	1781760 l/y	Veneto	Legnago	Paina	12-45	LEG01
	CALV	500 l/y	Veneto	Verona	Ca' di David	15	DAV
	CALV	500 l/y	Veneto	Verona	Binelunghe	15	BIN
	CALV	2000 l/y	Veneto	Isola della Scala	Borgodoltra	15	ISS
	CALV	2000 l/y	Veneto	Legnago	Paina	15	LEG01
	SIS	8.5%	Emilia Romagna	Ferrara			OCC02,ROF09, ROF10
	SIS	0.5%	Emilia Romagna	Forli Cesena	Forli		FRL66
	SIS	2.55%	Emilia Romagna	Forli Cesena	Cesena		CES06
	SIS	0.2%	Emilia Romagna	Rimini			RN07
	Ortotecnica	2000L/y	Emilia Romagna	Rimini	Bellaria	15	RN07
	CASA Mesola	30000l/y	Emilia Romagna	Ro Ferrarese		20	OCC02,ROF09, ROF10
	SIS	0.36%	Campania	Napoli			AC03
	Coppola Fertilizzanti	3000	Campania	Napoli	Accera	21	AC03
	Coppola Fertilizzanti	1000	Campania	Napoli	Lufrano	21	SN01
	SIS	13.86%	Campania	Salerno			FP,CIO,AV
	Coppola Fertilizzanti	4000	Campania	Salerno	Battipaglia	12	FP,CIO,AV
	Coppola Fertilizzanti	2500	Campania	Salerno	Eboli	12	FP,CIO,AV
	SIS	0.5%	Sicilia	Ragusa	Castellana		SCI
	Bioservice	250.000	Sicilia	Ragusa	Castellana	10	SCI
	SIS	3.76%	Sicilia	Ragusa	Scicli		FER, CAS
	Bioservice	100000L7y	Sicilia	Ragusa	Petraro	10	SCI
	SIS	3.16%	Sicilia	Caltanissetta	Gela		PAN02, PAN05
FRANCE	AGRIAL	5000l/y	Manche	Gatteville Le Phare		10	MA-F13,MA-F14, MA-

Country	Distributor	Amount per year	Region	Locality	Application Proximity to Wells	Years Used	Relevant Well Monitored (code)
							F16
	AGRIAL	120000l/y	Manche	Breteville sur Ay		20	MA-F18,MA-F21
	AGRIAL		Manche	Creances		20	MA-F18,MA-F21
	Agriviti	250	Haut Rhin	Katzenthal		15	HR-F5, HR-F6
	Agralia	80000 l/y	Landes	Ychoux		7	YP-F4,YP-F5, YP-F8,YP-F9
	Agralia		Landes	Parentis-en-Born		7	YP-F10
	La Centrale	1600-700	Pyrenee Orientales	Elne		4+	BY-F4, BY-F6, BY-F7
	La Centrale	800-500	Pyrenee Orientales	Saint Cyprien		4+	BY-F2,BY-F8
	Coop Agricole Provence Languedoc	3000-4550	Vaucluse	Athen-Chateauneuf/ Carpentras	Chateauneuf	4+	CA-F2,CA-F7
	Coop Agricole Provence Languedoc	1500-3500	Vaucluse	Jonquieres/ Orange	Jonquieres	4+	CA-F5,CA-F8
	Coop Agricole Provence Languedoc	1500-2265	Vaucluse	Courthezon/ Orange	Courthezon	4+	CA-F8
SPAIN	Agroquimicos Cespedes	1800 MT	Almeria	Almeria		>35	AL-1,AL-2,AL-3, AL-4,AL-5,AL-6, AL-7,AL-8
	Torrandell Ca'S Siulet	200 MT	Mallorca	Mallorca		>35	PM-1,PM-2,PM-3, PM-4,PM-5
	Enrique Ortuno	250MT	La Rioja	La Rioja		>35	R-1,R-2,R-3,R-4, R-5
	Fitesa	180 MT	Cadiz	Cadiz		>35	C-1,C-2
	Cahersa	1000 MT	Caceres	Caceres		>35	CC-1,CC-2,CC-3, CC-4,CC-5
UK	Boston Crop Sprayers	3600 l/y	Lincolnshire	SW Lincoln	Dunston	5	L D
	Boston Crop Sprayers	13500 l/y	Lincolnshire	N Scunthorpe	Winterton Holmes	5	L WH
	Frontier Ag	2000 L/y	Lincolnshire	N Scunthorpe	Winterton Holmes	11	L WH
	Boston Crop Sprayers	1800 l/y	Lincolnshire	W Grimsby	Ulceby	3	L U
	Boston Crop Sprayers	13000 l/y	Lincolnshire	NE Barrow Upon Humber	Goxhill No.2	5	L GT
	Boston Crop Sprayers	4500 l/y	Lincolnshire	SW Market Rasen	Sprindlington	2	L S
	Frontier Ag		Lincolnshire	SW Market Rasen	Sprindlington	12	L S
	Frontier Ag	20000	Lincolnshire	Dunston		10	LD

Country	Distributor	Amount per year	Region	Locality	Application Proximity to Wells	Years Used	Relevant Well Monitored (code)
	Frontier Ag	45000	Lincolnshire	Sprindlington		15	LS
	Frontier Ag	15000	Norfolk	NE Norwich	Ludham	10	N L
	Boston Crop Sprayers	9000	Norfolk	N Fackenham	Wighton	10	N W
	Boston Crop Sprayers	3000	Norfolk	N Norwich	Aylsham	10	N A
	Frontier Ag	15000	Norfolk	N Norwich	Aylsham	10	N A
	Boston Crop Sprayers	8000	Norfolk	SE Hunstanton	Sedgeford	10	N S
GREECE	N.Erasmio Xanthis	3MT	Thrace	Xanthi		15	KAV002,KAV003 KAV005,KAV015 KAV016
	Kouts Xanthi	4 MT	Thrace	Xanthi		10	KAV002,KAV003 KAV005,KAV015 KAV016
	Agroland Mavajirous	1 MT	Peloponisos	Filiatra		10	MES009,MES010,MES012, MES014, MES015
	Agro Titoe	8 MT	Crete	Mires	Tymbaki	15	HER007,HER009,HER012, HER013,HER015
	Tkeabephe	4 MT	Crete	Mires	Tymbaki	15	HER007,HER009,HER012, HER013,HER015
	ΙΩannhΣ	3 MT	Crete	Ierapetra	Ierapetra	15	LAS002,LAS005, LAS006, LAS015
	AgroService Zammetauhe	2 MT	Crete	Ierapetra	Ierapetra	15	LAS002,LAS005, LAS006, LAS015
	Geoplan Galanakis	8 MT	Crete	Ierapetra	Ierapetra	14	LAS002,LAS005, LAS006, LAS015

In formation on the label rates for all crops in EU Member States is given in annex 8.2. According to the notifier, these label rates have remained stable for at least the last 10 to 15 years. It must be noted that the recommended rates vary depending on soil type (light soils have lower rates than heavy soils); but the table below provides lowest and highest rate used in field use. In most cases the use rates are similar to or higher than the Annex 1 supported use rates.

Table 8.10.1.2-2: Maximum and minimum rates of 1,3-D supported in EU Member States

Country	Min rate	Max rate

	L/ha	L/ha
Belgium	150 (S Beet)	340 (various)
France	150 (S Beet)	500 (orchards)
UK	225 (Potatoes)	225 (Potatoes)
Italy	100 (herbaceous crops) 225 (Vegetables)	475 (Vines, citrus, orchards)
Spain	90 (S Beet) 150 (vegetables)	475 (Vines, citrus, orchards)
Greece	90 (vegetables)	200 (potatoes and ornamentals)

B.8.10.1.3 Explanations for the Origin of 3-Chloroacrylic Acid found in two Groundwater Wells in Cáceres, Spain

Report: Pulido Bosch, A., Jorreto Zajuirre, S., Knowles, S. (2005). Report No. GHE-P-11256 (Masterfile MK55) IIA 7.4/03 IIIA 9.2.1/04

To investigate the positive finding of 3-chloroacrylic acid at levels in groundwater >0.1 µg/L (at timing T4 in the Caceres region, at wells CC-2 (10 m depth), Casatejada (0.413 ug/l) and CC-4 (7 m depth), Tori l(0.116 µg/L)), a field assessment was made by local experts to evaluate the possible causes of the positive findings. The area was investigated to look at local topography, geology, hydrology, well construction and agricultural practices including waste disposal. In addition photographic evidence was collected to document findings from the investigation.

A number of contributing factors were found to be possible causes of the findings in the Caceres region. These are:

- nature of the terrain
- the proximity of agricultural activity
- current management practices in the area

With reference to the nature of the terrain, wells CC2 and CC4 are located in a terrain of gravels and sands, of high permeability. This contributes to the infiltration and movement of water and therefore the area favours the infiltration of part of the irrigation water. The phreatic level (nearby river flood level) is also close to the field and wells

.A further observations from the field assessment demonstrated the lack of preventive measures in the storage and handling of 1,3-D products. One of the farms next to the well CC-4 had cans of 1,3-D products that were stored without precaution. The lack of control measures in this aspect raises the possibility of accidents, involuntary can overturns and even spillages. Stewardship guidance and training has since been undertaken in Spain.

Given the combination of factors from this investigation and close proximity of the growing fields to the sampled GW well, finding the 3-chloroacrylic acid metabolite just above 0.1 µg/L in the supply water can be rationalised.

B.8.10.1.4 Borehole vulnerability assessment

Report: Hughes, G., Price, O., Humphrey R., Knowles, S. (2006). Report number: GHE-P-11388 (Masterfile MK56) Annex point reference IIA 7.4/06, IIIA 9.2.1/05

Report: Hughes, Price, Knowles (2008) Report No.: N/A (Masterfile Number: P K33). Annex point/reference IIA 7.4/07 IIIA 9.2.1/06

A groundwater vulnerability assessment for classifying all the boreholes (115) being monitored in France, UK, Italy, Spain and Greece was conducted to assess the relative risk of each borehole to potential contamination with 1,3-D in order to provide recommendations for the optimization of the monitoring programmes

The groundwater vulnerability assessment was undertaken via a GIS implementation of an index approach based largely on the Pesticide DRASTIC approach (Aller,L et al, 1997). It took the form of:

$$\text{Vulnerability Index} = \sum_{i=1}^{7} F_i W_i$$

Where F is the Factor rating and W the weight to be applied to each factor i. The factors and weight used are given in table 8.10.1.4-1. The factors ratings are given in table 8.10.1.4-2 and following.

Table 8.10.1.4-1: Factors and weighting used for landscape parameters in the borehole vulnerability assessment (after Aller et al, 1987)

Factor	Source	Weight
Slope (%)	Slope from Hydro1k	3
Soil Media	Topsoil Texture of dominant STU from SGDBEv2	5
Soil OC	Topsoil OC of dominant STU from SGDBEv2	3
Net Recharge (mm)	Calculated similar to FOCUS SW data using 10 minute resolution data from CRU	4
Vadose zone media	Parent material hydrogeological type from SGDBEv2	4
Groundwater Depth (m)	Average for catchment determined from the monitoring data	5
Aquifer	Hydrogeological class from SGDBEv2	3

Table 8.10.1.4-2: Ratings applied to different slope

Slope range(%)	rating
0-2	10
2-6	9
6-12	5
12-18	3
>18	1

Table 8.10.1.4-3: Ratings applied to different topsoil texture

Topsoil texture	rating
Coarse (18%< clay and > 65% sand)	9
Medium (18% < clay <35% and >15% sand or 18% < clay and 15< sand<65%)	6
Medium fine (<35% clay and < 15% sand)	5
Fine (35%<clay<60%)	4
Very fine (>60% clay)	3
No mineral texture (peat soils)	8
No information	2

Table 8.10.1.4-5: Ratings applied to different topsoil to organic carbon content

Topsoil to organic carbon content (%)	rating
0-1	8
1-2	6
2-6	4
>6	2

Table 8.10.1.4-6: Ratings applied to different average ammual recharge scenarios

Annual recharge (mm/y)	Rating
0-100	1
100-200	3
200-300	6
> 300	9

Table 8.10.1.4-7: Ratings applied to different parent hydrogeological type

Parent material hydrological type	rating
R=(Porous-Stor.~ Perm+) Hard, non or weakly porpous limestone (Karstic), sandstone and crystalline rocks with moderate storage capacity and high permeability because of well-fissured/jointed systems	10
C= (Porous2 Stor. ~ Perm+) Chalk and soft limestone rith bimodal porosity, mcroporous with moderate storage capacity but well developed fissure systems giving relatively high permeability.	9
S = (Porous1 Stor. ~ Perm+) Weakly consolidated sandstone and unconsolidated sand and gravel with unimodal porosity; macroporous with large storage capacity and relatively high permeability	8
L= (Stor-. Perm-) Weakly ou unconsolidated micropporous substrate with a low permeability and low storage capacity	4
H= (Hard. Stor-- Perm--) Hard massive rock with negligible permeability and negligible storage capacity	2
M= (Soft. Stor-- Perm--) Soft massive substrates with negligible permeability and negligible storage capacity	2
#= no information	5

Table 8.10.1.4-8: Ratings applied to different depths to groundwater

Depth to GW	rating

Class (m)	
0-1.5	10
1.5-4.5	9
4.5-9.0	7
9.0-15	5
15-22	3
22-30	2
>30	1

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Table 8.10.1.4-9: Ratings applied to different hydrogeological classes

hydrogeological class		rating
1: soil with permeable substratum,, remote from groundwater: seldom wet	R=(Porous-Stor.~ Perm+)	5
1: soil with permeable substratum,, remote from groundwater: seldom wet	C=(Porous2 Stor. ~ Perm+)	4
1: soil with permeable substratum,, remote from groundwater: seldom wet	S = (Porous1 Stor. ~ Perm+)	4
1: soil with permeable substratum,, remote from groundwater: seldom wet	L= (Stor-. Perm-)	3
1: soil with permeable substratum,, remote from groundwater: seldom wet	H= (Hard. Stor-- Perm--)	2
1: soil with permeable substratum,, remote from groundwater: seldom wet	M= (Soft. Stor-- Perm--)	2
2: lowland soil affected by groundwater, seasonally or permanently wet		9
3: soil with impermeable layers within 80 cm depth, seasonally or permanently wet		5
4: soils of the uplands and mountains	W	2
4: soils of the uplands and mountains	D	2

Derived vulnerability scores for ech borehole are included in the annex 8.1

The index derived, by its nature, ranges between a value of 47 and 252. Within this study in order to interpret these index values more objectively the scores were normalized to lie within the range 0-100 (normalized score=100x (weighted score-47)/250)

Each dataset listed in table 8.10.1.4-1 are available as continuous GIS coverage or raster surface for the entire study area.

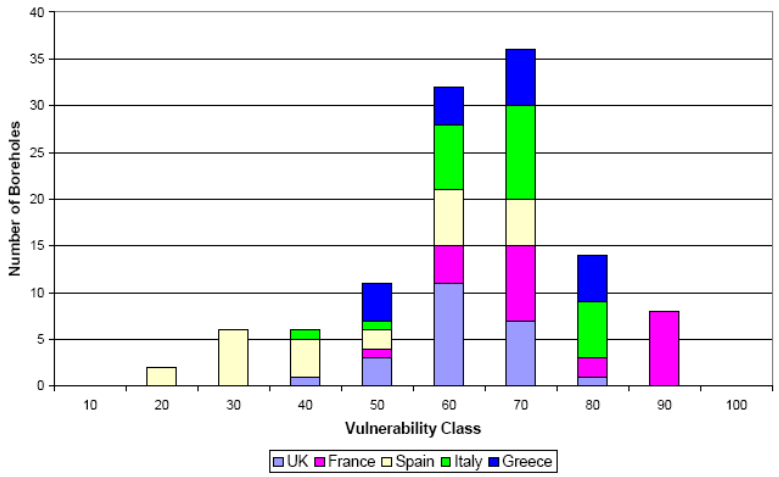
All surface water catchments within 10 km of each of the boreholes were selected and characterised. Each dataset was classed into the categories appropriate for that factor . These layers were processed by using ARGIS with the

spatial Analyst extention and the appropriate weighting applied to each layer in order to derive the Vulnerability Index. The index was then normalised to produce the final results.

The overall vulnerability of each borehole took account of the climatic/ topographic/ soils/aquifer properties of the catchment. Borehole vulnerability was ranked and classified as either 'higher' or 'lower' risk. This classification was assigned on a national basis, with the lowest 50% of borehole scores in each country being designated as low risk and the highest 50% as high risk. Ranking the boreholes on a country-by-country basis, rather than ranking the total boreholes in all five countries, ensured that local physiographic conditions are taken into account. The risk classifications assigned to each borehole are therefore relative risks and restricted to boreholes in the existing monitoring programme.

Findings: The groundwater vulnerability index results for each of the boreholes are summarised in Figure 8.10.1.4-1.

Figure 8.10.1.4-1: Histogram of borehole vulnerabilities for each country



This summary indicates that Spain has a larger number of lower vulnerability boreholes than the other countries. This is an artefact of the moderate groundwater recharge, larger depths to groundwater, flat terrain as well as high organic carbon values that characterise these sites. France on the other hand has a number of higher vulnerability sites and this is largely a function of shallow groundwater depths, larger recharge volumes and negligible soil organic carbon. France, Italy and Greece have similar distributions of sites skewed towards the higher end of the vulnerability scale. Similarly, the UK has a good distribution of sites in the higher vulnerability classes but also incorporates a number of sites with lower vulnerabilities.

If a groundwater vulnerability index of 50 is chosen to distinguish higher from lower vulnerability sites (Table 8.10.1.4-2) these observations are reinforced with all countries, except Spain, demonstrating a majority of higher vulnerability sites. However, the vulnerability scores for each borehole need to be contextualised within the catchment in which they occur as while they may appear to have a lower vulnerability than other sites, within a specific catchment and a product use context they may represent the higher vulnerability sites. In terms of the overall suitability of the sampling sites, the regional maps produced demonstrate the location of each borehole in relation to the regional catchment In the vast majority of cases, the boreholes are in locations that represent higher risk areas within a given catchment near to or adjacent to cropped areas where the product is actually used.

A summary of the boreholes relative to the entire monitoring programme, using the lowest 50% of all of the boreholes included in the project ranked together as lower risk and the highest 50% as higher risk is also given in Table 8.10.1.4-10.

Table 8.10.1.4-10: Summary of the proportion of higher and lower risk boreholes in each Member State. Risk is categorised using a vulnerability index (VI) threshold of 50 in columns 3 and 4 while ranking across all countries using the 50th percentile as a threshold is provided in columns 5 and 6

		VI threshold= 50		VI threshold= 50th percentile across all countries	
Country	Nº boreholes	Higher risk	Lower risk	Higher risk	Lower risk

UK	23	19	4	8	15
France	23	22	1	18	5
Spain	25	11	14	5	20
Italy	25	23	2	16	9
Greece	19	15	4	11	8

The percentage of boreholes located in the UK that are ranked in the top 50% of the most vulnerable boreholes in the five Member States is 35%. The percentage of boreholes located in France, Italy and Greece that are ranked in the top 50% of the most vulnerable boreholes in the five Member States is 78, 64 and 58%, respectively. The boreholes located in Spain are the least vulnerable in the monitoring campaign, with only 20% of the sampled boreholes in the top 50% of the most vulnerable boreholes in the five Member States.

Table 8.10.1.4-11: Summary of the proportion of higher and lower risk boreholes in each Member State. Risk is categorised using a vulnerability index (VI) threshold of 50th percentile across all countries

Country	Region	Nº boreholes	Nº boreholes classified as Higher risk	Nº boreholes classified as Lower risk
UK	South Yorkshire	5	4	1
	Licolnshire	5	2	3
	Nottinghamshire	5	1	4
	West Midlands	4	0	4
	Norfolk	4	1	3
France	Haut-Rhin	4	2	2
	Manche	5	5	0
	Landes	5	5	0
	Vaucluse	4	4	0
	Pyrenées Orientales	5	2	3
Spain	La Rioja	5	3	2
	Cáceres	5	2	3
	Cádiz	2	2	2
	Palma de Mallorca	5	0	5
	Almería	8	0	8
Italy	Sicilia	5	3	2
	Campania	5	3	2
	Lazio	5	3	2
	Veneto	5	3	2
	Emilia Romagna	5	4	1
Greece	Keramonti	5	5	0
	Ierapetra	4	1	3
	Timbaki	5	1	4
	Gargaliani	5	4	1

B.8.10.1.5 Overall summary and assessment of the GW monitoring programme conducted

This monitoring programme was instigated by DowAgroScience as a product stewardship programme for products containing 1,3-D. The results of the monitoring were published in Terry, D.Carter, Humphrey *et al* (2008)[12] (Masterfile Number PK32). This paper reports the results for 1,3-D and its metabolites. The primary goals of the monitoring programme are:

1. to evaluate the potential exposure of 1,3-D and its two major metabolites via groundwater used for commercial drinking water production in high Telone use areas.
2.- to provide data on the mobility in soil and the potential leaching to groundwater of 1,3-D, its metabolites and process impurities. to support Annex I listing

[12] Pest Mang Sci 64(9):923-32

The monitoring programme was conducted in UK, France, Spain and Italy during 2002-2004, with further extension of the programme beginning in Greece in January 2006 where process impurities were also monitored.

Country and site selections were based on areas of major use of 1,3-D and the need to characterise a range of agro climatic and management conditions. Within these countries, authenticated regional sales information and relevant cropping were assessed alongside local hydrogeological characteristics of the region in order to select target areas that were known to be potentially vulnerable to the leaching of 1,3-D and its metabolites up to five regions of 1,3-D high use were identified and characterised and within each region up to 8 wells were selected for inclusion of the sampling programme

Field specific, official, historical records of pesticide use were not generally available for the regions investigated. In the absence of documented data, additional sources of data were sought. For example farmers did provide verbal evidence that they were had previously used the active substance in fields around the selected wells. Distributors in each region were able to provide further confirmation through sales information and local knowledge that 1,3-D had been used in the study region.

Over 5000 groundwater samples were analysed for the presence of 1,3-D and its metabolites.

In UK , France and Italy there were no findings > 0.1 µg/l for any of the analytical targets. From 1200 determinations in Spain there were no findings > 0.1 µg/l for 1,3-D and 3-chloroallyl alcohol over a 2 year sampling period. There were two detections of >0.1 µg/l for 3-chloroacrylic acid in Caceres in March 2004 (0.12 µg/l in the CC4 well and 0.4 µg/l in the CC1 well, respectively) over the 2- years sampling period. All the other findings were < 0.1 µg/l . Three contributing factors were found to be possible causes of the findings in the Caceres region: nature of the terrain (gravels and sands, of high permeability); The phreatic level (nearby river flood level) is also close to the field and wells the lack of preventive measures in the storage and handling of 1,3-D products

In Greece, no residues of 1,3-D and related compounds were traced in any of the analysed samples with the exception of 1,2-dichloropropane. 1,2-Dichloropropane was found in one well in Timbaki region (B13HER007) from October 2006 to the end of the study (Oct 2007). 1,2.dichloropropane residue showed a decay over periods Oct 2006 to April 2007 inclusive (from 0.21 ug/l to 0.11ug/L). Over July 2007 residues increases (0.25 ug/L) and in October 2007 a decay evolution was seen again (0.19 ug/L). These results suggest that the release to the environment occurs in a specific period of time (probably July and/or August). An extended monitoring well network was implemented from April 2007 to October 2007 around the target well. Samples collected did not yield any positive results except in three sites (B13HER017; W13HER022; W13HER025). B13HER017 and W13HER022 showed similar concentrations than B13HER007 at April 2007, however, W13HER025 showed the highest concentration (0.21 ug/l). In July 2007 , no concentration was detected in W13HER025 and the highest concentration was detected in B13HER007 (0.25 ug/l). Contrary, the highest concentrations were detected in B13HER017 and W13HER02 in October 2007 (0.34 and 0.28 ug/l, respectively) .Findings in groundwater showed a rather spurious pattern that could be attributed to either a very localised accidental (still repeated) pollution incidents through leaching from the gravel pack or the casin wells, and/or local strong heterogeneities of the aquifer stratigraphy that results in preferential flow paths of the pollutant, and/or leaching of the pollutant from the fields through the unsaturated zone .

A vulnerability assessment of the site selection was retrospectively applied to the study wells. It was based largely on pesticide DRASTIC approach . Goundwater vulnerability assessment are useful tools to aid in the design of post registration monitoring programmes . This study was able to demonstrate that the vast majority of monitored boreholes were located in higher vulnerability catchments areas. These results are supported by the presence of Nitrogen compounds in some samples collected in Greece. as high concentrations of these compounds are indicative of pollution caused by agricultural practices. In Spain, data were available for wells in four of the sampling regions; eight wells had nitrate concentrations between 1 and 10mg L^{-1}, seven wells had concentrations between 10 and 100mg L−1 and three wells had concentrations greater than 100mg L^{-1} (there were no data for five of the wells in these four sampling regions). In the UK, nitrate concentrations were greater than 50mg L−1 in ten wells across four of the sampling regions.

The monitoring GW study provides an assessment of the potential for 1,3-D and related products to reach groundwater under a range of actual use conditions in five European countries. The lack of evidence for contamination of groundwater by 1,3-D and its soil metabolites is associated to the physicochemical properties and environmental fate behaviour, in spite of the leaching risk indicated by the low KOC values. The parent substance is volatile and all three compounds are rapidly degraded in soil. It is very likely that the combination

of loss of parent to the atmosphere and degradation in soil resulted in no significant downward movement through the soil profile, and therefore no significant contamination of groundwater.

B.8.11 Environmental fate and behaviour of process impurities

B.8.11.1 Hydrolytic degradation . Stability of Telone impurities in water

Report: Eversfield, S.G., Knowles, S. (2007) Report Nº: GHE-P-11384 (Masterfile: O49)

The chemical stability of the low level process impurities present in Telone technical was investigated as part of the analytical method development for the determination of 1,3-dichloropropene and its process impurities in water. The methodology was being developed prior to method validation for the analysis of groundwater samples which may contain trace levels of 1,3-dichloropropene and related compounds. In total 13 analytes were included in the investigation:

cis-1,3-dichloropropene
trans-1,3-dichloropropene
1,2-dichloropropane
[redacted]

The water samples were fortified with Telone impurities at concentrations of 5 ng/mL in headspace vials and then sealed. These samples were then stored at room temperature (~20°C) prior to analysis using an automated headspace sampler (HP7694) interfaced to a GC-MS (Agilent 6890 GC/ 5973 MSD). Analyses of the first vials were conducted immediately after preparation T=0, with subsequent analyses at approximately T=60, 120, 300, 500 minutes after sample preparation.

Findings: In the table below the stability of impurities in water during 8.3h are shown

Table 8.11.1-1: Stability of Telone impurities in water (ng/ml)

	0 min	57 min	113 min	256 min	497 min
1,2-dichloropropane	5.07	4.88	4.95	4.99	4.77
cis-1,3-dichloropropene	5.01	4.96	4.83	4.82	4.47
[redacted]	5.21	2.83	2.16	0.82	0.55
[redacted]	5.00	5.04	4.92	5.04	4.7
[redacted]	4.98	3.46	2.88	2.02	2.0
[redacted]	5.01	4.84	4.71	4.81	4.45
[redacted]	5.04	2.90	2.06	0.82	0.28
trans-1,3-dichloropropene	5.01	5.02	4.76	4.82	4.26
[redacted]	5.12	5.01	5.13	5.4	5.12
[redacted]	5.00	5.05	4.85	5.03	4.78
[redacted]	4.98	4.89	4.78	5.04	4.7
[redacted]	5.00	4.51	4.02	3.46	2.4

The impurities reported in table 8.11.1-2 were found to be unstable

Table 8.11.1-2: Degradation of process impurities in aqueous solution

Compound	Estimated DT50
[redacted]	1.5 hours
[redacted]	3.5 hours
[redacted]	1.5 hours
[redacted]	8 hours
[redacted]	1.2 hours

As these process impurities are not stable in water they are not likely to be observed in groundwater samples, therefore were not included in the final analytical method validation CEM 3294 (report GH-P-1142) (see point 8.10). The remaining compounds were found to be stable enough to include in the full method validation although even within the experimental timeframe of 8 hours there was evidence of degradation.

RMS: The study is considered relevant.

Report: Lamastra et al (2008) Report No. GHE-P-11780

This study was conducted to determine the hydrolytic stability of the low level process impurities in high purity water (abiotic chemical degradation) and in some natural waters (abiotic and biotic degradation).

A range of process impurities including : [redacted] 1,2-dichloropropane, 1,3-dichloropropane and 1,2,2-trichloropropane were investigated. The parent 1,3-dichloropropene was also used as a reference compound to validate the methodology. The results of the hydrolysis of 1,3-Dichloropropene were compared with the ones included in the list of end points.

Aliquots of the impurities were individually spiked into either MilliQ water or water extracted from agricultural soil samples to give sample concentrations of 200 ppb and 1ppm (for the most inestable analytes).

The sealed headpace vials were incubated at room temperature (+22/24 °C). Extraction of Telone process impurities was conducted by SPME and/or HS-SPME. Residues were determined with gas chromatography and with a mass-selective detector. Retention and selective ion monitoring were used for selective quantitation. Linearity was checked using calibration standards in the range 5 -200 ppb

Findings: The results are shown in Table 8.11.1-2

Table 8.11.1-2: Stability of Telone impurities DT50 (days) calculated assuming linear first order kinetics

Telone impurities	50% water (Milli Q water / 50%headspace)	100% water (MilliQ water / no headspace)	100% water extracted from agricultual soil (no headspace)
	HS SPME	SPME	SPME
[redacted]	0,3	0,41	
[redacted]	<0,1	<0,1	
[redacted]	0.4	0,2	
[redacted]	<0,1	<0,1	
[redacted]	<0,1		
[redacted]	0,1	0,1	
[redacted]	<0,1		
1,2-dichloropropane	4,9	5,5	7,3
[redacted]	6,7	9,2	8,0
[redacted]	2,3	3,9	4,7
(Z,E)-1,3-dichloropropene		4,9	4,1

RMS comments: The results are comparable to the ones proposed by Eversfield and Knowles (2007) except for two analytes: 2-chloro-1,5-hexadiene and 2-chloro-4-methylpentane. In the present study these chemicals were found to be degraded with a DT50= 9.5 h and 2.4 h respectively. However, Eversfield (2007) found these analytes to be stable for 8 h. The samples were exposed to ambient laboratory light. Therefore, the contribution of photodegradation in the study cannot be excluded.

The validation of the analytical method is based on the comparison of the results found for 1,3-D (DT50= 4.9 d at pH 5.85 and DT50= 4.1 dat pH 7.8) with the hydrolysis results summarised in the list of endpoints (DT50= 4.9-4.8 d at pH 4-9 for trans isomer; DT50= 4.2d-1.6 d at pH 4-9 for cis isomer). This is not considered valid. The intervals of

concentrations used in the calibration lines are very wide (< 10 ppb 50, 100, and 200ppb) No recoveries are included for these high concentrations in the report.

Despite this deviation, this study confirms the results reported previously (Eversfield and Knowles, 2007) and it can be concluded that the impurities of 1,3-D are not expected to persist in the environment. DT50 values reported in this report are not considered relevant

B.8.11.2 Phys-chem properties of process impurities

Report: Knowles, S 2007 Report GHE-P-11692 (Ref. Masterfile K85)

The volatilisation and partitioning parameters associated with all of the process impurities are likely to impact on their persistence in the environment. As a number of these impurities are analogues of each other, a range of the environmental parameters have been estimated using the US EPA. Estimation Programs Interface (EPI Suite™) Version 3.20 to show the similarities in the properties and potential environmental behaviour of these molecules. This software is a Windows® based suite of physical/chemical property and environmental fate estimation models developed by the EPA's Office of Pollution Prevention Toxics and Syracuse Research Corporation (SRC). EPI Suite™ uses a single input to run the following estimation models: KOWWIN™, AOPWIN™, HENRYWIN™, MPBPWIN™, BIOWIN™, BioHCWIN, PCKOCWIN™, WSKOWWIN™, WATERNT™, BCFWIN™, HYDROWIN™, KOAWIN and AEROWIN™, and the fate models STPWIN™, WVOLWIN™, and LEV3EPI™. EPI Suite™ was previously called EPIWIN. EPI Suite™ provides users with screening level estimations of physical/chemical properties and environmental fate properties. These properties are the building blocks of exposure assessment.

EPI Suite™ runs from a single input, a representation of the chemical structure in SMILES (Simplified Molecular Input Line Entry System) notation. A description of SMILES is available with the EPI Suite™ program.

Findings: Table 8.11.2-2 presents a summary of the environmental parameters

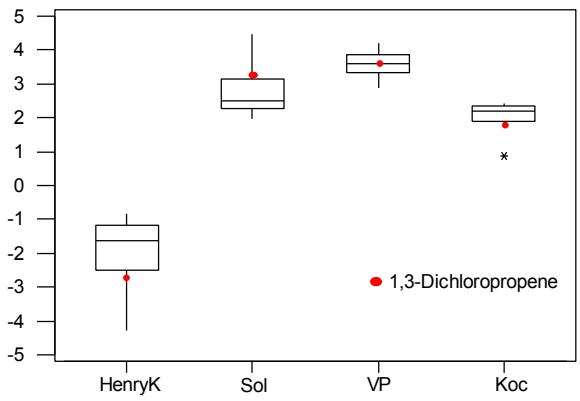
Table 8.11.2-2: Summary of environmental properties of process impurities. Estimated by EPI Suite

Compound code	Compound Name	Water Sol	Vapour Pressure	Koc	Henry's Contant	Atmospheric oxidation OH DT50	Volatilisation from water/ DT50 river,	Level III Fugacity Persistence time,)
		mg/L (measured)	Pa (measured)	mL/g (measured)	Atm/m3/ mole (measured)	(days/12-hr)	(days)	(days)
	1,3-dichloropropene	1994 (2250)	4532 (3800)	80.8 (44.7)	1.63E-3 (3.55E-3)	1.01	0.05	5.42
	IMPURITIES							
1	1,2-dichloropropane	2166 (2800)	5600	67.7 (47)	3.12E-3	24.2	0.05	8.08
3	[redacted]	991 (2750)	2440	80.8 (92)	1.65E-2	4.94	0.04	5.88
2	[redacted]	443	1746	96.6	1.66E-2	87.2	0.06	14.8
6	[redacted]	984	1292	125	3.00E-3	1.15	0.05	5.54
7	[redacted]	984	1292	125	3.00E-3	1.02	0.05	5.54
4	[redacted]	449	16665	154	1.46E-1	4.20	0.05	7.71
5a	[redacted]	268	8985	178	9.12E-2	3.91	0.05	8.00
5b	[redacted]	306	2839	193	2.68E-2	2.62	0.05	6.33
5c	[redacted]	306	6346	206	6.00E-2	4.03	0.05	6.67

Compound code	Compound Name	Water Sol	Vapour Pressure	Koc	Henry's Contant	Atmospheric oxidation OH DT50	Volatilisation from water/ DT50 river,	Level III Fugacity Persistence time,)
		mg/L (measured)	Pa (measured)	mL/g (measured)	Atm/m3/ mole (measured)	(days/12-hr)	(days)	(days)
11a		272	9706	178	7.28E-2	0.39	0.05	4.54
11b		305	4880	193	4.40E-2	0.20	0.05	7.08
8c		121	3280	275	2.77E-2	0.26	0.05	4.13
8a		92.9	6239	230	6.88E-2	0.27	0.05	3.77
8b		189	3973	241	2.37E-2	0.22	0.05	3.68
9a;9b		28778	780	7.42	5.05E-5	23.3	1.44	22.5
10		2229	9679	67.7	6.26E-3	0.53	0.05	4.16
12		186	3680	230	2.97E-2	0.37	0.05	6.92
13		159.7	1719.2	235.3	0.0149	2.551	0.0479	7.46

The Henry's Law Constant data shows that most of these volatile impurities are likely to behave like 1,3-dichloropropene. The Henry's Law Constant data showing where 1,3-D falls in the range is presented in a Box and Whisker plot, (lower line of Box is 1st quartile, top line is 3rd quartile, middle line is median, whiskers go to max/min values within the region limits, with an asterisk showing outliers).

Figure 8.11.2-1: Box and Whiskers Plot to show range of parameters for 1,3-D & impurities



Henry's Law Constants characterize the equilibrium distribution of dilute concentrations of volatile, soluble chemicals between gas and liquid. A Henry's Law Constant value > 10^{-3} atm-m3/mole indicates that volatilization from water is significant and rapid and a value > 10^{-5} atm-m3/mole indicates that volatilization from water is a significant route of dissipation for the molecule (Lyman, 1982). These data show that for all impurities except one (2-chloro-3-chloroethyl oxirane) volatilization from water is more significant and rapid than for 1,3-D. The modeled data also shows that EPI Suite is generating realistic estimates versus measured data. Water solubility is within an order of magnitude of 1,3-D. All of the impurities are shown to high vapour pressures which are expected for these low molecular weight alkanes and alkenes.

The Koc values also show that most of these impurities are likely to behave like 1,3-dichloropropene with respect to leaching. However the impurities are present at levels 1000-10000 times less from application of 1,3-D products so their risk of leaching to groundwater at significant levels is unlikely.

The degradation in air from atmospheric oxidation with hydroxyl radicals shows that most of the impurities have a DT50 < 2 days. A few of them have longer DT50's so long range transport should be considered. However the PECair above a treated plot predicted by Mackay et al, 2006, for these impurities is < 40 µg/m3 after 1 day (=0.04 µg/L of air). Given the high volatility of the impurities, the percentage of this mass entering a nearby waterbody will be low. Considering an extreme worst case, even if 100% of the impurity mass from 1 litre if air deposited into 1 litre of water, the PECsw would be 0.04 µg/L. This concentration is below the level of ecotoxicological concern. Based on Henry's Law and Fugacity models, the percentage of airborne impurities entering surface water from deposition is expected to be extremely low. This suggests that the above PECsw estimate of 0.04 µg/L is an extreme worst case and an overestimation of the PECsw from air deposition.

Finally the volatilization from river water, Level III fugacity and persistence time have been presented. Whilst fugacity has been evaluated in more detail by Mackay et al, 2006, the behaviour of the process impurities can be compared with that of the parent 1,3-dichloropropene. None of these volatile impurities are likely to persist in soil or water. Once in air, the concentrations away from the treated area will be infinitesimally low following dilution in air.

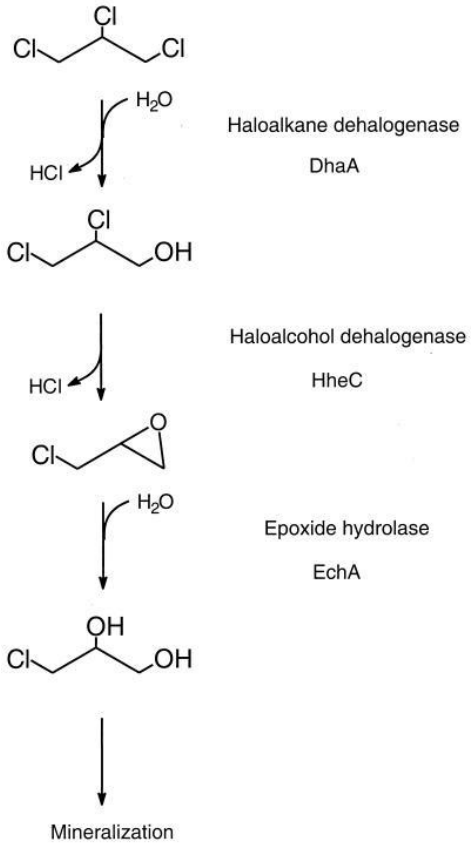
RMS comments: The study is considered relevant. These data show that the process impurities are likely to behave like 1,3-dichloropropene.

The impurities are all closely related short chain simple chlorinated hydrocarbons. The mechanisms for substitution reactions and dechlorination have been widely reported in the literature. The hydrolytic instability of alkenes and oxiranes is well documented in the literature. The hydrolysis of a halogenoalkane forms an alcohol.

$RCl + H2O \rightarrow ROH + H+ + Cl-$

Haloalkane dehalogenase is followed by Haloalcohol dehalogenase/epoxide hydrolase and then mineralisation

Once dechlorinated many of the impurites will be <C4 with C,H, O only so may be considered to be non-relevant.



Furthermore, it is well documented that oxiranes are reactive and undergo rapid hydrolysis to form diols. Closely related oxiranes degrade rapidly with DT50 in water ~ 7 days (pH 4- 10) so impurities 9a/b are unlikely to pose a long-term groundwater risk.

B.8.11.3 Dissipation of 1,3-D and Impurities from Soil. Fugacity Model

Report: Mackay, D., Webster, E., Knowles, S. 2006 Report No. GHE-P-11335 (Masterfile K84)

To demonstrate the rapid dissipation of these process impurities a fugacity model was applied (Mackay, 2001)[13]. The partitioning and concentrations of the fumigant are calculated between the phases present and estimates are made of the various rates of loss by volatilization, degradation and movement in soil. The concentration in the air canopy above the soil is also estimated.

The model was applied to two scenarios. The first (shank injection) addresses the fate of a fumigant injected into a soil outdoors in an agricultural setting. The second (drip irrigation) addresses the fate in a glasshouse with limited ventilation in which the fumigant is delivered by surface irrigation. The two scenarios are necessary because of the differences in the method of delivery of the fumigant.

The model for the outdoor injection scenario gives the fumigant distribution in the soil (30 cm) and (1m) canopy air ventilated by a winfd of a speed 3 m/s . Deposition from aerosols was ignored because these volatile chemicals do not appreciably associate with aerosols.

The drip irrigation indoor scenario does a similar calculation of distribution with the equilibrium module. The subsequent calculations now assume that the glasshouse is a closed but not hermetically sealed system since there are windows that permit some ventilation. The net effect is to reduce the "wind speed" considerably. This air movement can be derived using data for concentration in the glasshouse air as a function of time. The canopy height is the mean height (volume/area) in the glasshouse and is assumed to be 3 m. In this case the soil depth is set at the full depth of the soil, e.g. 30 cm. Again, the concentrations are calculated as a function of time for a period up to about 120 days.

Table 8.11.3-1: Properties of the soil environment. Values are based on the soil model by Mackay (2001)[10] except where noted.

	Symbol	Injection Scenario	Irrigation scenario
Area		10000 m^2	1000 m^2
Soil depth		0.05 m	0.15 m
Diffusion path length	YD	0.3 m[a]	0.05 m
Air height		1m	3m[a]
Wind speed		3 m/s	0.3 m/s
Volume fraction of aerosol in air	φ_Q	0	0
Rate of movement to soils below the layer modelled	LR	0.6mm/d	Virtually zero[b]
Rain rate	Rain	$2E^{-06}$ m/h[a]	Virtually zero[b]
Air boundary layer thickness	THICK	4.75 mm	4.75 mm
Molecular diffusivity in air	MDA	0.73 m^2/d	0.73 m^2/d
Molecular diffusivity in water	MDW	0.000043 m^2/d	0.000043 m^2/d
Mass fraction of OC in dry soil		0.02	0.02
Mass fraction of OC in organic matter		0.56	0.56
Volume fraction in soil Pore air Pore water	 φ_{air} φ_{water}	 0.25[a] 0.2[a]	 0.3 0.2
Densities			

[13] Mackay, (2001). Multimedia Environmental Models: The Fugacity approach. 2nd Ed . Lewis Publishers, Boca Raton 1-261 pp

Organic matter Mineral matter		1200 kg/m^3 2500 kg/m^3	1200 kg/m^3 2500 kg/m^3

a value supplied by DOW; b virtually zero is *ca* 10^{-11}

The phys-chem properties of 1,3-D and its process impurites used in the modelling are the ones estimated by EPI Suite™ see table 8.11.2-1. When a measured parameter was available it was introduced in the model. It is noteworthy that degradation DT50 data for the impurities are difficult to obtain or estimate. These DT50's depend on the chemical and on the nature of the soil microbial community. It was decided initially to assign a 10-day (240 h) DT50 to the saturated chloroalkanes, this value being similar to that reported for the dichloropropenes. For the olefins, dienes, and epoxide a shorter DT50 of 5 days (120 h) was initially selected. As a result of the fumigant addition the soil microbial community may be acclimated to the degradation of the chloroalkanes and alkenes and some co-metabolism of the impurities is likely. If desired, these DT50's can be varied, but in most cases results are relatively insensitive to these DT50's because evaporation is the primary dissipation process for these applications.

There were some comparisons made with monitoring data made from field application and glasshouse use. These comparisons are made without detailed information on soil type, meteorology or ventilation and injection depth; however the model gives results that appear to be accurate within a factor of about 3. It is concluded that the model provides a reliable screening level method of estimating the fate of similar compounds including impurities and degradation products.

Findings: The maximum concentrations for 1,3-D and its process impurites in soil and air canopy in injection and drip scenarios are summarized in tables Table 8.11.3-2 and Table 8.11.3-3, respectively. These tables also show the main loss process implied in the decline of concentrations in time.

Table 8.11.3-2: Maximum concentrations in the injection scenario

chemical	Amount g	Soil (µg/gdw)	Air (µg/m^3)	Maximum predicted loss at the end of simulation period	
				evaporation	degradation
1,3-dichlorpropene	2.24E+05	3.38E+02	1.16E+03	63.75%	31.98%
[redacted]	2.24E+02	3.38E-01	8.08E+03	0.25%	90.77%
1,2-dichloropropane	2.24E+02	3.38E-02	0.134	66.59%	29.71%
[redacted]	2.24E+02	3.38E-01	1.22E-01	16.56%	81.36%
[redacted]	2.24E+02	3.38E-01	1.9	74.82%	23.56%
[redacted]	2.24E+02	3.38E-01	5.07E-01	44.5%	52.57%
[redacted]	2.24E+02	3.38E-01	8.83	93.41%	6.33%
[redacted]	2.24E+02	3.38E-01	7.15	92.01%	7.71%
[redacted]	2.24E+02	3.38E-01	1.96	75.97%	23.18%
[redacted]	2.24E+02	3.38E-01	4.02	86.66%	12.91%
[redacted]	2.24E+02	3.38E-01	7.45	85.93%	13.82%
[redacted]	2.24E+02	3.38E-01	3.88	76.18%	23.52%
[redacted]	2.24E+02	3.38E-01	1.04E+01	89.56%	10.3%
[redacted]	2.24E+02	3.38E-01	3.43	73.82%	25.8%
[redacted]	2.24E+02	3.38E-01	5.84E-02	14.37%	81.65%

Table 8.11.3-3: Maximum concentrations in the drip scenario

chemical	Amount g	Soil (µg/gdw)	Air (µg/m^3)	Maximum predicted loss	
				evaporation	degradation
1,3-dichlorpropene	2.83E+04	1.57E+02	4.92E+03	86.44%	13.60%
[redacted]	2.83E+02	1.57	3.00E-01	0.75%	99.25%
1,2-dichloropropane	2.83E+02	1.57E-01	5.70	87.76%	12.28%
[redacted]	2.83E+02	1.57	5.26	39.75%	60.27%
[redacted]	2.83E+02	1.57	8.11E+01	91.08%	8.95%
[redacted]	2.83E+02	1.57	2.18E+01	73.21%	26.82%
[redacted]	2.83E+02	1.57	3.68E+02	97.92%	2.12%
[redacted]	2.83E+02	1.57	3.00E+02	97.45%	2.59%
[redacted]	2.83E+02	1.57	8.4E+01	91.36%	8.68%

chemical	Amount g	Soil (µg/gdw)	Air (µg/m³)	Maximum predicted loss	
[redacted]	2.83E+02	1.57	1.71E+01	95.58%	4.46%
[redacted]	2.83E+02	1.57	3.12E+02	95.18%	4.86%
[redacted]	2.83E+02	1.57	1.65E+02	91.22%	8.82%
[redacted]	2.83E+02	1.57	4.32E+02	96.48%	3.56%
[redacted]	2.83E+02	1.57	1.46E+02	90.18%	9.85%
[redacted]	2.83E+02	1.57	2.41	13.11%	86.9%

The uncertainty about the degradation DT50 of impurities translates into an associated uncertainty in the amount remaining and the corresponding concentrations. The magnitude of the uncertainty depends on the importance of the degradation rate relative to the other rates of evaporation and movement to soils below the layer modelled. Using the model, it is relatively easy to test various assertions that the degradation DT50 is larger by, for example, a factor of 1.1, 2, or 5. A simple, but excessively conservative approach is to set the degradation rate to zero (an infinite DT50) and generate the corresponding results. A series of simulations was conducted changing the DT50 of the impurity 1,2-dichloropropane, the results being given in Table 8.11.3-4 for up to 120 days.

Table 8.11.3-4: Estimated fate of impurity 1,2-dichloropropane as a function of time assuming different degradation DT50

DT50 (d)	time	% mass remaining	% loss by evaporation	%available for movement below modelled soil layer	% loss by degradation
10	0	100 (22.4 g)	0	0	0
	1	79.79	13.86	0.77	6.18
	3	49.66	33.52	1.87	14.95
	7	19.53	53.58	2.98	23.91
	14	3.81	64.05	3.57	28.57
	60	8.32E-05	66.59	3.71	29.71
	120	6.92E-11	66.59	3.71	29.71
20	0	100 (22.4 g)	0	0	0
	1	81.98	14.09	0.78	3.14
	3	55.10	35.11	1.95	7.83
	7	24.89	58.78	3.27	13.1
	14	6.2	73.36	4.08	16.36
	60	6.66E-04	78.2	4.35	17.44
	120	4.43E-09	78.21	4.35	17.44
50	0	100 (22.4 g)	0	0	0
	1	83.7	14.23	0.79	1.27
	3	58.65	36.12	2.01	3.22
	7	28.79	62.2	3.46	5.55
	14	8.29	80.11	4.46	7.15
	60	2.3E-03	87.35	4.86	7.79
	120	5.37E-08	87.35	4.86	7.79
1011	0	100 (22.4 g)	0	0	0
	1	84.87	14.33	0.8	0
	3	61.14	36.81	2.05	0
	7	31.72	64.68	3.6	0
	14	10.06	85.2	4.74	0
	60	5.32E-03	94.73	5.27	0
	120	2.84E-07	94.73	5.27	0

Using the estimated DT50 of 10 days the results in the first set are given. After 14 days 0.85 g of the original 22.4 g remain, i.e., 3.8%. Degradation accounts for nearly 30% of the losses. Increasing the DT50 by a factor of 2 to 20 days results in 6.2 % remaining after 14 days. Degradation now accounts for 16.4 % of the losses. Interestingly, the effect of this change on the masses remaining in the soil 7 days after application is relatively small. Specifically, on day 7 the mass remaining increases from 4.37 g to 5.58 g, an increase of only 1.21 g or 5.0 % of the original application of 22.4 g. A further increase in DT50 to 50 days, a factor of 5 increase, results in 8.3 % remaining after 14 days with degradation now accounting for only 7.1 % of the losses. The mass at day 7 increases slightly to 6.45

g, only a modest further increase. Finally, setting the DT50 to a near infinite value (1011) i.e., a degradation rate of virtually zero gives the fourth set of results with 7.11 g remaining after 7 days.

Inspection of these results shows that for times up to the assumed DT50 of the substance, the masses remaining are relatively insensitive to the change in, or uncertainty in, the DT50. The slower the degradation rate is relative to other loss processes the less sensitive the results are to variation in the degradation DT50.

Interestingly the masses remaining at long times, such as 120 days, become very sensitive to changes in the degradation DT50, i.e., the mass may change by a large multiple. For example, after 120 days the masses change from 1.55×10^{-11} to 9.92×10^{-10} to 1.20×10^{-8} to 6.35×10^{-8} g as the DT50 increases from 10, 20, 50 days to an infinite DT50, i.e., the mass changes by a factor of some 4000. These quantities are, of course negligible so even a change in mass by this large multiple is insignificant. A mathematical analysis was undertaken for this issue which showed that the sensitivity of the fraction of the mass remaining to the fractional change in the DT50 t½ is as follows:

$$(\Delta m/m)/(\Delta \text{ DT50}/ \text{DT50}) = -kR\ t = -\ln(2)\ t / \text{DT50}$$

This confirms the above observations. When t / DT50 is small the results are relatively insensitive to changes in DT50. Only when t >> DT50 is the effect large, but by this time the mass remaining is insignificant. Only when the chemical degradation reaction dominates as the loss mechanism are the results very sensitive to the assumed DT50. For the volatile impurities of 1,3-D, evaporation is the dominant route of dissipation.

RMS comments: The calculation is considered valid. Fugacity modelling shows that the main dissipation route of process impurities is volatilization. When evaporation is the dominant route of dissipation, the importance of the degradation rate is much less significant.

ANNEX 8.1: Derived vulnerability scores

Table A8.1-1: Vulnerability scores for boreholes in France

									Catchment vulnerability		Borehole vulnerability	
Borehole ID	GW depth class[1]	GW depth class[2]	Hydrogeology class	Parent Material Class	Recharge class	Slope class	OC class	Texture class	Score	Normalized score	Score	Normalized score
HR-F5	3	5	2	2	9	2	9	9	153	51.71	143	46.83
BY-F6	5	7	9	4	6	6	3	10	168	59.02	158	54.15
BY-F7	5	7	9	4	6	6	3	10	168	59.02	158	54.15
HR-F6	5	5	4	10	4	8	6	5	160	55.12	160	55.12
BY-F8	7	7	9	4	6	6	3	10	168	59.02	168	59.02
BY-F2	9	7	9	4	6	6	3	10	168	59.02	178	63.9
BY-F4	9	7	9	4	6	6	3	10	170	59.02	178	63.9
HR-F7	7	5	9	4	6	6	6	10	187	60	180	64.88
HR-F1	5	5	4	10	4	8	9	10	190	68.29	187	68.29
CA-F2	9	9	9	4	6	6	6	10	190	69.76	190	69.76
CA-F5	9	9	9	4	6	6	6	10	190	69.76	190	69.76
CA-F7	9	9	9	4	6	6	6	10	190	69.76	190	69.76
cA-F8	9	9	9	4	6	6	6	10	190	69.76	190	69.76
MA-F13	7	9	4	10	6	8	9	10	217	82.93	207	78.05
MA-F16	7	9	4	10	6	8	9	10	217	82.93	207	78.05
MA-F18	10	10	4	8	9	2	9	10	211	80	211	80
MA-F21	10	10	4	8	9	2	9	10	211	80	211	80
YP-F4	9	9	4	8	9	6	9	10	218	83.41	218	83.41
YP-F5	9	9	4	8	9	6	9	10	218	83.41	218	83.41
YP-F8	9	9	4	8	9	6	9	10	218	83.41	218	83.41
MA-F14	10	9	4	10	6	8	9	10	217	82.93	222	85.37
YP-F10	10	9	4	8	9	6	9	10	218	83.41	223	85.85
YP-F9	10	9	4	8	9	6	9	10	218	83.41	223	85.85

1 groundwater depth at borehole; 2 catchment average ground water depth

Table A8.1-2: Vulnerability scores for boreholes in UK

									Catchment vulnerability		Borehole vulnerability	
Borehole ID	GW depth class[1]	GW depth class[2]	Hydrogeology class	Parent Material Class	Recharge class	Slope class	OC class	Texture class	Score	Normalized score	Score	Normalized score
NN H	3	5	3	4	6	2	3	10	128	39.51	118	34.63
N L 2	7	7	3	4	5	2	3	10	133	41.95	133	41.95
N A	9	7	3	4	5	2	3	10	133	41.95	143	46.83
L D	9	7	3	4	6	2	3	10	138	44.39	148	49.27
L S	10	7	3	4	6	2	3	10	138	44.39	153	51.71
NN FB	1	5	4	8	9	2	6	10	174	61.95	154	52.2
WM BRA	2	2	4	8	9	2	6	9	156	53.17	156	53.17
WM DIM	2	2	4	8	9	2	6	9	156	53.17	156	53.17
SY GH	7	5	9	4	4	6	3	10	148	49.27	158	54.15
NN BOU	5	5	4	8	9	2	3	10	162	56.1	162	56.1
NN CH	5	5	4	8	9	2	3	10	162	56.1	162	56.1
N S	2	7	4	9	9	2	6	10	188	68.78	163	56.59
WM CO P	3	2	4	8	9	2	6	10	159	54.63	164	57.07
WM TOM	3	2	4	8	9	2	6	10	159	54.63	164	57.07
L U	7	7	5	4	6	6	6	10	168	59.02	168	59.02
L GT	9	7	5	4	6	6	6	10	168	59.02	178	63.9
L WH	7	7	9	4	8	6	3	10	178	63.9	178	63.9
NN BUD	7	5	4	8	9	2	6	10	188	68.78	188	68.78
N W	7	7	4	9	9	2	6	10	188	68.78	188	68.78
SY C	5	5	9	8	9	6	3	10	189	69.27	189	69.27
SY F	5	5	9	8	9	6	3	10	189	69.27	189	69.27
SY T	5	5	9	8	9	6	3	10	189	69.27	189	69.27
SY BP	9	5	9	8	9	6	3	10	189	69.27	209	79.02

1 groundwater depth at borehole; 2 catchment average ground water depth

Table A8.1-3: Vulnerability scores for boreholes in Italy

									Catchment vulnerability		Borehole vulnerability

Borehole ID	GW depth class[1]	GW depth class[2]	Hydrogeology class	Parent Material Class	Recharge class	Slope class	OC class	Texture class	Score	Normalized score	Score	Normalized score
EMR/FC/CES06	1	5	2	2	6	8	6	10	147	48.78	127	39.02
SIC/RG/FER	10	10	4	8	6	2	1	5	149	49.76	149	49.76
LAZ/LT/SAB02	2	5	9	4	6	2	9	9	167	58.54	152	51.22
LAZ/LT/CAM02	3	5	9	4	6	2	9	10	170	60	160	55.12
SIC/RG/CAS	10	10	4	8	6	2	1	9	161	55.61	161	55.61
VEN/VR/DAV	7	7	3	4	6	2	9	10	162	56.1	162	56.1
VEN/VR/BIN	1	7	9	1	9	2	9	10	195	72.2	165	57.56
CAM/NA/AC03	7	7	2	2	9	2	9	10	166	58.05	166	58.05
CAM/NA/SN01	7	7	2	2	9	2	9	10	166	58.05	166	58.05
CAM/SA/CIO	2	5	9	4	9	2	9	10	185	67.32	170	60
EMR/FC/FRL66	10	5	2	2	6	8	6	10	147	48.78	172	60.98
LAZ/LT/GIA03	7	5	3	2	6	8	9	10	162	56.1	172	60.98
SIC/RG/SCI	10	10	4	9	6	6	3	5	173	61.46	173	61.46
VEN/VER/ISS	10	7	3	4	6	2	9	10	162	56.1	177	63.41
SIC/CL/7PAN02	10	10	9	4	9	2	1	10	178	63.9	178	63.9
SIC/CL/7PAN05	10	10	9	4	9	2	1	10	178	63.9	178	63.9
LAZ/LT/CAR	9	5	3	2	6	8	9	10	162	56.1	182	65.85
VEN/RO/OCC02	5	7	9	4	6	6	9	10	192	70.73	182	65.85
CAM/SA/FP	5	5	9	4	9	2	9	10	185	67.32	185	67.32
LAZ/LT/FON07	10	10	3	10	4	8	9	5	197	71.71	194	71.71
EMR/RA/RN07	10	5	9	4	9	2	6	10	173	61.46	198	73.66
EMR/FE/ROF09	9	7	9	4	6	6	9	10	192	70.73	202	75.61
EMR/FE/ROF10	9	7	9	4	6	6	9	10	192	70.73	202	75.61
VWN/VR/LEG01	9	7	9	4	9	2	9	10	195	72.2	205	77.07
CAM/SA/AV	10	5	9	4	9	2	9	10	185	67.32	210	79.51

1 groundwater depth at borehole; 2 catchment average ground water depth

Table A8.1-4: Vulnerability scores for boreholes in Spain

									Catchment vulnerability		Borehole vulnerability

Borehole ID	GW depth class[1]	GW depth class[2]	Hydrogeology class	Parent Material Class	Recharge class	Slope class	OC class	Texture class	Score	Normalized score	Score	Normalized score
AL-6	1	1	3	4	6	2	1	5	85	18.54	85	18.54
AL-7	1	1	3	4	6	2	1	5	85	18.54	85	18.54
AL-1	1	1	3	4	6	2	1	9	97	24.39	97	24.39
AL-2	1	1	3	4	6	2	1	9	97	24.39	97	24.37
AL-3	1	1	3	4	6	2	1	9	97	24.39	97	24.39
AL-5	1	1	3	4	6	2	1	9	97	24.39	97	24.39
AL-8	1	1	3	4	6	2	1	9	97	24.39	97	24.39
AL-4	1	1	3	4	6	2	1	10	100	25.85	200	25.85
R-1	3	3	3	4	6	2	3	9	115	33.17	115	33.17
PM-3	1	2	3	4	6	2	6	9	122	36.59	117	34.15
PM-4	1	2	3	4	6	2	6	9	122	36.59	117	34.15
PM-1	3	2	2	2	6	6	6	9	123	37.07	128	39.51
PM-5	3	2	3	4	9	2	6	10	125	38.05	130	40.49
C-2	1	1	3	4	4	8	9	9	137	43.9	137	43.9
R-3	9	9	3	4	4	8	3	9	153	51.71	153	51.71
C-1	1	1	4	10	6	2	9	9	156	53.17	156	53.17
PM-2	9	2	3	4	6	2	6	10	125	38.05	160	55.1
CC-2	7	7	9	4	6	8	1	10	166	58.05	166	58.05
CC-3	7	7	9	4	6	8	1	10	166	58.05	166	58.05
CC-4	7	7	9	4	6	8	1	10	166	58.05	166	58.05
CC-1	7	7	9	4	6	8	3	10	174	61.95	174	61.95
CC-5	7	7	9	4	6	8	3	10	174	61.95	174	61.95
R-4	9	9	4	5	5	8	6	40	180	64.88	180	64.88
R-2	9	9	9	4	6	8	3	10	184	66.83	184	66.83
R-5	9	9	9	4	6	8	3	10	184	66.83	184	66.83

1 groundwater depth at borehole; 2 catchment average ground water depth

Table A8.1-5 Vulnerability scores for boreholes in Greece

									Catchment vulnerability		Borehole vulnerability	
Borehole ID	GW	GW	Hydrogeology	Parent Material	Recharge	Slope	OC	Texture	Score	Normalized	Score	Normalized

	depth class[1]	depth class[2]	class	Class	class	class	class	class		score		score
B01MES010	1	7	3	4	6	8	9	9	177	63.41	147	48.78
B13LAS005	1	3	3	4	6	8	9	9	157	53.66	147	48.78
B13HER009	1	1	3	4	6	8	9	9	147	48.78	147	48.78
B13HER015	1	1	3	4	6	8	9	9	147	48.78	147	48.78
B13HER012	2	1	3	4	6	8	9	10	150	50.24	155	52.68
B13LAS002	3	3	3	4	6	8	9	9	157	53.66	157	53.66
B13LAS006	3	3	3	4	6	8	9	9	157	53.066	157	53.66
B13HER007	3	1	3	4	6	8	9	9	147	48.78	157	53.66
B13HER013	7	1	3	4	6	8	9	10	150	50.24	180	64.88
B11KAV004	9	9	9	4	6	8	3	10	184	66.83	184	66.83
B11KAV016	9	9	9	14	3	8	3	10	184	66.83	184	66.83
B11KAV002	10	9	9	4	6	8	3	10	184	66.83	189	69.27
B11KAV003	10	9	9	4	6	8	3	10	184	66.83	189	69.27
B11KAV015	10	9	9	1	6	8	3	10	184	66.83	189	69.27
B01MES009	10	7	3	4	6	8	9	9	177	63.41	192	70.73
B01MES015	10	7	3	4	6	8	9	9	177	63.41	192	70.73
B13LAS015	10	3	3	4	6	8	9	9	157	53.66	192	70.73
B01MES012	10	7	3	4	6	8	9	10	180	64.88	195	72.2
B01MES014	10	7	3	4	6	8	9	10	18	64.88	195	72.2

1 groundwater depth at borehole; 2 catchment average ground water depth

ANNEX 8.2: Summary of the label rates for all crops in EU Member States

EU Country	**Belgium**	**Holland**	**France**	**France**	**UK**	**Italy**	**Spain**	**Spain**	**Spain**	**Spain**	**Greece**
		No longer Sold									
product	Telone II	Telone cis	Telone II Dorlone II	Dorlone 2000	Telone II	Telone 97	Telone II	Telone II EC	Dorlone II	Dorlone II EC	Condor
1.3 D content registered in grams per liter	1158	1160	1107	1179	1130	1178	1180	1120	1180	1080	1121
1,3 D content in % w/w-registered	95			97	min 94	97	97	93	97	91	91
general description identifying the uses	Soil Disinfectant - insects and nematodes	Soil disinfectant - nematicide	soil treatment	soil treatment	Broad spectrum nematicide..controls migratory and cyst. nem. by soil injection.	soil nematicide..galls (Meloydogyne)…..cysts (Heterodera)..lesions (Pratylenchus)	soil disinfestant to be applied on bare soil	soil disinfestant to be applied on bare soil	soil disinfestant to be applied on bare soil	soil disinfestant to be applied on bare soil	Broad spectrum nematicide
Type of use - Field or Greenhouse	not specified	Field		Field	Field only	Field only	Field	Mainly Greenhouse	Field	Mainly Greenhouse	field and glasshouse
application technique	soil injection	Soil injection	soil injection	soil injection	soil injection	soil injection	soil injection	drip irrigation	soil injection	drip irrigation	drip irrigation
Machinery specified	Not specified	Not specified		to be applied with a specific machine-not specified	A blade injector / Rumpstad	Not specified	A blade injector		A blade injector		

EU Country	**Belgium**	**Holland**	**France**	**France**	**UK**	**Italy**	**Spain**	**Spain**	**Spain**	**Spain**	**Greece**
pre-plant or pre-sowing interval-weeks or days	4-8 weeks	3-6 weeks	2-3 weeks	2-3 weeks	21 days	28 days	7 (x rate/ 100 l) days	7 (x rate/ 100 l) days	7 (x rate/ 100 l) days	7 (x rate/ 100 l) days	3-4 weeks
re-entry time	not specified	not specified		not specified	none	48 hours	no limits after	no limits after	no limits after	no limits after	none
Application rates by crop,and any notes	l/ha	l/ha	l/ha	l/ha	l/ha	l/ha	l/ha	l/ha	l/ha	l/ha	l/ha
onions		75									
potatoes	150	85	170	160	225		150-200	150-200	175	220	100-200
tobacco							100-150	100-150	90		
sugarbeets	150	75	150	140			90-150	90-150	175	220	
vegetables	240-340	120-230	170	160			150-200	150-200	90	90-150	90-150
strowberries	250-340	120-230			225		150-200	150-200			
nurseries	340	120-230					200	200			
orchards	340	120-230					400-475	400-475	400-475	500-750	100-200
flowers	340	120-230					150-200	150-200			
vines; apple,peach,plum orchards			500	475		330-475	400-475	400-475	400-475	500-750	
carnation			235	220			150-200	150-200			
roses			500	475			150-200	150-200			
citrus orchards			500	475		330-475	400-475	400-475	400-475	500-750	
narcissus		120-160			225						
hops					450						
herbaceous crops						100-190	90-150	90-150	90-175	100-220	
greenhouses				restricted	Not recomm.		150	150	90	100-150	100-200
Other		Not allowed in groundwater protected areas		Also pineapple, banana, sugar cane at 4751							

EU Country	**Belgium**	**Holland**	**France**	**France**	**UK**	**Italy**	**Spain**	**Spain**	**Spain**	**Spain**	**Greece**
Any labelled use restrictions				no use in closed spaces inc.grnhouses-except when open or before installation		under green houses and closed spaces				Apply a max of 40 l/ sq m of irrigation water	
Any re-entry restriction for greenhouse use								No		No	
Label Classification	Toxic, Harmful irritating	Toxic, Harmful irritating		Toxic,Harmful,Irritating	Toxic,Harmful, Irritating	Harmful	Toxic, Flammable	Toxic, Flammable	Toxic, Flammable	Toxic, Flammable	Toxic, Harmful, Irritant
Protective Clothing recommended on the label		Coveralls		Polyethylene coveralls	Coveralls	yes - S36, S37	S36/37/39	S36/37/39	S36/37/39	S36/37/39	Coveralls
Face protection	Face mask	Face mask		Face mask	Face mask	face mask	Yes-not specified	Yes-not specified	Yes-not specified	Yes-not specified	Face mask
Gloves	Yes	Yes		viton, neoprene or rubber	Neoprene	yes	Yes- not specified	Yes - not specified	Yes - not specified	Yes - not specified	Neoprene
Other				Viton, neoprene or rubber boots	Rubber Boots,		Boots	Boots	Boots	Boots	Boots
Container retrieval scheme	Yes	Yes		No	Yes	No					
Safety Data supplied with/on the label?	Yes	Yes		No	Yes	Yes - medical	No	No	No	No	Yes
Drum Venting information supplied?	Not specified	No		Yes	Yes	No	Yes	Yes	Yes	Yes	

B.8.12 References relied on.

Annex point/ reference no.	Author(s)	Year	Title Source (where different from company) Company, report no. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
IIA 7.4/01 IIIA 9.2.1/01	Knowles, S. Panagopoulos, S.A	2008	Residues of 1,3-Dichloropropene and Related Compounds in Groundwater in Greece - 2005 Report number: GHE-P-11707 (Masterfiel number: MK59) GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIA 7.4/02 IIIA 9.2.1/02	Kennedy	2008	Residues of 1,3-Dichloropropene and related compounds in Groundwater in Greece - 2006 to 2007 (final report) Report number: GHE-P-11693 (Masterfiel number: MK58) GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIA 7.4/03 IIIA 9.2.1/03	Dawson, J.	2006	Letter on Evidence of use of 1,3-D in EU countries - support to groundwater monitoring studies submitted in Europe (plus attachments) Dow AgroSciences DAS Report No:N/A (Masterfile Number K86): GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
IIA 7.4/05 IIIA 9.2.1/04	Antonio Pulido Bosch, Sara Jorreto Zajuirre	2005	Hydrological report on the possible explanations to the origin of the 1,3-D Metabolite (acid) in two wells of the sampling net of Caceres, Spain University of Almeria (Spain) DAS Report No.: GHE-P-11256 (Masterfile Number : MK55): GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
IIA 7.4/06 IIIA 9.2.1/05	Knowles,S. Hughes G Humphrey,R. Price,O.	2006	Borehole Vulnerability assessment in relation to 1,3-Dichloropropene groundwater monitoring programme in Europe ADAS UK Ltd DAS Report No GHE-P-11388 (Masterfile Number): MK56 GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
IIA 7.4/07 IIIA 9.2.1/06	Hughes G., Price O., Knowles, S.	2008	Pesticides in groundwater: Borehole vulnerability assessments to support a European groundwater quality monitoring programme Publication DAS Report No.: Not applicable (Masterfile Number): PK33 GLP/GEP (Y/N): N Published (Y/N): Y	N	P

Annex point/ reference no.	Author(s)	Year	Title Source (where different from company) Company, report no. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
IIA 7.4/08 IIIA 9.2.1/07	Terry D.Carter Humphrey et al	2008	A monitoring programme for 1,3-Dichloropropene and metabolites in 5 EU countries Publication DAS Report No.: Not applicable (Masterfile Number): PK32 GLP/GEP (Y/N): N Published (Y/N): Y (Pest Manag Sci 64(9):923-32)	N	P
IIIA 9.2.3/01	Knowles, S	2005b	Surface water exposure assessment, PECsw-open use Dow Agroscience report Nº: N/A (Masterfile: K88) GLP/GEP: N Published: N	Y	DAS
IIIA 9.2.3/02	Knuteson, J.A Wang, D.	2001	DripFume: a Visual Basic Interface Program for simulating soil Fumigatoin by Drip irrigation Dow Agroscience report Nº: GH-C 5358 (Masterfile:MK 42) GLP/GEP: N Published: N	Y	DAS
IIIA 9.2.3/03	Wang, D., Knowles, S., Knuteson, J	2005	Two-Dimensional Soil Transport Modelling of 1,3-D For Exposure Assessment Dow Agroscience report Nº: GHE-P-11175 (Masterfile: K83) GLP/GEP: N Published: N	Y	DAS
IIIA 9.2.3/04	Knutenson and Dolder	2000	Field Volatility of 1,3-Dichloropropene and Chloropicrin from Shallow Drip Irrigation Application of Telone C-35 to Strawberry Beds Covered with VIF Tarp Dow AgroSciences, Report Nº GH-C 5075 (Masterfile MK33) GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIA 7.4/09 IIIA 9.3/01	Knowles, S	2005a	Correlation of pedo-climatic conditions for field locations used in 1,3-D air monitoring studies- letter in response to EFSA evaluation meetinf Dow Agroscience report Nº: N/A (Masterfile: K82) GLP/GEP: N Published: N	Y	DAS
-	Eversfield, S.G Knowles, S.	2007	Method development for Telone analytes Dow Agroscience report Nº: GHE-P-11384 (Masterfile: O49) GLP/GEP: Y Published: N	Y	DAS

Annex point/ reference no.	Author(s)	Year	Title Source (where different from company) Company, report no. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
-	Lamastra, L., Ferrari, F., Trevisan, E., Capri, E., Knowles, S.	2008	Hydrolytic Stability of the Telone Process Impurities Dow AgroSciences, report No. GHE-P-11780 (Masterfile A78) GLP/GEP: N Published: N	Y	DAS
-	Knowles, S	2007	. Modelling The Environmental Characteristics of 1,3-Dichloropropene And Its Process Impurities Using The US EPA Estimation Programs Interface (EPI Suite) Version 3.20 Dow AgroSciences Report GHE-P-11692 (Ref. Masterfile K85) GLP/GEP: N Published: N	Y	DAS
-	Mackay, D., Webster, E., Knowles, S.	2006	Fugacity Modelling of 1,3-D And Its Process Impurities For Exposure Assessment Dow AgroSciences report No. GHE-P-11335 (Masterfile K84) GLP/GEP: N Published: N	Y	DAS

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ANNEX B

1,3-DICHLOROPROPENE

ADENDA V_REV_24_06_09

B - 9: ECOTOXICOLOGY

THIS ADDENDUM WAS PREPARED UNDER THE RESPONSIBILITY OF:

Mr. García - Baudín, J. Mª. Ph. D. (Co-ordinator).

Mr. Alonso - Prados, J. L. Ph D. (Scientific Co-ordinator).

Unidad de Productos Fitosanitarios I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FROM THE DOSSIERS SUBMITTED BY:

Task Force: Dow AgroScience & Kanesho Soil Treatment SPRL/BVBA

WITH THE ASSISTANCE OF THE FOLLOWING EXPERTS:

Ecotoxicology

Ms. Novillo Villajos, Apolonia Ph. D.

Unidad de Productos Fitosanitarios I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FOREWORD

This addendum has been prepared after the publication of the non-inclusion for 1,3-Dichloropropene[14] soil fumigant in Annex I of 91/414/EEC and taking into account the information provided by the notifier to address the critical areas of concern and outstanding data requirements regarding the identity of the active substance, as specified in the EFSA conclusion report[2] :

Critical areas of concern

- *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.*
-

List of studies to be generated, still ongoing or available but not peer reviewed

- *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*

[14] Commission Decision 2007/619/EC
[2] EFSA Scientific Report (2006) 72, 1-99

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).*

B.9. Ecotoxicology

Background: The active substance 1,3-dichloropropene (1,3-D) has been evaluated by the EFSA based on representative uses for control of soil nematodes prior to the planting of fruiting vegetable crops (e.g. tomatoes and peppers). For the evaluation of Annex I inclusion the representative uses of 1,3-D were

for indoor applications (defined as permanent structures) to bare soil via drip irrigation as Telone EC Drip (EF-1478), and outdoor applications to open fields by soil injection as Telone Injected (XRM-5048, also known as Telone II) and sealing by compaction.

The supported application rates are up to 283 kg 1,3-D/ha for indoor uses and up to 224 kg 1,3-D/ha for outdoor uses, with a maximum of one application per year. Typically the soil is treated with 1,3-D and then left for a minimum of 14 – 21 days before a fruiting vegetable crop (seedlings) is transplanted into the soil. For the indoor uses via drip irrigation, the EFSA concluded that there are no critical areas of concern for non-target species for the purposes of Annex I evaluation.

This document is primarily concerned with evaluating the risks to non-target organisms associated with soil injection of 1,3-D (XRM-5048) to open fields through the provision of new data and risk assessments.

The use of 1,3-D as a soil fumigant in all crops is limited to small areas of agricultural land within the EU (estimated to be less than 70,000 ha/year), while fruiting vegetables represent approximately one third of these uses and are concentrated in the south (Mediterranean countries). Approximately 60% of all uses in EU Member States are by injection to open fields, and the remainder by drip irrigation for indoor crops. The single application per year to a relatively small land area across the EU, of which a significant proportion is under cover, is important when considering the potential magnitude, duration and scale of any risks to non-target organisms from the high label use rates and intentional temporary soil sterilisation effects.

The areas requiring further information that were highlighted by EFSA with regard to ecotoxicology are summarised below:

- Data to address the risks to earthworm-eating and insectivorous birds and mammals for the outdoor uses. These data should include a long-term toxicity study with birds and a residue study on plants.
- The risk to mammals from inhalation of 1,3-D was considered to be low in the DAR based on the PEC_{air} values presented in the Fate and Behaviour section. If the PEC_{air} concentrations are estimated to be higher than those originally presented in the DAR then the inhalation risk to mammals would need to be reassessed.
- Provision of a risk assessment for aquatic organisms from the use as a direct soil injection method of application indoors and outdoors once the PEC in surface water become available. In addition, long term studies on fish and *Daphnia magna* with the metabolite (EZ)-3-chloroacrylic acid are required, and toxicity values for algae should be provided based on biomass.
- As the active substance can be found in the air even at distances of 800 m from the field, 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.
- Since the extended laboratory studies on soil arthropods (*Folsomia candida*, *Poecilus cupreus*, *Pardosa* spp. and *Aleochara bilineata*) were only evaluated for soil that had been aged for 1 day

prior to exposure, the immediate impact at application is not known. Furthermore, given the observed effects on *Folsomia candida* under laboratory test conditions, the risk to non-target arthropods for the outdoor uses should be addressed further.

- A high acute risk to earthworms was observed in the laboratory and so a study to address this risk for the outdoor uses is required.
- A high risk to soil micro-organisms was observed in the laboratory and so a field study to address this risk for the outdoor uses is required. This new field study should also cover the concern for the effects from the soil metabolites.
- 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 provided.
- It cannot be excluded that 1,3-D might be harmful if the waste water goes to sewage treatment plants.

EFSA proposed several data gaps during the Evaluation Meeting

The EFSA also requested further clarification of the content, nature and potential hazard of the impurities in the technical 1,3-D, as well as further information on their potential hazard to non-target organisms. The EFSA specifically requested that the ecotoxicological relevance of the impurity 1,2-dichloropropane be addressed, its levels confirmed in the ecotoxicological studies, and any implications to the ecotoxicology risk assessments be evaluated. Consideration of the nature and potential hazard of the impurities in technical 1,3-D, and their potential impact on the ecotoxicology assessments is relevant to all areas of the ecotoxicology dossier, and so is addressed in Section B 9.10. The EFSA also requested to submit pesticidal screening data for (*EZ*)-3-chloroacrylic acid.

B.9.1. Effects on birds

The EFSA Scientific Report (2006) highlighted the following critical areas of concern with regard to risk to birds from 1,3-D:

- A high acute risk to earthworm eating and insectivorous birds from 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.

Furthermore, the EPCO expert's meeting indicated that the residue data should be collected under conditions representative of Mediterranean conditions. Field studies have subsequently been conducted to measure residues of 1,3-D in plants (tomato), earthworms and insects under Mediterranean conditions, and these studies are summarised and evaluated in this document.

B.9.1.1. Acute oral toxicity

The EFSA Scientific Report (2006) lists the acute oral LD_{50} of 1,3-D for birds (*Colinus virginianus*) as 139.8 mg/kg bw for use in risk assessment. No additional acute oral LD_{50} studies have been submitted.

B.9.1.2. Short-term dietary toxicity

The EFSA Scientific Report (2006) lists the lowest short-term dietary LC_{50} of 1,3-D for birds (*Anas platyrhynchos*) as > 1264 mg/kg_{bw}/d (6243 mg a.s./kg_{food}), and the NOEC as 213.5 mg/kg_{bw}/d (1054 mg a.s./kg_{food}) for use in risk assessment. No additional short-term dietary LC_{50} studies have been submitted.

B.9.1.3. Subchronic toxicity and reproduction

Temple, D.L., Martin, K.H., Beavers, J.B. and Jaber, M. (2006).

Title: 1,3 Dichloropropene: A reproduction study with the northern bobwhite. Wildlife International Ltd Study 379-163. Dow AgroSciences Report 040491.

The test was conducted according to OECD 206 guidelines and under GLP. The study is considered acceptable.

The objective of the study was to evaluate the effects of dietary exposure to 1,3-D on northern bobwhite (*Colinus virginianus*) over a five month period. Additionally other study was also performed to evaluate the effects over a shorter period, approximately 7-weeks, occurring during three weeks pre-egg laying and during four weeks of egg production. The effects on reproduction were observed in the long-term study and in the shorter-term study.

Methods:

For ease of mixing of the test item with the diet, and to maintain stability of the test diet concentrations, 1,3-D was provided as microcapsules (Lot No M021805) containing 31.5% 1,3-D. All concentrations of the test substance in the diet were adjusted to 100% active ingredient, and all dietary exposure concentrations were expressed as ppm a.i. in the diet.

Northern bobwhite (160 males and 160 females; 35 weeks of age at test initiation) were randomly distributed into one negative control group, a micro-capsule control group and eight treatment groups. Each treatment and control group contained 16 pairs of birds with one male and one female per pen.

Four treatment groups were fed diets containing 25, 125, 250 or 400 ppm 1,3-D for approximately 20 weeks. Four additional treatment groups were fed diets also containing 25, 125, 250 or 400 ppm for approximately 7 weeks. The negative control group was fed diet comparable to the treatment groups but without the addition of the test substance or its micro-capsule carrier. The micro-capsule control group was fed diet containing the micro-capsule carrier at a level equivalent to that in the highest test concentration but without test substance.

Test diets were prepared by mixing the micro-capsules containing 1,3-D into a premix that was used for weekly preparation of the final diet. Both control diets, and each of the four treated diets, were prepared weekly throughout the test. The homogeneity and stability of the treated diets were determined at the start of the test. Concentrations of 1,3-D in the diet were determined during weeks 1, 4, 8, 12 and 20 of the test using gas chromatography equipped with an electron capture detector (GC-ECD).

Effects on adult health, weight gain and feed consumption were evaluated throughout the 20-week exposure period. For the seven week exposure groups, effects on feed consumption were evaluated during exposure and for the six weeks following the end of the exposure period. In addition, in both studies, the effects of adult exposure to 1,3-D on the number of eggs laid, normal development of eggs, embryo viability, percent hatchability, offspring survival, and egg shell thickness were evaluated.

Findings:

The concentration of the test item in the diet samples was homogeneous following preparation, and was stable (less than 20% loss) at ambient temperature over seven days. The mean (± standard deviation) measured concentrations of 1,3-D in the 25, 125, 250 and 400 ppm diets during the test were 22.8 ± 2.94, 112 ± 14.2, 214 ± 18.1 and 342 ± 22.9 ppm, which represented 91, 90, 86 and 86 % of nominal concentrations. No 1,3-D was detected in any of the control samples analysed.

There were no treatment-related mortalities, overt signs of toxicity or treatment-related effects upon body weight or feed consumption at any of the concentrations tested in either the 20-week or 7-week exposure studies (Table 9.1.3-1 through Table 9.1.3-4).

Table 9.1.3-1: Adult bobwhite quail body weights following dietary exposure to 1,3-D over a 20 week period.

Nominal concentration in the diet (ppm)		Mean body weight (g)						
		Week 0	Week 2	Week 4	Week 6	Week 8	Term	Total mean change
Control	M[a]	210	209	209	209	209	212	2
	F	205	205	204	205	209	251	46
Capsule	M	211	209	210	211	210	221	11
	F	211	208	209	209	212	249	38
25	M	211	209	208	208	210	222	10
	F	204	201	202	201	205	245	41
125	M	211	210	208	209	210	221	10
	F	205	203	202	203	207	245	40
250	M	207	207	207	206	207	216	8
	F	203	200	200	200	203	239	36
400	M	208	204	206	206	208	216	12
	F	202	201	202	201	205	248	46

[a] M: Males, F: Females.

Table 9.1.3-2: Adult bobwhite quail body weights following dietary exposure to 1,3-D over a 7 week period.

Nominal concentration in the diet (ppm)		Mean body weight (g)						
		Week 0	Week 2	Week 4	Week 6	Week 8	Term	Total mean change
Control	M[a]	210	209	209	209	209	212	2
	F	205	205	204	205	209	251	46
Capsule	M	211	209	210	211	210	221	11
	F	211	208	209	209	212	249	38
25	M	207	--[b]	--[b]	207	208	215	9
	F	208	--[b]	--[b]	207	207	246	38
125	M	209	--[b]	--[b]	211	211	221	11
	F	208	--[a]	--[b]	207	208	234	25
250	M	209	--[a]	--[b]	208	208	216	7
	F	204	--[b]	--[b]	203	204	242	38
400	M	206	--[b]	--[b]	205	206	211	5
	F	208	--[b]	--[b]	207	206	240	32

[a] M: Males, F: Females.
[b] Birds fed control diet during first 8 weeks and so weights not recorded at week 2 and 4.

Table 9.1.3-3: Adult bobwhite quail food consumption following dietary exposure to 1,3-D over a 20 week period.

Week	Food consumption (g/bird/day)					
	Control	**Capsule**	**25 ppm**	**125 ppm**	**250 ppm**	**400 ppm**
1	12	13	12	14	12	12
2	13	14	13	15	15	14
3	13	14	13	14	14	14
4	12	14	13	14	13	14
5	13	14	14	15	14	14
6	11	13	12	14	12	13
7	12	14	13	15	14	14
8	15	16	16	17	16	17
9	15	16	17	17	16	17
10	17	18	17	18	18	18
11	17	18	18	18	18	19
12	18	21	20	21	20	21
13	20	22	21	21	20	22
14	20	22	22	22	21	22
15	21	22	22	22	21	21
16	22	23	23	23	22	23
17	22	23	23	24	23	23
18	23	25	25	24	24	25
19	23	25	24	25	24	24
20	24	25	25	26	25	25
Mean	17	19	18	19	18	19

Table 9.1.3-4: Adult bobwhite quail food consumption following dietary exposure to 1,3-D over a 7 week period.

Week	Food consumption (g/bird/day)					
	Control	Capsule	25 ppm	125 ppm	250 ppm	400 ppm
1	12	13	--[a]	--[a]	--[a]	--[a]
2	13	14	--[a]	--[a]	--[a]	--[a]
3	13	14	--[a]	--[a]	--[a]	--[a]
4	12	14	--[a]	--[a]	--[a]	--[a]
5	13	14	--[a]	--[a]	--[a]	--[a]
6	11	13	--[a]	--[a]	--[a]	--[a]
7	12	14	--[a]	--[a]	--[a]	--[a]
8	15	16	19	20	19	20
9	15	16	15	15	15	17
10	17	18	16	18	17	18
11	17	18	17	19	18	18
12	18	21	20	21	20	20
13	20	22	20	22	21	21
14	20	22	21	21	21	20
15	21	22	22	23	21	22
16	22	23	22	23	21	22
17	22	23	23	23	23	24
18	23	25	25	26	25	25
19	23	25	24	25	23	23
20	24	25	25	25	24	24
Mean	17	19	18	19	19	19

--[a] Birds fed control diet during first 8 weeks and so food consumption not recorded during weeks 1-7.

There were no treatment-related effects upon any of the reproductive parameters measured in either the 20-week or 7-week exposure 25, 125, 250 or 400 ppm treatment groups (Table 9.1.3-5 and Table 9.1.3-6).

The no-observed-effect concentration for northern bobwhite exposed to 1,3-D in the diet for either seven or twenty weeks during the study was therefore 400 ppm, the highest concentration tested.

Table 9.1.3-5: Reproduction and offspring growth parameters of bobwhite quail following dietary exposure of adults to 1,3-D over a 20-week exposure.

Parameter	Reproduction Endpoints					
	Control	Capsule	25 ppm	125 ppm	250 ppm	400 ppm
No. Replicates	16	15	16	15	16	16
Eggs laid (Total)	826	763	829	733	761	877
Eggs cracked	21	23	11	17	25	17
Eggs set	729	665	734	641	655	778
Viable embryos	681	630	639	607	577	686
Live 3 week embryos	674	625	638	607	575	685
Hatchlings	652	608	621	588	548	662
14-d survivors	619	578	604	564	529	635
Eggs laid/hen	52	51	52	49	48	55
Eggs laid/hen/day	0.56	0.55	0.56	0.53	0.51	0.59
14-d survivors/hen	39	39	38	38	33	40
Mean egg shell thickness (mm)	0.221	0.220	0.223	0.222	0.218	0.228
Hatchling body weight (g)	6.3	6.3	6.2	6.6	6.2	6.3
14-d survivor body weight (g)	31	30	30	31	29	29

Table 9.1.3-6: Reproduction and offspring growth parameters of bobwhite quail following dietary exposure of adults to 1,3-D over a 7-week exposure.

Parameter	Reproduction Endpoints					
	Control	Capsule	25 ppm	125 ppm	250 ppm	400 ppm
No. Replicates	16	15	16	15	16	16
Eggs laid (Total)	826	763	716	756	745	708
Eggs cracked	21	23	36	18	15	42
Eggs set	729	665	606	658	652	586
Viable embryos	681	630	552	616	615	555
Live 3 week embryos	674	625	551	613	611	553
Hatchlings	652	608	532	592	574	536
14-d survivors	619	578	515	568	555	515
Eggs laid/hen	52	51	45	50	47	44
Eggs laid/hen/day	0.56	0.55	0.48	0.54	0.50	0.48
14-d survivors/hen	39	39	32	38	35	32
Mean egg shell thickness (mm)	0.221	0.220	0.215	0.221	0.217	0.228
Hatchling body weight (g)	6.3	6.3	6.2	6.2	6.2	6.4
14-d survivor body weight (g)	31	30	30	29	30	30

Based on the concentration of 1,3-D in the diet, adult body weights, and the amount of food consumed, the daily dietary doses for the 25, 125, 250 and 400 ppm treatment groups during the 20-week exposure were calculated to be 2, 11, 22 and 36 mg/kg bw/day (Table 9.1.3-7). For the 7-week exposure, the calculated daily dietary doses for the 25, 125, 250 and 400 ppm treatment groups during the exposure phase were also 2, 11, 22 and 36 mg/kg bw/day (Table 9.1.3-8).

Table 9.1.3-7. Estimated Maximum Mean Daily Dietary Dose of 1,3-D (mg/kg bw/day) during 20-week exposure.

Nominal Test Concentration (ppm)	*Mean Body Weight (g)*	*Mean Food Consumption (g/bird/day)*	*Estimated Daily Dietary Dose (mg/kg bw/day)*
0	***211***	***17***	***0***
Capsule	***214***	***19***	***0***
25	***211***	***18***	***2***
125	***211***	***19***	***11***
250	***208***	***18***	***22***
400	***209***	***19***	***36***

Table 9.1.3-8. Estimated Maximum Mean Daily Dietary Dose of 1,3-D (mg/kg bw/day) during 7-week exposure.

Nominal Test Concentration (ppm)	*Mean Body Weight (g)*	*Mean Food Consumption (g/bird/day)*	*Estimated Daily Dietary Dose (mg/kg bw/day)*
0	***211***	***17***	***0***
Capsule	***214***	***19***	***0***
25	***213***	***18***	***2***
125	***214***	***19***	***11***
250	***212***	***19***	***22***
400	***211***	***19***	***36***

Therefore, based on these data the NOEC is summarised in Table 9.1.3-9.

Table 9.1.3-9. Results.

Result	**1,3-D (nominal ppm)**	**1,3-D (nominal mg/kg bw/day)**
NOEC	400	36
LOEC	> 400	> 36

In summary: The NOEC for bobwhite quail exposed to 1,3-D in the diet for seven or twenty weeks was 400 ppm, the highest concentration tested. Taking into account mean food consumption and adult body weight, the daily dietary dose for birds fed diet containing 400 ppm 1,3-D was 36 mg/kg bw/day.

B.9.1.4. Risk assessment for birds

The EFSA Scientific Report (2006) concluded that the indoor use of 1,3-D in glasshouses 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. This will therefore not be considered further.

The risk assessment presented below is based only on the realistic worst-case scenario of a single application of 224 kg as/ha, by injection outdoors to bare soil, for pre-planting control of nematodes prior to introduction of a fruiting vegetable crop at least 14 days after soil treatment. This is the maximum rate for all use patterns, so a separate risk assessment for lesser rates is not necessary. The EFSA Scientific Report (2006) concluded that exposure of birds via contaminated drinking water is not expected due to the method of application via soil injection, and the risk to fish eating birds will be low because the log P_{ow} of 1,3-D is below 3. Therefore, these exposure routes have not been considered further.

Toxicity endpoints

The acute oral LD_{50} value of 1,3-D for birds was determined to be **139.8 mg/kg body weight** in bobwhite quail, *Colinus virginianus* (**EFSA Scientific Report, 2006**).

The lowest short-term dietary LDD_{50} value of 1,3-D for birds was determined to be **>1264 mg/kg$_{bw}$/d** for the mallard duck, *Anas platyrhynchos* (**EFSA Scientific Report, 2006**).

The long-term dietary NOEL value of 1,3-D for birds was determined to be at least **36 mg/kg$_{bw}$/d** for the bobwhite quail in a study summarised above (**Temple *et al*, 2006**).

Species at risk

The EFSA Scientific Report (2006) identified that the risk posed by 1,3-D to birds should be assessed for an herbivorous, insectivorous and earthworm eating bird for outdoor uses.

Exposure assessment

The application of 1,3-D differs significantly from most other plant protection products with the material being injected into the soil profile, typically at a depth of 20-30cm, followed by capping to help seal the soil to maximise efficacy and minimise volatile losses. Typically, the soil is then harrowed to "open" the soil before the crop is planted, with a minimum interval between soil treatment and crop planting of 14 days. This interval between treatment and crop planting is necessary because 1,3-D may be phytotoxic to some crop seedlings at the high initial soil concentrations achieved immediately following injection. Consequently, estimation of the residue of 1,3-D in plants and invertebrates based on modelled soil concentrations does not accurately predict realistic residue levels under field conditions. For the purposes of a dietary risk assessment, residues in plants and invertebrates collected under field conditions are therefore most relevant since field residues incorporate the various environmental, chemical and biological factors which affect residue uptake, including depth- and time-dependent soil concentrations.

a) Residue in vegetation

A study has been conducted to determine residue levels of 1,3-D in tomato seedlings following soil injection in accordance with good agricultural practice and is summarised below. Based on these field residue data, the **residues of 1,3-D in plants were found to be less than the limit of detection, 0.002 mg/kg**. Therefore, in the refined risk assessment for herbivorous birds, the risk has been assessed based on the field-measured residue of less than 0.002 mg 1,3-D/kg in crop plants following application of Telone by injection at a target rate of 224 kg a.s./ha to bare soil, and minimum pre-planting interval of 14 days.

Rawle, 2005. Residues of 1,3-D in plants (tomato seedlings)

Title: Residues of 1,3-dichloropropene in transplanted tomato plants at intervals following a single application of Telone II (XRM-5048), Italy – 2005. Dow Agrosciences Report GH-P-11176. Not specific guidelines were followed however the study was conducted under GLP. The study is considered acceptable.

Four trials were conducted in Italy (EU Southern Zone), in the Emilia Romagna and Puglia regions. A single application of Telone II (XRM-5048, batch no. SL 212920T1, soil fumigant containing approximately 97% 1, 3-D) was made by shank injection at 20cm depth during May 2005, at a nominal application rate of 224 kg 1,3-D/ha, equivalent to 190 L Telone II/ha.

The soils were classified as sand (Trial CEMS-2710A: 86% sand, 10% silt, 4% clay, 0.9% organic matter, pH 7.5; Trial CEMS-2710B: 84.4% sand, 7.9% silt, 7.7% clay, 1.1% organic matter, pH 7.87), silty clay (Trial CEMS-2710C: 9% sand, 42% silt, 49% clay, 2.4% organic matter, pH 8.3) and clay loam (Trial CEMS-2710D: 38% sand, 33% silt, 29% clay, 2.03% organic matter, pH 8.36). On the days of application, soil temperature ranged between 19 and 22^{o}C and air temperature ranged between 22 - 31^{o}C at the four sites.

Tomato plants were transplanted into the soil 14 days after treatment, and then whole plants excluding roots sampled 0, 1, 3, 7, 10, 14 and 21 days after transplanting (i.e. 14, 15, 17, 21, 24, 28 and 35 days after the soils were treated). The plants were at growth stage BBCH 11-12 during the initial sampling dates (0-1 days after transplanting) and at BBCH 61-62 by the final sampling date (21 days after transplanting).

All samples were placed in freezers within 6 hours of sampling and transported frozen to CEMAS. Samples were stored frozen at less than -18^{o}C prior to analysis. Residues of 1,3-D (total cis + trans) in transplanted tomato plants were measured with a limit of quantification of 0.01 mg/kg (0.005 mg/kg each of cis and trans) and limit of detection of 0.002 mg/kg.

The analytical method yielded recoveries of cis 1,3-D in the range 76 – 92 % (mean 86%), and recoveries of trans 1,3-D in the range 77 – 97 % (mean 86%). The detector response was shown to be linear for both analytes over the range 0.5 – 100 ng/mL. Residues of 1,3-D were not detected in untreated samples or any plants taken from the treated soil sites on any sampling occasion (the limit of detection, LOD, was 0.002 mg/kg).

In summary: Residues of 1,3-D were below the level of detection in tomato plants transplanted into soils previously treated with Telone II taken and sampled between 1 and 21 days following transplanting (i.e. 14 – 35 days after soil treatment). Since the limit of detection, LOD, was 0.002 mg/kg, it can be concluded that residues of 1,3-D were below 0.002 mg/kg.

b) Residue in invertebrates

Background: In the DAR, potential exposure of earthworm (and insect) eating birds to 1,3-D was calculated from the PEC_{soil} and an estimated earthworm bioconcentration factor (despite the fact that the log P_{ow} of 1,3-D is below 3). Based on the Tier I risk assessment the acute risk to earthworm and insect eating birds was considered high, while the short term risk was assessed to be low. To refine the acute risk assessment a residue study on earthworms conducted in N. EU during autumn application of Telone II was submitted to the RMS and evaluated, but the EPCO expert's meeting considered that this study could not be used to refine the risk assessment, in part because it was considered not representative for the supported GAP (spring/summer applications under Mediterranean conditions). In addition, EFSA did not agree that measured residue levels of 1,3-D in earthworms could be extrapolated to residues in insects to address the risks to insect eating birds. Therefore, a further field study has been conducted, in which residue levels of 1,3-D in arthropods and earthworms were determined following use of 1,3-D at 224 kg a.s./ha under Mediterranean conditions.

Small, 2007. Residues of 1,3-D in insects and earthworms

Title: Determination of residues of 1,3-dichloropropene in arthropod communities and earthworms following Telone II soil injection in Italy. I2L unpublished report No. 06/11.

The study was conducted following any specific guideline, but under GLP. The study is considered acceptable.

Four field trial sites in Italy, in the region of Emilia Romagna in an area east of Ferrara and south of the delta of the river Po, were selected from among a number of possible sites for this study. A summary of the trial areas used in this study to determine residues of 1,3-dichloropropene (1,3-D) in arthropod communities and earthworms is summarised below.

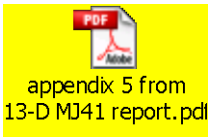
Telone II is commonly used in this area to control nematode pests of fruiting vegetable crops. The sites were selected on the basis of soil types typical for Telone II use and on the presence of small mammals, earthworms and surface active macroarthropods (beetles, spiders, etc.).

Application method: Telone II fumigant (Lot No. TF222920T1) was injected into the soil (15-20 cm) of the four selected trial plots using a dispensing machine (trademark OLIVER – John Blue Co. Huntsville, ALA. US) hauled by a tractor at a rate of 190 L/ha (i.e. 224 kg a.s./ha), according to the GAPs.

Site Nº	Farm	Site Location		Trial Area [ha]
		Lattitude	Longitude	
4	Antonietta Farm	44º 49' 12'' N	12º 10' 17'' E	2.65
7	Andrea Farm	44º 49' 12'' N	12º 09' 55'' E	2.78
8	Andrella Farm	44º 46' 55'' N	12º 08' 37'' E	2.55
9	Rizzati Farm	44º 44' 01'' N	12º 11' 00'' E	3.23

On seven occasions the invertebrate fauna (earthworms, macroarthropods, microarthropods) were sampled on the trial sites for the purpose of residue determination. Residues on earthworms and arthropods were analysed with a gas chromatograph fitted with a micro electron capture detector. Analysis of the arthropod and earthworm samples was performed on the trans-1,3-D isomer only as the quality of the chromatography for the cis-isomer was not acceptable at the level of sensitivity required. The method validation at fortification levels of 0.05 and 0.4 mg/kg resulted in mean recovery of trans-1,3-D in arthropods and earthworms of 98% (CV = 5.6%) and 96% (CV = 10.5%) respectively. Procedural recoveries during the field sample analyses ranged between 87 and 116%.

Field samples were taken up to 2 weeks before application; 0 days after application (immediately after treatment application); 3, 5, 7, 14 and 21 days after application. Earthworms were sampled from the top 10 cm of soil in a 1 m² quadrat by digging the soil. At least 10 replicate samples of earthworms were taken from each field site. Where earthworms were few in numbers, further sampling effort was made by increasing the number of replicate samples. A total of 25 pitfall traps were set at each field site to collect arthropods on each sampling occasion. Traps were arranged in 5 clusters of 5 traps across each field site. Where possible, clusters were 25 m apart. Within each cluster there was a gap of approximately 5 m between each trap. All samples of earthworms and arthropods were sorted, counted and weighed. Dead arthropods and earthworms were also collected, counted and weighed. See attached Appendix 5 where number of dead/alive earthworms and arthropods were recorded in site 4, 7, 8 and 9.



All samples were frozen and shipped on dry ice to CEMAS for analysis of 1,3-D residues.

One sample of soil was taken from each of the field study sites and their characteristics determined at the laboratories of Laboratorio Analisi Roberta Ghedini, Via Zenzalino, n 205/A - Ospital Monacale, 44011 Argenta (FE), Italy. Characteristics determined were: soil type (% sand, % silt, % clay); soil texture; pH; % organic matter (OM); and cation exchange capacity (CEC).

Maximum and minimum air temperatures and rainfall measurements were obtained from the Regional Meteorological Service at Ostellato (FE), Italy (Latitude: 44° 42', Longitude: 11° 53'). Maximum and minimum soil temperatures were obtained from a HOBO outdoor data logger buried at a depth of 20 cm on Felice Barboni Farm (LATITUDE 44° 44,0912' N, LONGITUDE 12° 9,4134' E) close to the 4 field study sites. All agricultural operations were recorded.

Invertebrate fauna (earthworms, macroarthropods, microarthropods) were sampled from agricultural fields where Telone II had been applied for the purpose of residue determination. No earthworms were found at site 9 at any of the sampling intervals.

The weight of earthworms and arthropods analysed, and the residue analysis results are presented below.

Site	Time (Days)	Earthworms		Arthropods	
		Weight of Sample Analysed / g	1,3-D[1] (mg/kg)	Weight of Sample Analysed / g	1,3-D[1] (mg/kg)
4	Pre	0	-	1.389	<LOQ
	0	2.025	<LOQ	0.267	<LOQ
	3	0.734	<LOQ	0.151	<LOQ
	5	1.803	0.40	0.302	<LOQ
	7	0.612	0.40	0.105	<LOQ
	14	1.492	<LOQ	0.450	<LOQ
	21	2.010	<LOQ	2.000	<LOQ
7	Pre	2.000	<LOQ	1.950	<LOQ
	0	2.010	0.14	2.000	<LOQ
	3	2.008	<LOQ	0.501	<LOQ
	5	2.020	0.10	0.941	<LOQ
	7	2.001	<LOQ	0.395	<LOQ
	14	2.022	<LOQ	0.769	<LOQ
	21	2.038	<LOQ	1.840	<LOQ
8	Pre	2.060	<LOQ	1.08	<LOQ
	0	2.020	0.30	0.95	<LOQ
	3	2.023	<LOQ	0.79	<LOQ
	5	2.055	0.32	1.71	1.52
	7	2.021	<LOQ	0.40	<LOQ
	14	2.046	<LOQ	0.31	<LOQ
	21	2.038	<LOQ	1.76	<LOQ
9	Pre	0	-	1.505	<LOQ
	0	0	-	2.030	<LOQ

3	0	-	0.159	<LOQ
5	0	-	0.137	<LOQ
7	0	-	2.035	<LOQ
14	0	-	0.485	<LOQ
21	0	-	0.331	<LOQ

[1] Residues were determined for trans-1,3-D as the quality of the chromatography for the cis isomer was unacceptable at the level of sensitivity required. Since technical 1,3-D consists of 50% trans-1,3-D and 50% cis-1,3-D, the total 1,3-D residue was calculated by multiplying the trans-1,3-D residue by 2.

LOQ: The Limit of Quantitation (LOQ) varied depending upon the available sample weight, and ranged between 0.10 and 2.0 mg 1,3-D/kg for arthropods, and between 0.10 and 0.34 mg 1,3-D/kg for earthworms.

Quantifiable amounts of 1,3-D residues were only detected in earthworms sampled from Site 4 after 5 and 7 days post-treatment, and from Sites 7 and 8 immediately after treatment and 5 days post-treatment. Earthworm biomass was generally low at all sites for most sampling intervals (range from 0 5.89 g/m^2 prior to application).

A quantifiable amount of 1,3-D residues was only detected in one of the pooled samples of arthropods, that was collected from Site 8 after 5 days post-treatment (1.52 mg 1,3-D/kg wet weight of arthropods). This was also the highest 1,3-D residue found in any of the invertebrate samples during the study.

It was noted during sampling that most earthworms extracted during soil sampling were found towards the bottom of the 10 cm sampling depth. This is likely due to the sandy nature of the soils at the field sites selected for this study, and which are typical for Telone II use in the region of Emilia Romagna, which drain freely and tend to dry quickly near the surface after rainfall. At this depth, earthworms may not come into contact with the highest concentrations of Telone II and may also be driven deeper into the soil upon treatment. The method used for sampling arthropods trapped only those which were surface active as these are the potential prey items for small mammals and birds since the surface was sealed by a heavy roller to keep the Telone II fumigant in the soil until shortly before crop planting at 14 days post-treatment. Therefore, soil active arthropods were unlikely to have come into contact with high concentrations of Telone II.

Residues of 1,3-D, not exceeding 1.52 mg/kg, were measured in samples of earthworms and arthropods taken from field sites during the first week following a typical application of Telone II by sub-surface soil injection at 190 L/ha (i.e. 224 kg a.s./ha). In particular, the highest residues were 0.40 mg/kg in earthworm samples and 1.52 mg/kg in arthropod samples. No residues were detected in samples of earthworms and arthropods taken two or three weeks post treatment.

In summary, the study showed that residues were generally below the limit of quantification on most occasions, even immediately after soil injection. The maximum measured residue levels on any sampling occasion were 1.52 mg/kg for insects and 0.40 mg/kg for earthworms**.** The residue patterns in earthworms and arthropods indicate that no residues were found after two o three weeks. This residue decline pattern is in agreement with previous residue studies on earthworms conducted in N. European conditions (Philips, D., 2005; see Addendum II B9, April 2005)**.** Thus**,** in the field study conducted on

N. Europe, residue in earthworms sampled from soil surface and 10 cm below soil surface following Telone injection decline from 5.65 to 1.13 mg/kg (day 0 to day 20); maximum residues levels where reached at day 3, 20.4 mg/kg (see Table 9.1.4-1). In contrast, low level residues of 1,3-D on earthworms was observed in field study conducted in South Europe (Italy) (see Table above, maximum levels 0.4 mg/kg). These differences could be explained because of earthworm biomass in the two studies. Thus, in field sites from Italy pre-treated with Telone earthworms biomass are in very low. Abundance on sites sampled was between 0 and 27 earthworms/m^2 (0 – 23.1 g earthworm fresh weight/m^2), though the majority of samples were less than 5 earthworms/m^2 (less than 5 g earthworm fresh weight/m^2). Two days before treatment in South Europe earthworms biomass range from 0 to 5.89 g/m^2 (Small, 2007). However, in field sites from UK the earthworm biomass 2 days before application was 39.8 g/m^2 (Philips, 2005), seven times more.

Table 9.1.4-1: Residues of 1,3-D in earthworms collected from the soil surface and sub-surface layers following application of Telone II (AR = 215 kg a.s./ha**,** Philips, 2005, Addendum II). Study conducted in UK, autumm

Time (DAT)	**Total biomass g/m^2**	Residues in earthworms (mg/kg fresh weight)	
		on soil surface Mean (Min – Max)	in sub-surface **Mean (Min – Max)**
0	39.8 (2 d prior test)	< LOD	< LOD
1	-	1.36 (0.66 – 2.22)	4.29 (1.02 – 12.60)
3	-	0.95 (0.79 – 1.39)	20.42 (10.77 – 46.41)
7	-	0.28 (<0.12 – 0.35)	9.17 (2.85 – 22.55)
10	4.3	0.40 (<0.12 – 0.67)	4.57 (2.74 – 8.09)
14	-	0.79 (0.28 – 2.08)	0.98 (0.73 – 1.28)
20	0	0.47 (<0.12 – 0.79)	0.66 (0.31 – 1.19)

LOD = 0.12 mg 1,3-D/kg wet weight earthworm.
LOQ= 0.4 mg/kg wet weight

Therefore, basis on low level of residues detected and in order to be conservative, for the refined risk assessment of insectivorous and earthworm eating birds, the risk has been assessed based on the maximum measured field residues following application of Telone by injection at 224 kg a.s./ha in Mediterranean field conditions. Thus, maximum measured residue levels of 1.52 mg/kg for insects and 0.40 mg/kg for earthworms.

RMS assessment: Residues of 1,3-D present in arthropod communities and earthworms following field application of Telone II by sub-surface soil injection at 224 kg as/ha has been measured in four field agriculture sites in Italy, in the region of Emilia Romagna in an area east of Ferrara and south of the delta of the river Po. Samples were taken two weeks before application, and at 0, 3, 7, 14 and 21 days post-application. Suitable field sites were selected based on agriculture sandy soils typically for Telone II use, the presence of mammals, enough earthworms and surface active macro arthropods.

For earthworms, the first 10 cm of soil layer was sampled, and the rationale for sampling to this depth is that earthworms will only be accessible to small mammals near to the soil surface. The number of earthworms was very low in some of the sites (pre-treatment earthworm biomass range from 0 to 5.89 g/m^2), and in one of the field sites (nº 9) no earthworms were found at any sampling point. Where

earthworms biomass was too low to provide sufficient material for residue analysis, additional sampling effort was made by increasing the number of samples (up to 17 samples were taken). Where no earthworms were found in any of the initial 10 replicate soil samples, excavation of soil samples was continued up to a maximum of 1 h. If no earthworms were found during this sampling period, the sampling was ceased. Prior to residue analysis, all samples for a specific field and time-point were combined to provide sufficient material for analysis.

Thus, earthworm abundance per se was not determined as would be in an "effects" study, although it was evident at one site that earthworm abundance within the sampled soil was zero before and after Telone application. At the other sites, abundance was between 0 and 27 earthworms/m^2 (0 – 23.1 g earthworm fresh weight/m^2), though the majority of samples were less than 5 earthworms/m^2 (less than 5 g earthworm fresh weight/m^2)

For arthropods (spiders, beetles and other arthropods), the first 10 cm of soil layer was sampled, and the rationale for sampling to this depth is that arthropods should be accessible to small mammals near to the soil surface from the soil surface were sampled.

Some shortcomings of the study are as follow: a) residues levels were only measured for trans 1,3-D because quality of the chromatography for the cis-isomer. To account for all 1,3-D residues (since technical 1,3-D consists of 50% trans-1,3-D and 50% cis-1,3-D), the total 1,3-D residue was calculated by multiplying the trans-1,3-D residue by 2. b) The limit of quantitation (LOQ) varied depending upon the available sample weight, and ranged between 0.10 and 2.0 mg 1,3-D/kg for arthropods, and between 0.10 and 0.34 mg 1,3-D/kg for earthworms. c) the abundance of earthworms was very low in some of the sites sampled. d) Concentrations of the compound in the soil are not measured, so it is not clear the actual exposure in the study.

Tho deal with the shortcomings point out by RMS the following argumentation was provided by the notifier:

*Residues levels were only measured for trans 1,3-D: The log Kow for both the cis and trans isomers of 1,3-D are low (trans: 2.10, cis: 1.82), indicating that both have similarly low potential for bioaccumulation, with trans representing the worst-case based on measured log Kow. Furthermore, both the cis and trans isomers of 1,3-D have similar stability in soil and water (e.g. hydrolysis half-life, soil degradation) such that the magnitude and duration of exposure of earthworms to the cis and trans isomers would not have differed to any significant extent. Indeed, under Florida field conditions, following application of Telone II the levels and rate of decline of the cis and trans isomers of 1,3-D were found to be similar, with levels of trans generally being slightly higher than cis (see Table IV of study **MK09**) indicating that under field conditions the initial levels and decline of the two isomers is very similar as would be expected based on their similar physical-chemical properties. Therefore, since cis and trans are present in equal amounts in 1,3-D products, both have similar (low) bioaccumulation potential, and both have similar (low) persistence in soil, there is no reason to believe that the residues of the cis isomer in earthworms would have differed significantly from the residues of the trans isomer. Therefore, due to the practical constraints (poor quality of the chromatography for the cis-isomer) DAS believe the approach of assuming that the residue levels of cis and trans would be equivalent is adequate.*

The limit of quantitation (LOQ) varied depending upon the available sample weight, and ranged between 0.10 and 2.0 mg 1,3-D/kg for arthropods, and between 0.10 and 0.34 mg 1,3-D/kg for earthworms: DAS propose that this is taken into account by using the maximum measured residue or the LOQ, whichever is the greatest. For the submitted risk assessment DAS used a worst-case residue level of 1.52 mg/kg for arthropods and 0.40 mg/kg for earthworms. DAS propose that this is amended by using 2.0 mg/kg (LOQ) for arthropods and 0.40 mg/kg for earthworms. This will have no significant impact on the resulting TER values (all TER_A and TER_{LT} values for birds and mammals exceed Annex VI triggers if the maximum measured residue or the maximum LOQ is used).

DAS would like to point out that this approach is highly conservative since the LOQ for earthworms was <0.1 mg 1,3-D/kg on 2 sites on every sampling occasion, and was only 0.34 mg/kg on one occasion on one site (7-DAA). The LOQ for arthropods was <0.5 mg 1,3-D/kg on 1 site on every sampling occasion; <0.7 mg 1,3-D/kg on 1 sites on every sampling occasion; and <1.5 mg 1,3-D/kg on 1 site on every sampling occasion. Therefore, using a value of <2.0 mg/kg (from a single time point on a single field) for insectivorous bird and mammal risk assessments is highly conservative based on the available data.

Abundance of earthworms was very low in some of the sites sampled: This has limited relevance to the findings in the study. The field sites were chosen primarily as "typical" agricultural fields in S EU which may be treated with a fumigant prior to planting of fruiting vegetable crops. The purpose of the study was to determine residue levels, and so the only earthworm abundance criterion for field selection was whether sufficient earthworms could be collected for residue determination. Where earthworms biomass was too low to provide sufficient material for residue analysis, additional sampling effort was made by increasing the number of samples up to a maximum of 1 h (up to 17 samples were taken). If no earthworms were found during this sampling period, the sampling was ceased. Thus, earthworm abundance per se was not determined, and was not a critical criterion for site selection, as this was less relevant to the purpose of the study than the representativeness of the field and climate scenario.

Concentrations of the compound in the soil are not measured: The purpose of this study was to estimate the magnitude of 1,3-D residues on insects and earthworms under field conditions; the sites were replicated (4 sites) to account for between site variability/uncertainty. The only meaningful purpose of measuring soil concentrations on the sites would be to confirm that application of 1,3-D to the soil was carried out correctly. However, this was not considered necessary since the study was conducted to GLP, and all aspects of the application were checked and documented in the final report (batch of material used, preparation and calibration of application equipment, application volumes used, etc). Sampling of the soil to measure 1,3-D would have been extremely difficult due to the nature of the application (injection and capping of soil surface) and the equipment required to sample 1,3-D accurately from the soil (to minimize potential volatile losses – e.g. see non-conventional soil sampling methods used for field dissipation and leaching study). The difficulty associated with accurately measuring 1,3-D soil concentrations were considered disproportionally high compared to the limited value the data would provide to satisfying the study objective.

RMS opinion is that the study should be considered acceptable for risk assessment. Maximum residues levels were 1.52 mg/kg for arthropods and 0.40 mg/kg for earthworms during the first week post-treatment, and not further residues were detected in samples of earthworms and arthropods taken two or three weeks post treatment.

Conclusion: The AR applied in the study covers the intended outdoors use of Telone II and the method of application in the study is the same from the application in practice. The study is considered acceptable for risk assessment, and considered as a realistic study representative of agriculture sites of the South of Europe where Telone is applied. For risk assessment refinement the maximum residue level of 1.52 mg/kg for arthropods and 0.40 mg/kg for earthworms will be used for calculations.

Refined risk assessment on birds

The acute, short-term and long-term risk assessments have been conducted in accordance with the Guidance Document on Risk Assessment for Birds and Mammals (SANCO/4145/2000) by comparing the lowest toxicity endpoints with the maximum measured residue levels of 1,3-D in plants and invertebrates, and have not taken into account any decline in residues for the long-term assessment.

Exposure: The application technique for 1,3-D differs significantly from most other pesticide products with the material being injected into the soil profile, typically at a depth of 25 - 35 cm, followed by capping to help seal the soil to maximise efficacy, and minimise volatility losses, of 1,3-D.

Consequently, determination of an environmentally relevant bioconcentration factor (BCF) for 1,3-D in soil organisms using models generated for non-volatile chemicals will not adequately simulate realistic residue levels (magnitude or duration) likely to occur in soil organisms. For the purposes of a dietary risk assessment, residues in earthworms collected under field conditions are therefore more relevant than estimates based on artificially determined BCF values. Furthermore, the logPow of 1,3-D is lower that 3, therefore the potential for bioaccumulation is expected to be low.

Also, it has been assumed that a bird will feed exclusively within the treated field, and only on food items containing the maximum residue of 1,3-D.

Table 9.1.4-2. Acute, short-term and reproduction TER values for birds.

Diet	Exposure	Measured residue level (mg/kg diet)	FIR/bw	ETE (mg/kg $_{bw}$/day)	Toxicity (mg/kg $_{bw}$/day)	TER
Plants	Acute	< 0.002	0.76	<0.00152	139.8	> 91000
	Short-term	< 0.002	0.76	<0.00152	> 1264	> 830000
	Reproduction	< 0.002	0.76	<0.00152	36	> 23000
Insects	Acute	1.52	1.04	1.58	139.8	88
	Short-term	1.52	1.04	1.58	> 1264	>790
	Reproduction	1.52	1.04	1.58	36	23
Earthworms	Acute	0.40	1.1	0.44	139.8	320
	Short-term	0.40	1.1	0.44	> 1264	> 2800
	Reproduction	0.40	1.1	0.44	36	82

In summary, based on measured residues of 1,3-D determined under field conditions according to the outdoor intended use of Telone II, the acute, short-term and reproduction risk to herbivorous,

insectivorous and earthworm-eating birds was determined to be acceptable (TER_A, TERst > 10 and TERlt > 5). Low risk is expected if Telone II is applied according to the GAPs.

B.9.2. Effects on aquatic organisms.

The EFSA Scientific Report (2006) highlighted the following critical areas of concern with regard risk to aquatic organisms from 1,3-D:

- 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.

Furthermore, the EFSA also required that the following additional data be provided:

- long term studies on fish and *Daphnia magna* with the metabolite (EZ)-3-chloroacrylic acid
- toxicity values for algae based on biomass.

B.9.2.1. Acute toxicity to fish.

Active substance

The EFSA Scientific Report (2006) lists two toxicity endpoints for acute toxicity to fish from the active substance for use in risk assessment; a 96 hour LC_{50} of 0.87 mg 1,3-D/L for sheepshead minnow and a 96 hour LC_{50} of 2.78 mg 1,3-D/L for rainbow trout. No additional acute toxicity studies have been submitted for 1,3-D.

Effect of metabolites in fish

The EFSA Scientific Report (2006) lists toxicity endpoints for acute toxicity to fish for the metabolites 3-chloroallyl alcohol (3-CAA) and 3-chloroacrylic acid (3-CACA) for use in risk assessment. The **96 hour LC_{50} for rainbow trout exposed to 3-CAA is 0.986 mg 3-CAA /L**, and the **96 hour LC_{50} for rainbow trout exposed to 3-CACA is 69.5 mg 3-CACA /L**. No additional acute toxicity studies with the metabolites have been submitted.

B.9.2.2. Chronic toxicity to fish.

B.9.2.2.1. Chronic toxicity test on juvenile fish.
B.9.2.2.2. Fish early fife stage toxicity test.

Active substance

The EFSA Scientific Report (2006) lists the toxicity endpoint for long-term toxicity to fish from the active substance for use in risk assessment; the **33 day NOEC for fathead minnow early life stages exposed to 1,3-D is 0.0318 mg 1,3-D/L**. No additional long-term toxicity studies with 1,3-D have been submitted.

Metabolites

A long-term study with 3 chloroacrylic acid (3-CACA) was required by EFSA and has been conducted. The study is summarised below.

Marino, T.A., Carr, M.S., Yaroch, A.M. (2007)

Title: 3-chloroacrylic acid: Toxicity to the early life stages of the Fathead Minnow, *Pimephales promelas.* Dow AgroSciences, unpublished report No. 071099. The test was conducted according to OECD Guideline 210, fish early-life stage toxicity test and USEPA OPPTS 850.1400 (Draft 1996). No major deviations from OECD Test Guideline 210. The test was conducted under GLP.

Test substance: 3-Chloroacrylic acid (1:1 cis/trans), Lot No. XW7-36970-12, Identification No. TSN106180, purity of 100% (42.5% cis-3-chloroacrylic acid and 57.5% trans-3-chloroacrylic acid).

The purpose of this study was to evaluate the toxicity of 3-chloroacrylic acid (1:1 cis/trans) to the early-life stages of the fathead minnow, *Pimephales promelas*. The effect endpoints evaluated were the number of embryos that hatched (embryo survival), time to hatch (day-to-mean hatch), normal larvae/juvenile fish at hatch and test termination, post-hatch survival, overall survival, and growth (length and weight). These data were used to determine the no-observed-effect concentration (NOEC), lowest-observed-effect concentration (LOEC), and the maximum-acceptable-toxicant concentration (MATC). The MATC is defined as the theoretical threshold or allowable chronic concentration; it is the geometric mean of the NOEC and LOEC values. The LOEC is defined as the lowest dose concentration showing a statistically significant toxic response when compared to the controls.

This study was conducted under flow-through conditions with embryos and larvae/juvenile fish exposed to nominal concentrations of 0 (water control), 1.30, 2.16, 3.60, 6.00, and 10.0 mg/L. One hundred fathead minnow embryos per test level (4 replicates of 25 embryos), ≤ 22-hours post fertilization, were used to initiate the test. The test system was maintained for 28 days post hatch of the control embryos (33 days total).

Analytical verification of test solutions concentrations were performed on samples collected on a weekly schedule throughout the study. Measured concentrations from the weekly analysis of test solutions yielded percent of target values ranging from 84.3% to 106%. The mean measured concentrations for the study were less than the lowest level quantified of 0.07 mg/L for the water control, and 1.30, 2.22, 3.41, 5.77, and 9.91 mg/L for the treatment solutions.

The statistical determination of the NOEC and LOEC were calculated using mean measured 3-chloroacrylic acid concentrations for all of the effect endpoints evaluated.

Findings:

Dissolved oxygen levels during the study ranged from 5.8-10.0 mg/L (remained ≥72 % saturation), temperatures ranged from 24-26°C, pH ranged from 6.5-7.0, and light intensity ranged from 428-790 lux. Water hardness (as $CaCO_3$) was 42 to 62 mg/L in the control water and 44 to 62 mg/L in the highest treatment level. Alkalinity (as $CaCO_3$) was 23 to 36 mg/L in the control water and 20 to 35 mg/L in the highest treatment level. Conductivity was 156 to 175 µmhos/cm in the control water and 154 to 180 µmhos/cm in the highest treatment level.

No statistically significant (alpha = 0.05) effects between the control group and the treatment groups were observed in this study up through the highest exposure level tested of 9.91 mg/L for the percent embryos hatched, days-to-mean hatch, percent normal juvenile fish at test termination, percent post-hatch survival, percent overall survival and growth (dry weights and standard length) effect endpoints; the resulting NOEC and LOEC values were 9.91 and >9.91 mg/L respectively

Statistically significant (alpha = 0.05) effects between the control group and the treatment groups were observed for the percent normal larvae at hatch effect endpoint down to the 3.41 mg/L treatment level (the only sublethal effect observed was pale coloration). The mean percent normal larvae at hatch was 100% in the control group and ranged from 93.9 to 100% across all treatment groups. This statistically significant effect is not believed to have any biologically significance as there was no resulting impact on overall survival or percent normal juvenile fish at test termination. Nevertheless, on the basis of statistical significance only the resulting NOEC and LOEC values were 2.22 and 3.41 mg/L respectively.

The overall NOEC and LOEC for this study based on the most sensitive endpoint observed (percent normal larvae at hatch) are 2.22 and 3.41 mg/L respectively. However, the lack of statistically significant effects on percent embryos hatched, days-to-mean hatch, percent normal juvenile fish at test termination, percent post-hatch survival, percent overall survival and growth (dry weights and standard length) indicate that these represent a conservative estimate of the chronic toxicity of 3-chloroacrylic acid to fish early life stages.

Table 9.2.2.2-1: Embryo survival

Test Conc. (mg/L)[a]	**Embryo survival (% hatch)**	**Days to mean hatch**	**Post-hatch survival (%)**	**Overall survival (%)**	**Normal larvae at hatch (%)**	**Normal juvenile at test end (%)**	**Length at test end (mm)**	**Weight at test end (mg)**
0 (Control)	99	4.0	81.8	81	100.0	81.8	10.43	2.07
1.30	99	3.8	90.8	90	100.0	90.8	10.15	1.95
2.22	100	4.0	90.0	90	98.0	90.0	9.98	1.83
3.41	99	3.8	85.8	85	96.0*	85.8	10.20	2.07
5.77	98	4.0	84.7	83	93.9*	84.7	10.33	2.06
9.91	100	3.8	77.0	77	94.0*	76.0	10.40	2.13

[a] Mean analyzed 3-chloroacrylic acid concentrations.
* Statistically significant

Table 9.2.2.2-2: Results.

Effect Endpoint	NOEC[a] (mg/L)	LOEC[a] (mg/L)
Percent Embryos Hatched	9.91	>9.91
Days-to-Mean Hatch	9.91	>9.91
Percent Post-Hatch Survival	9.91	>9.91
Percent Overall Survival	9.91	>9.91
Percent Normal Larvae at Hatch	**2.22**	**3.41**
Percent Normal Juvenile Fish at Test Termination	9.91	>9.91
Length (mm)	9.91	>9.91
Weight (mg)	9.91	>9.91

[a] Based on mean analyzed 3-chloroacrylic acid concentrations.

In summary: the lowest NOEC for 3-chloroacrylic acid to the early life stages of the fathead minnow (*Pimephales promelas*) was 2.22 mg/L (measured) based on percent normal larvae at hatch. However, this statistically significant effect was not believed to be biologically significant as there was no resulting impact on overall survival or percent normal juvenile fish at test termination.

B.9.2.2.3. Fish life cycle test.

B.9.2.3. Bioconcentration in fish.

In view of low log K_{ow} for 1,3-D (log Kow values of 1.82 and 2.10 for the *cis*- and *trans*- isomers, respectively) and the rapid dissipation of 1,3-D from the aquatic environment, a fish bioaccumulation study is unnecessary. The EFSA Scientific Report (2006) concluded that the risk for bioconcentration in fish for 1,3-D and metabolites (EZ)-3-chloroallyl alcohol and (EZ)-3-chloroacrylic acid is considered to be low. Not further information is required.

B.9.2.4. Acute toxicity to aquatic invertebrates.

Active substance

The EFSA Scientific Report (2006) lists two toxicity endpoints for acute toxicity to aquatic invertebrates from the active substance for use in risk assessment; a **48 hour EC_{50} of 3.58 mg 1,3-D/L for *Daphnia magna*** and a **96 hour EC_{50} of 0.64 mg 1,3-D/L for eastern oyster (*Crassostrea virginica*).** No additional acute toxicity studies with 1,3-D and aquatic invertebrates have been submitted.

Effect of metabolites

The EFSA Scientific Report (2006) lists two toxicity endpoints for acute toxicity to aquatic invertebrates from the metabolites 3-chloroallyl alcohol (3-CAA) and 3-chloroacrylic acid (3-CACA) for use in risk assessment. **The 48 hour EC_{50} for *Daphnia magna* exposed to 3-CAA is 2.30 mg/L**, and **the 48 hour EC_{50} for *Daphnia magna* exposed to 3-CACA is 55.0 mg/L**. No additional acute toxicity studies with the metabolites have been submitted.

B.9.2.5. Chronic toxicity to aquatic invertebrates.

Active substance

The EFSA Scientific Report (2006) lists the endpoint for long-term toxicity to aquatic invertebrates from the active substance for use in risk assessment; the **21 day NOEC for *Daphnia magna* exposed to 1,3-D is 0.0701 mg/L**. No additional long-term toxicity studies with 1,3-D have been submitted.

Metabolites

A long-term study on 3-chloroacrylic acid was required by EFSA and has been conducted. The study is summarised below.

Marino, T.A., Currie, R.J., Carr, M.S., Yaroch, A.M. (2007).

Title: 3-chloroacrylic acid (1:1 cis/trans): A 21 day chronic toxicity study with the daphnid *Daphnia magna.* Dow AgroSciences, unpublished report No. 071106.

OECD Guideline 211; USEPA OPPTS 850.1300. No major deviations from OECD Test Guideline 211. The study was conducted under GLP. The study is considered acceptable.

Test substance: 3-Chloroacrylic acid (1:1 cis/trans), Lot No. XW7-36970-12, Identification No. TSN106180, purity of 100% (42.5% cis-3-chloroacrylic acid and 57.5% trans-3-chloroacrylic acid).

The chronic toxicity of 3-chloroacrylic acid (1:1 cis/trans) to the freshwater daphnid, *Daphnia magna* was evaluated. A 21-day static-renewal life cycle study was conducted and endpoints included adult daphnid survival, reproduction (number of young produced per surviving adult female), and growth (length and weight of surviving adults).

The study was conducted with ten daphnids (one individual per replicate with ten replicates per dose level) exposed to nominal concentrations of 0 (water control), 0.625, 1.25, 2.5, 5.0 and 10.0 mg 3-chloroacrylic acid/L. Test solutions were renewed each Monday, Wednesday, and Friday through-out the 21-day exposure. Daily observations were made and the number of surviving daphnids recorded. Reproduction was evaluated by counting and removing neonates daily. At test termination (day 21), lengths and dry weights of all surviving parent daphnids were measured and recorded.

The bulk test solutions were sampled at test initiation and on days 4, 7, and 14 of the study for analytical verification of 3-chloroacrylic acid concentrations. Spent test solutions (10 replicates per dose level) were pooled and analyzed on day 7 and at test termination (day 21). The samples were analyzed for 3-chloroacrylic acid using high performance liquid chromatography with ultraviolet detection (HPLC/UV). The resulting mean measured test concentrations were 0.595, 1.24, 2.53, 5.08, and 10.1 mg/L; no 3-chloroacrylic acid was detected in the water control at a test concentration exceeding the lowest level quantified (LLQ) of 0.06 mg/L. Results from the analyses of the test solution during the 21-day study yielded daily percent recovery of target concentrations ranging from 88.8 to 106%.

The statistical determination of the NOEC and LOEC were calculated using mean measured 3-chloroacrylic acid concentrations for all of the effect endpoints evaluated.

Dissolved oxygen levels ranged from 7.2-9.8 mg/L (81-110% oxygen saturation), temperatures ranged from 20-21°C, and pH ranged from 7.3-8.3. Light intensity ranged from 469-793 lux.

The NOEC for survival, reproduction, and growth (weight at study termination) was 10.1 mg/L and the LOEC was greater than 10.1 mg/L, which was the highest concentration tested. The NOEC for length at study termination was 2.53 mg/L, while the LOEC was 5.08 mg/L. The 21-day EC_{50} values for survival and reproduction were both greater than the highest concentration tested of 10.1 mg/L.

Table 9.2.5-1: Effects of 3-CACA on Daphnia magna.

Mean Measured Concentration (3-chloroacrylic acid)	Percent Survival	Average Cumulative Progeny Per Surviving Female Adult (mean ± SD)	Length in Millimeters (mean ± SD)	Dry Weight in Milligrams (mean ± SD)
0 ([a]<LLQ)	100	118.5 ± 11.2	4.5 ± 0.08	0.73 ± 0.10
0.595	100	130.2 ± 24.2	4.5 ± 0.11	0.76 ± 0.12
1.24	100	117.1 ± 23.0	4.4 ± 0.07	0.77 ± 0.15
2.53	80*	127.1 ± 13.9	4.5 ± 0.28	0.73 ± 0.11
5.08	90*	109.2 ± 12.5	4.2 ± 0.09**	0.74 ± 0.08
10.1	100	104.1 ± 17.5	4.0 ± 0.10**	0.62 ± 0.07

[a]<LLQ=Less than Lowest Level Quantified = 0.06 mg 3-chloroacrylic acid/L ALDW
*Replicates with adult mortality were not included in statistical analyses
** significant differences at $p < 0.05$

Table 9.2.5-2: Results.

Effect Endpoint	**NOEC[a] (mg/L)**	**LOEC[a] (mg/L)**
Survival	10.1	>10.1
Weight	10.1	>10.1
Length	2.53	5.08
Reproduction (total young)	10.1	>10.1

[a] Based on mean analyzed 3-chloroacrylic acid concentrations.

In summary: the lowest NOEC of 3-chloroacrylic acid to *Daphnia magna* was 2.53 mg/L, as measured, based on length of the adults at test termination.

B.9.2.6. Effects on algal growth.

A summary of the studies presented in the EFSA Scientific Report (2006) is provided below. Upon the request of EFSA, the toxicity end-points for algae have been re-calculated in terms of biomass (E_bC_{50}) and growth rate (E_rC_{50}) using the cell counts reported in the original studies. This additional information is provided below for each of the respective studies. The calculations provided are considered acceptable.

The source data used for the calculations of E_bC_{50} and E_rC_{50} are provided below. Algal growth rate (day^{-1}) and biomass (area under the growth curve) were determined based on mean measured or initial test concentrations in accordance with the methods adopted by the RMS for determining the EC_{50} values based on final cell count summarised in the Draft DAR (Section B.9.2.5).

The E_rC_{50} values were calculated for 0 – 96 hours for *Selenastrum* or 0 – 120 hours for *Navicula*, *Anabaena*, and *Skeletonema* by regression using the percent reduction in mean specific growth rate for each exposure group compared to the control group against the mean measured or initial test concentrations. The E_rC_{50} values were determined by inverse estimation from the regression equations. The following formula was used to calculate growth rate:

$$\mu_{i-j} = \frac{\ln N_j - \ln N_i}{t_j - t_i}$$

Where: μ = mean specific growth rate from moment i to j ($days^{-1}$)

Ln = natural logarithm

Ni	=	initial cell density (cells/ml x 10^4)
Nj	=	cell density at end of exposure
ti	=	the time at the start of the exposure period
tj	=	the time at the end of the exposure period

The E_bC_{50} values were determined for 0 - 96 hours for *Selenastrum* and 0 - 120 hours for *Navicula, Anabaena, and Skeletonema* by regression using the percent inhibition in area under the growth curves for each exposure group compared to the control against mean measured or initial test concentrations. Area under the growth curve was calculated using the following formula:

$$A = \frac{N_1 - N_0}{2} \times t_1 + \frac{N_1 + N_2 - 2N_0}{2} \times (t_2 - t_1) + \frac{N_{n-1} + N_n - 2N_0}{2} \times (t_n - t_{n-1})$$

Where:

A	=	area under the growth curve
N_0	=	nominal number of cells/mL (x 10^4) at t_0
N_1	=	measured number of cells/mL (x 10^4) at t_1
N_n	=	measured number of cells/mL (x 10^4) at t_n
t_1	=	Time of first measurement after beginning of test
t_n	=	time of n^{th} measurement after beginning of test

For all of the studies, cell counts were only performed at the start (day 0) of the exposure and at the end (day 4 for *Selenastrum*, day 5 for the other species). For consistency with the methods used in the original studies the control and solvent control biomass values were pooled for the purposes of comparison to the biomass for each treatment level.

All calculations of E_bC_{50} and E_rC_{50} were carried out using SAS version 6.12.

Active substance

Kirk *et al*, 1999: The toxicity of Telone to *Selenastrum capricornutum* was evaluated by the RMS, considered valid, and summarised in the DAR. The 96 hour EC_{50} was presented in the DAR as 20 mg 1,3-D/L. At the request of the EFSA, the E_bC_{50} and E_rC_{50} have subsequently been calculated from the original cell density data in the report and are presented below.

***Selenastrum capricornutum*: Estimated E_bC_{50} and E_rC_{50}**

Initial measured Concentration (mg/L)	Mean No cells (Day 0)	Mean No cells (Day 4)	Mean Area x 10^4 (Day 0 - 4)	% Inhibition	Mean Growth Rate (Day 0 - 4)	% Inhibition
0	6556	739525	3518	-	0.0492	-
solvent control	7321	672263	3192	-	0.0471	-
Pooled controls	6939	705894	3355	-	0.0482	-
0.0787	6805	723760	3441	-3	0.0486	-1
0.293	6852	771453	3670	-9	0.0492	-2
0.915	6283	841271	4008	-19	0.0510	-6
2.87	7011	768296	3654	-9	0.0489	-2

9.5	7453	667101	3166	6	0.0468	3
31.7	7166	34660	132	96	0.0164	66
96.9	6666	3194	-17	100	-0.0077	116
			E_bC_{50}: 14.9 mg/L		**E_rC_{50}: 13.6 mg/L**	

The 96 hour EC_{50} for *Selenastrum capricornutum* based on biomass is 14.9 mg 1,3-D/L and the EC_{50} based on growth rate is 13.6 mg 1,3-D/L as initial measured values. **For the purposes of risk assessment, the 96h E_rC_{50} of 13.6 mg 1,3-D/L will be used**.

Kirk *et al*, 1999: The toxicity of Telone to *Navicula pelliculosa* was evaluated by the RMS, considered valid, and summarised in the DAR. The 120 hour EC_{50} was presented in the EFSA Scientific Report (2006) as 2.35 mg 1,3-D/L. At the request of the EFSA, the E_bC_{50} and E_rC_{50} have subsequently been calculated and are presented below.

***Navicula pelliculosa*: Estimated E_bC_{50} and E_rC_{50}**

Initial measured Concentration (mg/L)	Mean No cells (Day 0)	Mean No cells (Day 5)	Mean Area x 10^4 (Day 0 – 5)	% Inhibition	Mean Growth Rate (Day 0 - 5)	% Inhibition
0	12270	529445	3103	-	0.0314	-
solvent control	12278	1053195	6246	-	0.0371	-
Pooled	12274	791320	4674	-	0.0342	-
0.074	10852	798949	4729	-1	0.0358	-5
0.246	10623	498129	2925	37	0.0321	6
0.878	10847	569616	3353	28	0.0330	4
2.76	11876	876394	5187	-11	0.0358	-5
9.53	10924	274020	1579	66	0.0269	22
28.8	11327	7227	-25	101	-0.0037	111
89.8	11526	4942	-40	101	-0.0071	121
			E_bC_{50}: 3.64 mg/L		**E_rC_{50}: 5.84 mg/L**	

The 120 hour EC_{50} for *Navicula pelliculosa* based on biomass is 3.64 mg 1,3-D/L and the EC_{50} based on growth rate is 5.84 mg 1,3-D/L as initial measured values. These are higher than the 120 hour EC_{50} of 2.35 mg 1,3-D/L presented in the EFSA Scientific Report (2006), and so **for the purposes of risk assessment, the 120h EC_{50} of 2.35 mg 1,3-D/L will be used**.

Kirk *et al*, 1999: The toxicity of Telone to *Anabaena flos-aquae* was evaluated by the RMS, considered valid, and summarised in the DAR. The 120 hour EC_{50} was presented in the DAR as 62.58 mg 1,3-D/L. At the request of the EFSA, the E_bC_{50} and E_rC_{50} have subsequently been calculated from the original cell density data in the report and are presented below.

***Anabaena flos-aquae*: Estimated E_bC_{50} and E_rC_{50}**

Initial measured Concentration (mg/L)	Mean No cells (Day 0)	Mean No cells (Day 5)	Mean Area x 10^4 (Day 0 – 5)	% Inhibition	Mean Growth Rate (Day 0 - 5)	% Inhibition
0	8633	63604	330	-	0.0166	-
solvent control	17170	64585	284	-	0.0110	-
Pooled	12902	64095	307	-	0.0138	-
0.33	8944	68951	360	-17	0.0170	-23
1.07	9499	61863	314	-2	0.0156	-13
3.49	14541	62999	291	5	0.0122	12
11.3	9075	63107	324	-6	0.0162	-17
38.8	9860	34562	148	52	0.0105	24
125	20158	35171	90	71	0.0046	66
			E_bC_{50}: 64.3 mg/L		**E_rC_{50}: 96.3 mg/L**	

The 120 hour EC_{50} for *Anabaena flos-aquae* based on biomass is 64.3 mg 1,3-D/L and the EC_{50} based on growth rate is 96.3 mg 1,3-D/L as initial measured values. These are higher than the 120 hour EC_{50} of 62.58 mg 1,3-D/L presented in the EFSA Scientific Report (2006), and so **for the purposes of risk assessment, the 120h EC_{50} of 62.58 mg 1,3-D/L will be used**.

Kirk *et al*, 1999. The toxicity of Telone to *Skelotonema costatum* was evaluated by the RMS, considered valid, and summarised in the DAR. The 120 hour EC_{50} was presented in the DAR as 21.67 mg 1,3-D/L. At the request of the EFSA, the E_bC_{50} and E_rC_{50} have subsequently been calculated from the original cell density data in the report and are presented below.

***Skeletonema costatum:* Estimated E_bC_{50} and E_rC_{50}**

Initial measured Concentration (mg/L)	Mean No cells (Day 0)	Mean No cells (Day 5)	Mean Area x 10^4 (Day 0 – 5)	% Inhibition	Mean Growth Rate (Day 0 - 5)	% Inhibition
0	56509	1186332	6779	-	0.0254	-
solvent control	67244	1185901	6712	-	0.0239	-
Pooled	61877	1186117	6745	-	0.0246	-
0.0727	75394	1171076	6574	3	0.0229	7
0.235	83835	1202057	6709	1	0.0222	10
0.798	76608	1237650	6966	-3	0.0232	6

2.7	80514	1276209	7174	-6	0.0230	7
8.78	64128	1167354	6619	2	0.0242	2
29.7	57241	110751	321	95	0.0055	78
101	58048	79580	129	98	0.0026	89
			E_bC_{50}: 13.4 mg/L		**E_rC_{50}: 18.7 mg/L**	

The 120 hour EC_{50} for *Skelotonema costatum* based on biomass is 13.4 mg 1,3-D/L and the EC_{50} based on growth rate is 18.7 mg 1,3-D/L as initial measured values. **For the purposes of risk assessment, the 120 h E_bC_{50} of 13.4 mg 1,3-D/L will be used.**

Metabolites

Kirk *et al*, 1999: The toxicity of 3-chloroallyl alcohol (3-CAA) to *Selenastrum capricornutum* was evaluated by the RMS, considered valid, and summarised in the DAR. The 96 hour EC_{50} was presented in the DAR as 56.0 mg 3-CAA/L. At the request of the EFSA, the E_bC_{50} and E_rC_{50} have subsequently been calculated from the original cell density data in the report and are presented below.

Selenastrum capricornutum: **Estimated E_bC_{50} and E_rC_{50}**

Mean measured Concentration (mg/L)	Mean No cells (Day 0)	Mean No cells (Day 4)	Mean Area x 10^4 (Day 0 - 4)	% Inhibition	Mean Growth Rate (Day 0 - 4)	% Inhibition
0	10953	1137182	5406	-	0.0484	-
solvent control	10293	1186258	5645	-	0.0494	-
Pooled controls	10623	1161720	5526	-	0.0489	-
3.20	9821	1205302	5738	-4	0.0501	-2
6.38	10566	1183256	5629	-2	0.0491	0
12.7	10777	979514	4650	16	0.0470	4
25.7	9895	812476	3852	30	0.0459	6
50.8	10258	583214	2750	50	0.0421	14
98.0	10625	188532	854	85	0.0300	39
			E_bC_{50}: 55.5 mg/L		**E_rC_{50}: >98.0 mg/L**	

The 96 hour EC_{50} for *Selenastrum capricornutum* based on biomass is 55.5 mg 3-CAA/L and the EC_{50} based on growth rate is >98.0 mg 3-CAA/L as initial measured values. **For the purposes of risk assessment, the 96h E_bC_{50} of 55.5 mg 3-CAA/L will be used**.

Kirk *et al*, 1999: The toxicity of 3-chloroallyl alcohol (3-CAA) to *Anabaena flos-aquae* was evaluated by the RMS, considered valid, and summarised in the DAR. The 120 hour EC_{50} was

presented in the DAR as >47.5 mg 3-CAA/L. At the request of the EFSA, the E_bC_{50} and E_rC_{50} have subsequently been calculated from the original cell density data in the report and are presented below.

Anabaena flos aquae: **Estimated E_bC_{50} and E_rC_{50}**

Mean measured Concentration (mg/L)	Mean No cells (Day 0)	Mean No cells (Day 5)	Mean Area x 10^4 (Day 0 - 5)	% Inhibition	Mean Growth Rate (Day 0 - 4)	% Inhibition
0	19094	1256936	7427	-	0.0349	-
solvent control	21558	1103104	6489	-	0.0328	-
Pooled controls	20326	1180020	6958	-	0.0339	-
2.59	17272	1208315	7146	-3	0.0354	-4
5.64	17495	1231980	7287	-5	0.0355	-5
12.6	17676	1223749	7236	-4	0.0353	-4
24.3	18512	1058019	6237	10	0.0337	1
47.5	21446	1058182	6220	11	0.0325	4
92.6	21101	920579	5397	22	0.0315	7
			E_bC_{50}: >92.6 mg/L		**E_rC_{50}: >92.6 mg/L**	

The 120 hour EC_{50} for *Anabaena flos-aquae* based on biomass is >92.6 mg 1,3-D/L and the EC_{50} based on growth rate is >92.6 mg 1,3-D/L as initial measured values. These are higher than the 96 hour EC_{50} of >47.5 mg 3-CAA/L presented in the EFSA Scientific Report (2006), and so **for the purposes of risk assessment, the 96h EC_{50} of >47.5 mg 1,3-D/L will be used**.

Kirk *et al*, 1999: The toxicity of 3-chloroallyl alcohol (3-CAA) to *Skelotonema costatum* was evaluated by the RMS, considered valid, and summarised in the DAR. The 120 hour EC_{50} was determined to be 0.727 mg 3-CAA /L. At the request of the EFSA, the E_bC_{50} and E_rC_{50} have subsequently been calculated from the original cell density data in the report and are presented below.

Skeletonema costatum: **Estimated E_bC_{50} and E_rC_{50}**

Initial measured Concentration (mg/L)	Mean No cells (Day 0)	Mean No cells (Day 5)	Mean Area x 10^4 (Day 0 – 5)	% Inhibition	Mean Growth Rate (Day 0 - 5)	% Inhibition
0	134655	903194	4611	-	0.0200	-
solvent control	86151	834910	4493	-	0.0189	-
Pooled	110403	869052	4552	-	0.0195	-
0.0251	110641	821060	4263	6	0.0167	14

0.0822	143951	842935	4194	8	0.0147	24
0.267	136157	770472	3806	16	0.0144	26
0.825	94947	262622	1006	78	0.0085	56
2.510	101069	170384	416	91	0.0044	78
7.180	91561	163205	430	91	0.0048	75
			E_bC_{50}: 0.492 mg/L		**E_rC_{50}: 0.637 mg/L**	

The 120 hour EC_{50} for *Skelotonema costatum* based on biomass is 0.492 mg 3-CAA/L and the EC_{50} based on growth rate is 0.637 mg 3-CAA/L as initial measured values. **For the purposes of risk assessment, the 120 h E_bC_{50} of 0.492 mg 3-CAA/L will be used.**

Kirk *et al*, 1999: The toxicity of 3 chloroallyl alcohol (3-CAA) to *Navicula pelliculosa* was evaluated by the RMS and summarised in the DAR. The study was not considered valid by the RMS and so the endpoints were not recalculated.

Kirk *et al*, 1999: The toxicity of 3 chloroacrylic acid (3-CACA) to *Selenastrum capricornutum* was evaluated by the RMS, considered valid, and summarised in the DAR. The 96 hour EC_{50} was was presented in the EFSA Scientific Report (2006) as 0.691 mg 3-CACA /L. At the request of the EFSA, the E_bC_{50} and E_rC_{50} have subsequently been calculated from the original cell density data in the report and are presented below.

***Selenastrum capricornutum:* Estimated E_bC_{50} and E_rC_{50}**

Mean measured Concentration (mg/L)	Mean No cells (Day 0)	Mean No cells (Day 4)	Mean Area x 10^4 (Day 0 - 4)	% Inhibition	Mean Growth Rate (Day 0 - 4)	% Inhibition
0	7671	878633	4181	-	0.0494	-
solvent control	6443	818627	3898	-	0.0505	-
Pooled controls	7057	848630	4040	-	0.0500	-
0.0387	8489	823415	3912	3	0.0477	5
0.183	8844	808477	3838	5	0.0470	6
0.764	8046	200312	923	77	0.0335	33
3.099	9543	83752	356	91	0.0226	55
12.909	9890	17123	35	99	0.0057	89
52.978	10791	0	0	100	0.0000	100
			E_bC_{50}: 0.663 mg/L		**E_rC_{50}: 1.746 mg/L**	

The 96 hour EC_{50} for *Selenastrum capricornutum* based on biomass is 0.663 mg 3-CACA/L and the EC_{50} based on growth rate is 1.746 mg 1,3-D/L as measured values. **For the purposes of risk assessment, the 96h E_bC_{50} of 0.663 mg 3-CACA/L will be used.**

Kirk *et al*, 1999: The toxicity of 3 chloroacrylic acid (3-CACA) to *Navicula pelliculosa* was evaluated by the RMS, considered valid, and summarised in the DAR. The 120 hour EC_{50} was presented in the DAR as 7.15 mg 3-CACA /L. At the request of the EFSA, the E_bC_{50} and E_rC_{50} have subsequently been calculated from the original cell density data in the report and are presented below.

Navicula pelliculosa: **Estimated E_bC_{50} and E_rC_{50}**

Mean measured Concentration (mg/L)	Mean No cells (Day 0)	Mean No cells (Day 5)	Mean Area x 10^4 (Day 0 - 5)	% Inhibition	Mean Growth Rate (Day 0 - 5)	% Inhibition
0	8164	1429662	8529	-	0.0430	-
solvent control	7853	1287723	7679	-	0.0425	-
Pooled controls	8009	1358693	8104	-	0.0428	-
2.59	7746	1459050	8708	-7	0.0437	-2
5.01	6867	864667	5147	36	0.0403	6
10.1	7004	20127	79	99	0.0088	79
20.5	7256	13809	39	100	0.0054	87
39.4	6790	12402	34	100	0.0050	88
76.5	6566	9855	20	100	0.0034	92
			E_bC_{50}: 7.09 mg/L		**E_rC_{50}: 10.6 mg/L**	

The 120 hour EC_{50} for *Navicula pelliculosa* based on biomass is 7.09 mg 3-CACA/L and the EC_{50} based on growth rate is 10.6 mg 3-CACA/L as measured values. **For the purposes of risk assessment, the 96h E_bC_{50} of 7.09 mg 3-CACA/L will be used.**

Kirk *et al*, 1999: The toxicity of 3 chloroacrylic acid (3-CACA) to *Anabaena flos-aquae* was evaluated by the RMS, considered valid, and summarised in the DAR. The 120 hour EC_{50} was presented in the DAR as 6.32 mg 3-CACA /L. At the request of the EFSA, the E_bC_{50} and E_rC_{50} have subsequently been calculated from the original cell density data in the report and are presented below.

Anabaena flos aquae: **Estimated E_bC_{50} and E_rC_{50}**

Mean measured Concentration (mg/L)	Mean No cells (Day 0)	Mean No cells (Day 5)	Mean Area x 10^4 (Day 0 - 5)	% Inhibition	Mean Growth Rate (Day 0 - 4)	% Inhibition
0	14941	1884938	11220	-	0.0403	-
solvent control	20116	1560543	9243	-	0.0363	-
Pooled controls	17529	1722741	10232	-	0.0383	-

0.427	14225	1681216	10002	2	0.0398	-4
0.848	16301	1549149	9197	10	0.0380	1
1.74	21908	1671540	9898	3	0.0361	6
3.40	12738	1163715	6906	33	0.0376	2
6.93	17737	277734	1560	85	0.0229	40
12.4	12413	134980	735	93	0.0199	48
			E_bC_{50}: 3.63 mg/L		**E_rC_{50}: >12.4 mg/L**	

The 120 hour EC_{50} for *Anabaena flos-aquae* based on biomass is 3.63 mg 3-CACA/L and the EC_{50} based on growth rate is >12.4 mg 3-CACA /L as measured values. **For the purposes of risk assessment, the 96h E_bC_{50} of 3.63 mg 3-CACA/L will be used.**

Kirk *et al*, 1999: The toxicity of 3 chloroacrylic acid (3-CACA) to *Skelotonema costatum* was evaluated by the RMS, considered valid, and summarised in the DAR. The 120 hour EC_{50} was presented in the DAR as 60.0 mg 3-CACA/L. At the request of the EFSA, the E_bC_{50} and E_rC_{50} have subsequently been calculated from the original cell density data in the report and are presented below.

Skeletonema costatum: **Estimated E_bC_{50} and E_rC_{50}**

Mean measured Concentration (mg/L)	Mean No cells (Day 0)	Mean No cells (Day 5)	Mean Area x 10^4 (Day 0 – 5)	% Inhibition	Mean Growth Rate (Day 0 - 5)	% Inhibition
0	54122	567613	3081	-	0.0196	-
solvent control	46853	553881	3042	-	0.0206	-
Pooled	50488	560747	3062	-	0.0201	-
2.98	51804	591429	3238	-6	0.0203	-1
5.94	55197	574587	3116	-2	0.0195	3
12.1	52959	587707	3208	-5	0.0201	0
23.9	51090	529279	2869	6	0.0195	3
47.4	42115	329398	1724	44	0.0171	15
97.0	42885	70746	167	95	0.0042	79
			E_bC_{50}: 56.2 mg/L		**E_rC_{50}: 72.3 mg/L**	

The 120 hour EC_{50} for *Skelotonema costatum* based on biomass is 56.2 mg 3-CACA/L and the EC_{50} based on growth rate is 72.3 mg 3-CACA/L as measured values. **For the purposes of risk assessment, the 120 h E_bC_{50} of 56.2 mg 3-CACA/L will be used.**

The calculated E_bC_{50} and E_rC_{50} values are summarized below. The EC_{50} values based on final cell counts determined by the RMS and presented in the draft DAR are presented in the same tables to aid comparison.

1,3-D

Species	E_bC_{50} (mg/L)	E_rC_{50} (mg/L)	EC_{50} (mg/L)	Study Reference
Selenastrum	14.9	13.6	20	Kirk *et al* (1999).
Navicula	3.64	5.84	2.35	Kirk *et al* (1999).
Anabaena	64.3	96.3	62.58	Kirk *et al* (1999).
Skeletonema	13.4	18.7	21.67	Kirk *et al* (1999).

3-chloroallyl alcohol (3-CAA)

Species	E_bC_{50} (mg/L)	E_rC_{50} (mg/L)	EC_{50} (mg/L)	Study Reference
Selenastrum	55.5	>98.0	56.0	Kirk *et al* (1999).
Anabaena	>92.6	>92.6	>47.5	Kirk *et al* (1999).
Skeletonema	0.492	0.637	0.727	Kirk *et al* (1999).

3-chloroacrylic acid (3-CACA)

Species	E_bC_{50}	E_rC_{50}	EC_{50}	Study Reference

	(mg/L)	(mg/L)	(mg/L)	
Selenastrum	0.663	1.746	0.691	Kirk *et al* (1999).
Navicula	7.09	10.6	7.15	Kirk *et al* (1999).
Anabaena	3.63	>12.4	6.32	Kirk *et al* (1999).
Skeletonema	56.2	72.3	60.0	Kirk *et al* (1999).

Based on calculated E_rC_{50} (growth rate), E_bC_{50} (area under the growth curve) and EC_{50} (final cell density) values for algae exposed to 1,3-D, or the metabolites 3-CAA or 3-CACA, **the lowest end-points for use in a risk assessment are:**

- **1,3-D**: 2.35 mg/L (*Navicula* EC_{50})
- **3-CAA:** 0.492 mg/L (*Skeletonema* E_bC_{50})
- **3-CACA**: 0.663 mg/L (*Selenastrum* E_bC_{50})

B.9.2.7. Effects on sediment dwelling organisms.

In the DAR it was concluded that in view of the rapid dissipation of 1,3-D from the aquatic environment, 1,3-D is unlikely to partition into sediments and, therefore, a study to determine effects on sediment-dwelling organisms is unnecessary. Not further information is required.

B.9.2.8. Aquatic plants.

Active substance

The EFSA Scientific Report (2006) lists the **14 day EC_{50} for 1,3-D as 14.56 mg a.s./L** for use in a risk assessment. No additional studies have been submitted.

Metabolites

The EFSA Scientific Report (2006) lists the **14 day EC_{50} for 3-chloroallyl alcohol as 0.454 mg/L**, and the **14 day EC_{50} for 3-chloroacrylic acid as 0.26 mg/L**. No additional studies have been submitted.

B.9.2.9. Aquatic risk assessment.

The EFSA Scientific Report (2006) concluded that 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 associated with this use will therefore not be considered further.

The risk assessment presented below has been based on the realistic worst case scenarios of a single application of 224 kg a.s./ha by injection to bare soil for fruiting vegetables (tomatoes). Since technical grade 1,3-D is essentially the product (Telone injected), the same data may be used to assess the risk from active substance and product.

Predicted environmental concentrations of 1,3-D in surface water (PEC_{sw}) for the outdoor injection use of Telone II have been calculated for three different routes of entry; deposition from air, drainage, and run-off (IIA B.8.6). In addition, the PEC_{sw} of the metabolites, 3-chloroallyl alcohol and 3-

chloroacrylic acid, have been calculated and presented in IIA B.8.6. For the purpose of a Tier I risk assessment the maximum PEC_{sw}, assuming that the peak PEC_{sw} from all three routes of entry occur at the same time, has been used as the worst-case exposure to 1,3-D, 3-chloroallyl alcohol or 3-chloroacrylic acid.

Table 9.2.9-1: Predicted peak environmental concentrations of 1,3-D and its major metabolites in surface water following outdoor use of Telone II.

Route of entry	**Maximum initial PECsw (mg/L)**		
	1,3-D	**3-chloroallyl alcohol**	**3-chloroacrylic acid**
Deposition from air	0.000500	0.000416	0.000480
Drainage/lateral flow	0.000466	0.000388	0.000447
Run-off	0.002240	0.001870	0.002150
Total	**0.003206**	**0.002674**	**0.003077**

The TER values have been calculated from the LC_{50} (or EC_{50}) and NOEC values of the most sensitive species of each group and the maximum initial PEC_{sw} following application. The LC_{50} (or EC_{50}) and NOEC values of the most sensitive species of each group is presented in the following table.

Table 9.2.9-2: Acute and chronic endpoints of the most sensitive species of each group for use in risk assessment.

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)	Source
Fish					
Sheepshead minnow *Cyprinodon variegates*	Technical 1,3-D (96%)	Acute	96h LC_{50}	0.87	DAR IIA 9.2.1/07 EFSA Scientific Report (2006)
Rainbow trout *Oncorhynchus mykiss*	(EZ)-3-chloroallyl alcohol	Acute	96h LC_{50}	0.986	DAR IIA 9.2.1/09 EFSA Scientific Report (2006)
Rainbow trout *Oncorhynchus mykiss*	(EZ)-3-chloroacrylic acid	Acute	96h LC_{50}	69.5	DAR IIA 9.2.1/10 EFSA Scientific Report (2006)
Fathead minnow *Pimephales promelas*	Technical 1,3-D (96%)	Chronic (early life stage)	33 d NOEC	0.032	DAR IIA 9.2.2/01 EFSA Scientific Report (2006)
Fathead minnow *Pimephales promelas*	(EZ)-3-chloroacrylic acid	Chronic (early life stage)	33 d NOEC	2.22	DAR IIA 9.2.2.2/02 Marino *et al* (2007)
Invertebrates					
Daphnia magna	Technical 1,3-D (100%)	Acute	48 h EC_{50}	3.58	DAR IIA 9.2.4/01 EFSA Scientific

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)	Source
					Report (2006)
Eastern oyster *Crassostrea virginica*	Technical 1,3-D (96%)	Acute	96h EC_{50}	0.64	DAR IIA 9.2.4/05 EFSA Scientific Report (2006)
Daphnia magna	(EZ)-3-chloroallyl alcohol	Acute	48 h EC_{50}	2.30	DAR IIA 9.2.4/03 EFSA Scientific Report (2006)
Daphnia magna	(EZ)-3-chloroacrylic acid	Acute	48 h EC_{50}	55.0	DAR IIA 9.2.4/02 EFSA Scientific Report (2006)
Daphnia magna	Technical 1,3-D (96%)	Chronic	21 d NOEC	0.0701	DAR IIA 9.2.5/01 EFSA Scientific Report (2006)
Daphnia magna	(EZ)-3-chloroacrylic acid	Chronic	21 d NOEC	2.53	DAR IIA 9.2.5/02 Marino *et al* (2007)
Algae					
Navicula pelliculosa	Technical 1,3-D (96%)	Acute	5 d EC_{50}	2.35	DAR IIA 9.2.6/02 EFSA Scientific Report (2006)
Skelotonema costatum	(EZ)-3-chloroallyl alcohol	Acute	5 d E_bC_{50}	0.49	DAR IIA 9.2.6/08 Kirk *et al,* 1999
Selenastrum capricornutum	(EZ)-3-chloroacrylic acid	Acute	5 d E_bC_{50}	0.66	DAR IIA 9.2.6/09 Kirk *et al,* 1999
Plant					
Lemna gibba	Technical 1,3-D (96%)	Acute	14 d EC_{50}	14.56	DAR IIA 9.2.8/01 EFSA Scientific Report (2006)
Lemna gibba	(EZ)-3-chloroallyl alcohol	Acute	14 d EC_{50}	0.454	DAR IIA 9.2.8/02 EFSA Scientific Report (2006)
Lemna gibba	(EZ)-3-chloroacrylic acid	Acute	14 d EC_{50}	0.26	DAR IIA 9.8.2/03 EFSA Scientific Report (2006)

The TER values have been calculated for the most sensitive species of each group using the LC_{50} (or EC_{50}) and NOEC values from Table 9.2.8-2 and the maximum initial PEC_{sw} from Table 9.2.8-1. The resulting TER values for 1,3-D, 3-CAA and 3-CACA are presented in the following tables.

Active Substance

Table 9.2.9-3. Toxicity exposure ratio values for 1,3-D.

Species	Test substance	Application Rate (kg a.s./ha)	Toxicity Endpoint (mg/L)	PEC_{sw} (mg/L)	TER_A	Annex VI Trigger
Cyprinodon variegates	Technical 1,3-D (96%)	224	96h LC_{50}: 0.87	0.003206	271	100
Daphnia magna	Technical 1,3-D (100%)	224	48 h EC_{50}: 3.58	0.003206	1117	100
Crassostrea virginica	Technical 1,3-D (96%)	224	96h EC_{50}: 0.64	0.003206	200	100
Navicula pelliculosa	Technical 1,3-D (96%)	224	5 d EC_{50}: 2.35	0.003206	733	10
Lemna gibba	Technical 1,3-D (96%)	224	14 d EC_{50}: 14.56	0.003206	4541	10

Table 9.2.9-4. Long-term toxicity exposure ratio (TER_{LT}) for fish and aquatic invertebrates values for 1,3-D.

Species	Test substance	Application Rate (kg/ha)	Toxicity Endpoint (mg/L)	PECsw (mg/L)	TER_{LT}	Annex VI Trigger
Pimephales promelas	Technical 1,3-D (96%)	224	33 d NOEC: 0.032	0.003206	10	10
Daphnia magna	Technical 1,3-D (96%)	224	21 d NOEC: 0.0701	0.003206	22	10

Metabolites

Table 9.2.9-5: Acute toxicity exposure ratio (TER_A) values for 3-chloroallyl alcohol (3-CAA) and 3-chloroacrylic acid (3-CACA).

Group	Test substance	Application Rate (kg a.s./ha)	Toxicity Endpoint (mg/L)	PECsw (mg/L)	TER_A	Annex VI Trigger
3-chloroallyl alcohol (3-CAA)						
Oncorhynchus mykiss	(EZ)-3-chloroallyl alcohol	224	96h LC_{50}: 0.986	0.002674	369	100
Daphnia magna	(EZ)-3-chloroallyl alcohol	224	48 h EC_{50}: 2.30	0.002674	860	100
Skelotonema costatum	(EZ)-3-chloroallyl alcohol	224	5 d E_bC_{50}: 0.492	0.002674	184	10
Lemna gibba	(EZ)-3-chloroallyl alcohol	224	14 d EC_{50}: 0.454	0.002674	170	10
3-chloroacrylic acid (3-CACA)						
Oncorhynchus mykiss	(EZ)-3-chloroacrylic acid	224	96h LC_{50}: 69.5	0.003077	22587	100
Daphnia magna	(EZ)-3-chloroacrylic acid	224	48 h EC_{50}: 55.0	0.003077	17875	100
Selenastrum capricornutum	(EZ)-3-chloroacrylic acid	224	4 d E_bC_{50}: 0.663	0.003077	215	10
Lemna gibba	(EZ)-3-chloroacrylic acid	224	14 d EC_{50}: 0.26	0.003077	84	10

Table 9.2.9-6. Long-term toxicity exposure ratio (TER_{LT}) values for 3-chloroacrylic acid (3-CACA).

Species	Test substance	Application Rate (kg a.s./ha)	Toxicity Endpoint (mg/L)	PECsw (mg/L)	TER_{LT}	Annex VI Trigger

Species	Test substance	Application Rate (kg a.s./ha)	Toxicity Endpoint (mg/L)	PECsw (mg/L)	TER_{LT}	Annex VI Trigger
Pimephales promelas	(EZ)-3-chloroacrylic acid	224	33 d NOEC: 2.22	0.003077	721	10
Daphnia magna	(EZ)-3-chloroacrylic acid	224	21 d NOEC: 2.53	0.003077	822	10

Long-term toxicity studies have not been conducted for 3-CAA. This metabolite has similar acute toxicity to fish and *Daphnia* as 1,3-D, but the DT_{50} soil of 3-CAA is less than 1 day, the DT_{50} in the sediment-water system is less than 2 days, and the maximum amount formed in the sediment-water study was less than 10 % AR (Vol. 3, B.8.4.1.3.2). Therefore, since the maximum PEC_{sw} for 3-CAA is lower than that of 1,3-D (or 3-chloroacrylic acid), and any exposure to peak 3-CAA concentrations will be transient, chronic testing of 3-CAA with fish and *Daphnia* is not necessary (in accordance with SANCO/3268/2001). RMS agrees and not long term toxicity studies with the metabolite 3-CAA are needed.

In summary, all Tier I TER_A and TER_{LT} values exceed the respective Annex VI triggers (TER_A > 100 for fish and invertebrates, TER_A > 10 for algae and plants, TER_{LT} for fish and invertebrates > 10) and so indicate that 1,3-D and the metabolites 3-chloroallyl alcohol and 3-chloroacrylic acid will not pose an unacceptable risk to aquatic organisms. Buffer zones of 3 m should be implemented to protect aquatic organisms.

B.9.3. Effects on other terrestrial vertebrates.

The EFSA Scientific Report (2006) highlighted the following areas of concern with regards risk to mammals from 1,3-D:

- A high acute risk to earthworm eating and insectivorous mammals is identified for the outdoor uses.
- A residue study on plants is awaited to assess the risk to herbivorous mammals.
- The risk to mammals from inhalation of 1,3-D was considered to be low in the DAR based on the PEC_{air} values presented in the Fate and Behaviour section. If the PEC_{air} concentrations are estimated to be higher than those originally presented in the DAR then the inhalation risk to mammals should be reassessed.

The EPCO expert's meeting indicated that any residue data should be collected under conditions representative of Mediterranean conditions. Field studies have subsequently been conducted to measure residues of 1,3-D in plants (tomato), earthworms and insects under Mediterranean conditions, and these studies are summarised in B.9.1.

B.9.3.1. Effects on terrestrial vertebrates other than birds.

The acute oral toxicity endpoint (LD_{50}) for mammals for use in risk assessment is listed in the EFSA Scientific Report (2006) list of endpoints as 130 mg a.s./kg bw (rat).

The long-term oral toxicity endpoint (NOAEL) is listed in the EFSA Scientific Report (2006) list of endpoints as 2.5 mg a.s./kg bw/d (2 year dietary study in rats). However, the EFSA Scientific Report (2006) also mentions that *"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 LD50 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".*

The PPR Panel opinion on the choice of endpoints to assess the long term risk to mammals was subsequently adopted in 2006 (The EFSA Journal (2006) 344, 1-22). In this opinion the PPR Panel recommended that while all available toxicity studies should be considered when assessing the risk for mammals, the main focus should be on studies that directly assess reproductive performance. Furthermore, some of the more sensitive endpoints, such as histopathological effects, not accompanied by clinical or physiological changes, were not considered relevant as they will have little or no impact on total individual reproductive success. In addition, and probably more appropriate in the case of 1,3-D, the NOEL should be chosen from studies with a treatment duration close to the expected exposure duration in the field, or if longer-term studies are used the NOEL should be chosen for the treatment duration closest to the expected exposure duration in the field. Specifically, for endpoints such as changes in body weight, the PPR Panel recommended to evaluate the endpoint for the exposure period relevant to the ecotoxicological assessment.

The long-term oral toxicity endpoint (NOAEL: 2.5 mg a.s./kg bw/d) listed in the EFSA Scientific Report (2006) was taken from the 2 year dietary study in rats, and since 1,3-D does not persist in food items (as demonstrated in the studies summarised in B.9.1.4) the notifier has been re-evaluated below the chronic toxicity endpoint.

Ecotoxicologically relevant endpoint: Effects on body weight are reported in some non-reproduction studies, ranging from 2 weeks to 2 years in duration, conducted with rats and mice. According to the PPR Panel opinion, effects on body weight may have some relevance to breeding success of wild mammals (e.g. establishing breeding site, pairing and mating) and so should be considered. These are therefore considered further, in the context of the treatment duration closest to the expected exposure duration in the field as advised by the PPR Panel.

RMS agrees with the proposal of body weight as a relevant endpoint.

Short-term exposure (two weeks of duration)

Sub-acute studies have been conducted with rat and mouse in which animals were exposed to Telone over a period of 2 weeks. Rats were dosed at 0, 10, 25, 50 or 100 mg/kg_{bw}/day for two weeks, and a statistically identified decrease in body weight was reported for male rats fed 50 or 100 mg/kg_{bw}/day. There was no statistically identified reduction in body weight for females at any dose, although there was a slight decrease in body weight gain for females fed 50 or 100 mg/kg_{bw}/day. In addition, after one week of the study, feed consumption was decreased for male rats fed 50 or 100 mg/kg_{bw}/day indicating a lack of palatability at these dose levels. The NOEL (body weight) for rats exposed to 1,3-D for two weeks was therefore 25 mg/kg_{bw}/day.

Mice dosed at 0, 25, 50, 100 or 175 mg/kg_{bw}/day for two weeks showed a statistically significant reduction in body weight after 8 days in males and females fed 175 mg/kg_{bw}/day. Only males showed reduced body weight gain at 100 mg/kg/day, and only after 15 days. The reduced body weight gains for males and females fed 175 mg/kg_{bw}/day may have been related to a slight reduction in feed consumption during the first week. The NOEL (body weight) for mice exposed to 1,3-D for two weeks was therefore 50 mg/kg_{bw}/day.

Therefore, since residues in arthropods and earthworms were consistently undetected in the field 2 weeks after treatment with Telone II, short-term dietary studies with mammals of appropriate duration (i.e. 2 weeks) are environmentally relevant, and these studies resulted in a lowest relevant NOEL (body weight) of 25 mg/kg_{bw}/day (rat) and the LOEL was 50 mg/kg_{bw}/day.

90 days exposure

In the rat 90-day oral study (Haut et al., 1993, summarized in the DAR) effects on body weight were only detected after 49 days exposure to 5 and 15 mg/kg_{bw}/day in males. Effects at 50 and 100 mg/kg_{bw}/day were detected in males within 7 days of exposure. Females were less affected, with no effects even after 90 days at 5 mg/kg_{bw}/day, and effects at 15 mg/kg_{bw}/day only detected after 84 days. Following the 4-week recovery period, rats fed 100 mg/kg/day showed definitive signs of recovery in most of the parameters examined including body weight.

Notifier proposal: considering the environmentally relevant exposure period of 2 weeks, the NOEL (body weight), for males, was 15 mg/kg_{bw}/day and the LOEL was 50 mg/kg_{bw}/day.

RMS proposal: Based on the results of this study, the no-observed-adverse-effect level (NOAEL) for male rats and the no-observedeffect level (NOEL) for female rats based on body weight was determined to be 5 mg Telone II/kg body weight/day. This value is suitable for risk assessment refinement.

In the mouse 90-day oral study (Stebbings et al., 1993, summarized in the DAR) the main effect was a decrease in body weight at 50 mg/kg_{bw}/day after 13 days oral administration. The NOEL was 15 mg/kg_{bw}/day. Therefore, considering the environmentally relevant exposure period of 2 weeks, the NOEL (body weight), was 15 mg/kg_{bw}/day and the LOEL was 50 mg/kg_{bw}/day.

2 year study

In the rat 2 year oral study effects on body weight gain in males were only detected after 92 days exposure to 12.5 mg/kg_{bw}/day, while effects at 25 mg/kg_{bw}/day were detected from 15 days. Females showed a consistent reduction in body weight from 549 days at 12.5 mg/kg_{bw}/day, and from 8 days at 25 mg/kg_{bw}/day. Therefore, considering the environmentally relevant exposure period of 2 weeks, the NOEL (body weight) was 12.5 mg/kg_{bw}/day and the LOEL was 25 mg/kg_{bw}/day.

In the mouse 2 year oral study no effects on body weight gain in males or females were detected after 2 years exposure to 2.5 mg/kg_{bw}/day, while effects at 25 and 50 mg/kg_{bw}/day were detected from 9 days in males and 16 days in females. Therefore, considering the environmentally relevant exposure period of 2 weeks, the NOEL (body weight) was 2.5 mg/kg_{bw}/day and the LOEL was 25 mg/kg_{bw}/day.

The results of each of these studies (14-day, 90-day and 2-year) may be considered together, and the effect on body weight considered with respect to an appropriate environmentally relevant exposure period for wild mammals to 1,3-D. Since residues in arthropods and earthworms were consistently undetected in the field 2 weeks after treatment with Telone II, and no residues were detected in seedlings transplanted into treated soil, an appropriate environmentally relevant exposure period for wild mammals can be considered to be 2 weeks. The results of the studies are combined below for rats and mice.

Effect of 1,3-D on body weight of rats during first 2 weeks exposure to 1,3-D in long-term studies. Where effects were observed during first 2 weeks, the first day when an effect was detected is provided in brackets.

Concentration Tested (mg/kg_{bw}/day)	14-day study: Effects on body weight detected (Yes/No)	90-day study: Effects on body weight detected during first 2 weeks exposure (Yes/No)	2-year study: Effects on body weight detected during first 2 weeks exposure (Yes/No)
2.5	-	-	No
5		No	
10	No	-	-
12.5	-	-	No
15	-	No	-
25	No	-	Yes (after 8 days)
50	Yes (after 8 days)	Yes (after 7 days)	-
100	Yes (after 8 days)	Yes (after 7 days)	-

Taking into account the intended use and time of application of 1,3-D, the 90 days oral exposure study is suitable for risk assessment. Based on the results from 90d-oral exposure studies in rat the no-observed-adverse-effect level (NOAEL) for male rats and the no-observedeffect level (NOEL) for female rats based on body weight was determined to be 5 mg Telone II/kg body weight/day. Furthermore, based on the combined results presented above the highest concentration tested in long-

term dietary studies with rats and mice which did not cause effects on body weight is 5 mg/kg_{bw}/day. This estimated NOAEL is used in the wild mammal risk assessment presented below.

In summary, the acute oral toxicity endpoint (LD_{50}) for mammals for use in risk assessment is 130 mg a.s./kg bw (rat) as presented in the EFSA Scientific Report (2006) list of endpoints.

The ecologically relevant reproductive effects endpoint (NAOEL) to be used for refinement in risk assessment is 5 mg/kg_{bw}/day (rat), based effects on body weight.

Inhalation route: The EFSA Scientific Report (2006) lists the NOAEL from a 2-generation inhalation reproduction study as 90 ppm (87 mg/kg bw/day). In addition, the Scientific Report (2006) indicates that no fetal adverse effects were observed at any dose level tested up to a maximum of 120 ppm in an inhalation developmental study in rats, while in rabbits no signs of developmental toxicity were observed at the highest dose tested, 120 ppm. It was concluded in the Scientific Report (2006) that 1,3-D had no adverse effects on reproduction or development following exposure by the inhalation route. Exposures levels have not been changed therefore not further calculations through inhalation route are needed.

Environmentally relevant exposure: Notifier proposes to use 2 weeks as an appropriate environmentally relevant exposure period for wild mammals as step for refinement. This proposal is based on real residue data decline of 1,3-D in earthworms and arthropods (field study conducted in South European conditions, Small, 2007) and that no residues were detected in seedlings transplanted into treated soil (Rawle, 2005). RMS considers the proposal acceptable basis on low residue levels observed at two weeks, and that only one application of Telone is intended. Therefore, long-term exposure is not expected.

RMS opinion is that the environmental relevant exposure of two weeks is considered appropriate for risk assessment.

B.9.3.2 Risk assessment for mammals

Exposure assessment

The EFSA Scientific Report (2006) concluded that the indoor use of 1,3-D in glasshouses is defined as a permanent structure to which entry of mammals (and birds) is limited and hence the risk to mammals (and birds) for the indoor uses is regarded to be low. This will therefore not be considered further.

For outdoor uses, the application of 1,3-D differs significantly from most other plant protection products with the material being injected into the soil profile, typically at a depth of 15 - 20 cm, followed by capping to help seal the soil to maximise efficacy and minimise volatile losses. Typically, the soil is then harrowed to “open” the soil before the crop is planted, with a minimum interval between soil treatment and crop planting of 14 days. This interval between treatment and crop planting is necessary because 1,3-D is phytotoxic at the high initial soil concentrations achieved immediately following injection. Consequently, estimation of the residue of 1,3-D in plants and invertebrates based on modelled soil concentrations does not accurately predict realistic residue levels under field

conditions. For the purposes of a dietary risk assessment, residues in plants and invertebrates collected under field conditions are therefore most relevant since field residues incorporate the various environmental, chemical and biological factors which affect residue uptake, including depth- and time-dependent soil concentrations.

The application technique for 1,3-D differs significantly from most other pesticide products with the material being injected into the soil profile, typically at a depth of 25 - 35 cm, followed by capping to help seal the soil to maximise efficacy, and minimise volatility losses, of 1,3-D.

Consequently, determination of an environmentally relevant bioconcentration factor (BCF) for 1,3-D in soil organisms using models generated for non-volatile chemicals will not adequately simulate realistic residue levels (magnitude or duration) likely to occur in soil organisms. For the purposes of a dietary risk assessment, residues in earthworms collected under field conditions are therefore more relevant than estimates based on artificially determined BCF values. Furthermore, the logPow of 1,3-D is lower that 3, therefore the potential for bioaccumulation is expected to be low. Also, it has been assumed that a mammal will feed exclusively within the treated field, and only on food items containing the maximum residue of 1,3-D.

The EFSA Scientific Report (2006) concluded that exposure of mammals via contaminated drinking water is not expected due to the method of application via soil injection, and the risk to fish eating mammals will be low because the log P_{ow} of 1,3-D is below 3. These exposure scenarios have therefore not been considered further in this assessment. EFSA also concluded that based on measured air concentrations of 1,3-D in the field, there is a low risk to mammals from inhalation of 1,3-D. Since the estimated PEC_{air} concentrations are no different to those originally presented in the DAR, the inhalation risk to mammals does not need to be reassessed.

a) Residue in vegetation

A study has been conducted to determine residue levels of 1,3-D in tomato seedlings following soil injection and is summarised in Rawle (2005). Based on field residue data, the residues of 1,3-D in plants were found to be less than the limit of detection, 0.002 mg/kg. Therefore, in the refined risk assessment for herbivorous mammals, the risk has been assessed based on the field-measured residue of less than 0.002 mg 1,3-D/kg in crop plants following application of Telone by injection at a target rate of 224 kg a.s./ha to bare soil, and minimum pre-planting interval of 14 days. This is a realistic scenario.

RMS agrees with the proposal and for risk assessment the field-measured residue of less than 0.002 mg 1,3-D/kg in crop plants should be used for the refined risk assessment of herbivorous mammals.

b) Residue in invertebrates

In the DAR, exposure of earthworm (and insect) eating mammals to 1,3-D was calculated using the PEC_{soil} and an estimated earthworm bioconcentration factor. Based on the Tier I risk assessment the acute and long-term risk to earthworm and insect eating mammals was considered high. To refine the risk assessments a residue study on earthworms was submitted to the RMS and evaluated, but the EPCO expert's meeting decided that this study could not be used to refine the risk assessment, in part because

it was considered not representative for Mediterranean conditions. In addition, EFSA did not agree that a risk assessment based on measured residue levels of 1,3-D in earthworms could be extrapolated to address the risks to insect eating mammals. Therefore, a further field study has been conducted, in which residue levels of 1,3-D in insects and earthworms were determined following use of 1,3-D under Mediterranean conditions. The results of this study are summarised in Small (2007) and showed that residues were generally below the limit of quantification on most occasions, even immediately after soil injection. The maximum measured residue levels on any sampling occasion were 1.52 mg/kg for insects and 0.40 mg/kg for earthworms. Therefore, in the refined risk assessment for insectivorous and earthworm eating mammals, the risk has been assessed based on the maximum measured field residues following application of Telone by injection at 224 kg a.s./ha.

RMS agrees with the proposal to use the maximum measured residue levels of 1.52 mg/kg for insects and 0.40 mg/kg for earthworms for risk assessment.

Refined risk assessment

The acute and long-term risk assessments have been conducted in accordance with the Guidance Document on Risk Assessment for Birds and Mammals (SANCO/4145/2000) by comparing the lowest toxicity endpoints (NOEL of 5 mg/kg bw/d from 90 d rat study) with the maximum measured residue levels of 1,3-D in plants and invertebrates, and have not taken into account any decline in residues for the long-term assessment.

Exposure:

Table 9.3.2-1. Acute and long-term TER values for mammals.

Diet	Exposure	Measured residue level (mg/kg diet)	FIR/bw	ETE (mg/kg $_{bw}$/day)	Toxicity endpoint (mg/kg $_{bw}$/day)	TER
Plants	Acute	< 0.002	1.39	<0.00278	130	>46700
	Reproduction	< 0.002	1.39	<0.00278	5	> 1798
Insects	Acute	1.52	0.63	0.96	130	135
	Reproduction	1.52	0.63	0.96	5	5.2
Earthworms	Acute	0.40	1.4	0.56	130	232
	Reproduction	0.40	1.4	0.56	5	8.9

In conclusion, the acute risk to herbivorous, insectivorous and earthworm eating mammals is acceptable (TER_A > 10). The reproduction risk to insectivorous, herbivorous and earthworm eating mammals is also acceptable (TER_{LT} > 5) even when using the maximum measured residue of 1,3-D in insects or earthworms. Low risk on mammals is expected if Telone II is applied according to the GAPs.

Further refinement

Furthermore, to evaluate the potential exposure of small mammals to 1,3-D, the presence of mammals on fields treated with Telone II was monitored for the same fields as were used to determine the residues in invertebrates. The presence and relative abundance of small mammals on fields treated with 1,3-D and the surrounding habitat was monitored immediately before Telone injection, immediately after injection, and approximately 14 days after crop planting. The study is summarised below, and showed that the presence of small mammals was reduced, while abundance in the adjacent habitats increased. The study indicated that the reduced presence of wild mammals on the fields was not due to poisoning, but most probably due to the physical disturbance of the field habitat (ploughing, Telone II application, harrowing and tomato seedling planting) since a number of individual animals which were initially found foraging on the field prior to the agricultural operations were subsequently found alive and foraging almost exclusively in the surrounding habitat.

Blanckenhagen, F. (2006)

Title: Presence of small mammals on fields treated with Telone II - Italy. Dow AgroSciences, unpublished report No. 060041, 24 November 2006.

Guidelines: Not applicable; the test was designed for the purpose of the study. The study was conducted under GLP.

A commercial batch of Telone II (Lot No. TF222920T1) was used to treat commercial agricultural fields during this study.

The study was conducted in northern Italy in the Po valley which is a typical Southern European agricultural area where fields may be treated with soil fumigants before crop planting. The aim of this study was to identify those wild small mammal species that may be active on fields during the period immediately following soil injection with Telone II, and to determine their habitat preference including their food source / choice. Since no crop plants are grown at the time of Telone II treatment, the species potentially feeding on the treated field are omnivores (e.g. wood mice) and insectivores (e.g. shrews).

The study was conducted in spring at four field sites in the Po valley around the municipality Lagosanto (Italy). On each of the selected fields, and their adjacent surroundings, small mammal traps were set and the fields were observed with a thermal image camera device once before, once after Telone II (soil fumigation) application, and once after tomato seedlings were planted. The description of the trial areas is summarized below.

Site N°	**Farm**	**Site location Dimension (UTM[1] T33)**		**Trial Area [ha]**	**Description of field trapping area.**	**Description of adjacent habitat trapping area.**
		Easting ↔	**Northing ↕**			
4	Antonietta Farm	276238 276080	4965110 4964700	2.65	1st trapping period: approx. 14	Woodland, with temporary canal and field track between

					days, bare soil. 2nd trapping period: approx. 14 days after injection with Telone II and soil sealed with heavy roller. 3rd trapping period: approx. 14 days after tomato crop planted.	field and woodland.
7	Andrea Farm	275723 275623	4965252 4964888	2.78		Grassland strip with canal bank, separated from field by temporary ditch.
8	Andrella Farm	273844 273721	4962822 4962380	2.55		Tree plantation, with temporary ditch between field and plantation.
9	Rizzati Farm	276904 276653	4957168 4956848	3.23		Narrow row of trees separated from field by temporary ditch.

1) Universal Transverse Mercator coordinate system

Live trapping of small mammals with individual marking and subsequent recapture was conducted over the whole study period to identify those species that may use cultivated fields as a part of their natural home range. In each of the selected sites approx. 70 „Ugglan' live traps were installed on the field and approx. 30 in the surroundings in a shape that suited best the field structure and the adjacent surrounding habitat. Rolled oats, hazelnuts and cucumber were used as bait. Traps were activated in the evening and checked in the morning. Each captured animal was individually marked, and species, sex, weight, reproductive state, animal ID, location (trap) and date of trapping were recorded.

In addition, the occurrence of small mammals on study fields was quantified by „scan sampling' observations using a thermal image camera. A defined area inside the field in the form of a circular arc (area scanned: 1080 m^2) was observed during one complete night (starting at sunset and ending at sunrise) with scans carried out every 10 minutes. Scans were carried out on each field once before, once after Telone II application and once after tomato seedlings had been planted.

Agricultural operations on the fields were recorded throughout the monitoring period. Climatic conditions (rainfall, temperature) over the study period were obtained from the nearest climate station.

The data were analysed to determine the relative abundance of small mammal species on agricultural fields and in the surrounding habitats during the period immediately before fumigation, immediately after fumigation, and approximately 14 days after a typical vegetable crop (in this case tomato seedlings) is planted.

The results of study are summarized below.

Marked individuals	***Apodemus sylvaticus***	***Microtus savii***	***Crocidura sp.***
Site 4	16	1	
Site 7	49		1
Site 8	18		
Site 9	19	2	
Total	102	3	1

Trapping efficiency[1] of *Apodemus sylvaticus*	**Before Telone**		**After Telone**		**Tomato planted**	
	Field	**Surrounding**	**Field**	**Surrounding**	**Field**	**Surrounding**
Site 4	0.87	5.42	0.69	8.75	0.23	11.67
Site 7	8.96	8.18	1.95	25.15	0.00	30.00
Site 8	0.85	2.61	1.29	3.21	0.00	5.98
Site 9	0.20	4.55	0.00	28.75	0.00	12.22
Mean	2.72	5.19	0.98	16.47	0.06	14.97

1) captures/100 trap nights

Scan sampling observation[2]	**Mammals < 50 g**	**Mammals > 50 g**	**Mammals < 50 g**	**Mammals > 50 g**	**Mammals < 50 g**	**Mammals > 50 g**
Site 4	0.00	0.00	0.00	0.00	0.00	0.15
Site 7	1.45	0.00	0.00	0.00	0.00	0.00
Site 8	0.28	0.00	0.00	0.14	0.00	0.00
Site 9	1.66	0.00	0.00	0.00	0.00	0.16
Mean	0.85	0.00	0.00	0.04	0.00	0.08
90%tile	1.60	0.00	0.00	0.10	0.00	0.16
50%tile	0.87	0.00	0.00	0.00	0.00	0.08

2) individuals/scan/ha

The number of marked individuals on the study sites indicated that the focal species (i.e. the most frequently occurring and abundant species) in this agricultural landscape was the wood mouse, *Apodemus sylvaticus*.

The trapping efficiencies in the surrounding habitats were generally higher than in the field plots with one exception on site 7 prior to Telone II application. Following Telone II application and tomato planting the trapping efficiencies stayed low on the fields and increased in the surrounding habitats. This indicates a habitat preference for the surrounding habitats.

The scan sampling observation showed low presence of mammals in general on the study sites. The main focus was on small mammals (< 50 g), which were only observed before Telone II application on the fields. Following Telone II application and tomato transplanting only large mammals (> 50 g, rabbit, *Oryctolagus cuniculus* and coypu, *Myocastor coypus*) were occasionally observed crossing the scan area.

The wood mouse, *Apodemus sylvaticus*, was clearly the dominant small mammal species at all four sites sampled in this study. In spring, it was the most captured and observed species in the agricultural landscape around Lagosanto (Italy).

Before the agricultural fields were treated with the soil fumigant Telone II wood mice were regularly captured in small numbers on the fields and generally more so in the surrounding uncultivated landscape. During the scan sampling of the agricultural land using a thermal image camera small mammals were observed to be active on the fields.

Following field injection with Telone II, and soil sealing, the surface of the fields was plane and compressed. Wood mice were caught on the fields, but the trapping efficiency on the fields was lower than in the surrounding habitats of all sites and no small mammals were observed on the fields during scan sampling.

Following planting of tomato seedlings, two weeks after Telone II injection, there was still no appreciable vegetation cover on the fields. The trapping efficiency further decreased on all fields and no small mammals were observed during scan sampling. In the surrounding, uncultivated, habitat numbers of wood mice remained high.

Since a number of individual mice were caught repeatedly throughout the study it was possible to get an indication of their survival and preferred foraging habitat over the monitoring period, and this is summarised below:

a) At Site 4, three individuals were captured before and after Telone II injection.

b) One mouse was captured on the field prior to Telone II injection on two occasions, but after soil injection the same animal was only captured in the surrounding habitat (on six separate occasions) and was still alive 25 days after soil treatment.

c) A second mouse was captured on the field the day before Telone II injection and again six days after injection. However, it was also caught in the surrounding habitat following soil injection (on eleven separate occasions) and was still alive 26 days after soil treatment.

d) One wood mouse was captured only in the surrounding habitat before and after soil treatment.

e) At Site 7, fourteen individuals were captured before and after Telone II application, of which eight were captured before Telone II application on the field. One mouse was captured on the field eight days before soil treatment and again 10 days after soil treatment in the surrounding habitat. The second mouse was captured at the field edge three days before soil treatment, and then captured on eight separate occasions in the surrounding habitat, before being captured alive on the field on the final occasion 19 days after soil treatment. The third mouse was captured twice on the field before soil treatment, and then recaptured on nine separate occasions in the surrounding habitat alive on the final occasion 24 days after soil treatment. The fourth mouse was captured on the field three days before soil treatment and again six days after soil treatment, but subsequently captured on seven separate occasions only in the surrounding habitat, being alive on the final occasion 24 days after soil treatment. The fifth mouse was captured exclusively on the field on nine separate occasions, and was alive and active on the field 9 days after soil treatment. The sixth mouse was captured on the field three days before soil treatment and then captured on nine separate occasions in the surrounding habitat, being captured alive on the final occasion 24 days after soil treatment. The seventh mouse was captured exclusively on the field on seven separate occasions, and was alive and active on the field 11 days after soil treatment. The eighth mouse was captured exclusively on the field on three separate occasions, and was still alive and active on the field 4 days after soil treatment. The ninth mouse was captured three days before Telone II application in the surrounding habitat and then captured six days after Telone II application on the field and subsequently on eight occasions in the surrounding habitat, being alive on the final occasion 24 days after soil treatment. The other 5 wood mice were captured before and after Telone II application only in the surrounding habitat.

f) At Site 8 only a single wood mouse was repeatedly captured before and after Telone injection. The first capture occurred two days before Telone II application in the surrounding habitat, and the individual was then recaptured three times on the field and 10 times in the surrounding habitat after Telone II application; the final capture occurring 25 days after soil treatment.

g) At Site 9 four individuals were captured before and after Telone II.One mouse was captured once on the field prior to Telone injection and four times in the surrounding habitat, but after soil injection the same animal was only captured in the surrounding habitat (on 6 separate occasions) and was still alive 11 days after soil treatment.The other three animals were only captured in the surrounding habitat before and after Telone II application.

h) These results for individual mice captured before and after agricultural operations (including Telone II injection) illustrated that the overall reduction in abundance of the mouse population on the fields was not due to poisoning of the animals (no dead mice were observed on the fields), but due to a change in foraging behaviour as the mice showed preference for the surrounding habitat rather than the fields. This was probably due in part to the lack of crop cover, and also due to the ongoing disturbance associated with the intensive agricultural practices of ploughing, Telone injection, soil sealing, and then crop planting 14 days later.

In conclusion, the presence of small mammals on bare fields in spring appeared to depend on agricultural practices. Ongoing disturbance through agricultural practices like Telone II application and tomato seedling planting appeared to reduce the preference of wood mice for the bare fields,

resulting in an increase in foraging activity in the adjacent habitats. The planting of tomato seedlings did not immediately increase the presence of wood mice on the fields.

RMS assessment: the study is considered acceptable for refinement; the field study is conducted under realistic scenarios in the Mediterranean area where Telone II is intended to be used. The relative abundance of small mammal species (e.g. wood mice) on agricultural fields and in the surrounding habitats during the period immediately before fumigation, immediately after fumigation, and approximately 14 days after a typical vegetable crop (in this case tomato seedlings) is planted were analysed. Based on available data it is expected a low preference of wood mice for the fields where Telone II is applied.

It can be concluded that exposure and risk posed by Telone II to insectivorous, herbivorous and earthworm-eating mammals will be low if Telone is applied according to GAPs.

B.9.4. Effects on bees.

The EFSA highlighted the following critical area of concern with regard to risk to bees from 1,3-D:

- As the active substance can be found in the air even at distances of 800 m from the field, 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.

A study to determine the toxicity of 1,3-D vapour to bees has subsequently been conducted and is summarised in B.9.4.1.

B.9.4.1. Acute toxicity.

No acute toxicity studies are summarised in the DAR. The EFSA Scientific Report (2006) concluded that "*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*."

However, the RMS and EFSA considered that an inhalation study with bees should be conducted as the active substance can be found in the air outside of the treated field and under such circumstances bees may be exposed. Therefore, an inhalation toxicity study with bees has been conducted and is summarised below.

Fussell, S. (2005)

Title: An inhalation toxicity test to determine the effect of Telone II on adults of the honeybee, *Apis mellifera*, under laboratory conditions. Dow AgroSciences, unpublished report No. 050348. Not specific guidelines and the study was conducted under GLP.

Telone II, nominally containing 975 mL/L 1,3-dichloropropene (Lot No. SA 272920T1. Batch No. TSN 104897).

Worker honeybees (*Apis mellifera* L.: Hymenoptera, Apidae) from a commercial beekeeper (Roselea Apiaries, East Wellow, Hampshire) were exposed to vapours of Telone II for a 6-h period and their survival then monitored over the remainder of a 48-h period.

For the test the bees were confined in cages in groups of ten, with three replicates (i.e. 30 bees) per treatment rate. To expose the bees, the individual cages were lowered into cylinders of clear acrylic tubing and a measured droplet of the volatile test item placed at the base of each cylinder before a lid was placed over the top to seal the units. After 6 h the cages were removed from the cylinders and placed in a clean-air environment for the remainder of the bioassay. Assessments of the condition of the bees were made up to 48 h after treatment.

The treatments evaluated included five application rates of the test item (nominally equivalent to 151, 76, 38, 19 and 9.5 g Telone II per m^3), a toxic reference treatment of Diclorcal 50 (a 500 g/L EC formulation of dichlorvos, applied at a rate equivalent to 1.6 µL per m^3) and an untreated control treatment

Analyses were carried out on the treated air in an attempt to quantify the vapour concentrations to which the bees had been exposed. For the test arenas in which the bees had been placed, samples were taken 1 h after treatment application. For additional „dummy' arenas (one replicate per treatment) that were set up without bees present (control, 151, 38 and 9.5 g/m^3 treatment rates of Telone II only), air samples were also taken at 0.5, 1, 2 and 6 h after treatment.

Assessments were made for bee mortality after 48 h (for determination of the LC_{50} of Telone II).

Statistical analysis of the 48-h mortality data was by Fisher's Exact Test and probit analysis to determine the median lethal concentration (LC_{50}).

The results for the test item and control treatments are summarised below. The toxic reference treatment resulted in 100% mortality after 6 h.

Effects on the honeybee, Apis mellifera, exposed to Telone II in a laboratory trial

	Nominal Dose Telone II (mg/m^3)	Mean amount Telone II detected (mg/m^3)		Mortality at 48 h [%]	Corrected mortality [c] [%]
		Arenas with bees [a]	Arenas without bees [b]		
Control (untreated)	-	None detected #	~	7	-
Telone II	**151321**	5548	30566	100	100
	75661	643	~	100	100
	37830	263	7091	100	100
	18915	813	~	47	46
	9458	379	115	7	0

a) Samples taken from arenas containing bees 1 h after treatment (mean of 3 replicates per treatment).
b) Samples taken from treated arenas not containing bees at 0.5, 1, 2 and 6 h after treatment (mean of four values, one replicate per treatment).
c) Mortality corrected for any control treatment deaths using Abbott's formula.
Minimum possible detection rate = 20 mg/m^3.
~ No sample taken

Mean measured air concentrations of Telone II in arenas with and without bees were significantly lower than nominal concentrations, and ranged between 115 and 30566 mg/m^3. In arenas without bees measured air concentrations correlated with nominal concentrations, though there was significant variability in concentrations over the 6 h exposure duration. The 1 hour measured air concentrations in arenas with bees showed no correlation with nominal concentrations, or with the subsequent bee response in the same arenas. High spatial and temporal variability in measured air concentrations was observed and notifier proposes to calculate LC50 after 48 hours expressed as nominal air concentrations. RMS did not agree with this proposal and toxicity values for risk assessment should be calculated basis on mean measure air concentrations.

The 48-h inhalation LC_{50} of Telone II to worker honeybees, *Apis mellifera* was nominally 18907 mg/m^3 (95% confidence limits = 16351 and 22044 mg/m^3), this correspond to a mean measured concentration approximately of 831 mg/m^3) at 1h, not measures are available for 6h).

At the nominal concentration of 9458 mg/m^3 mortality was not significantly different from controls; this corresponded to a mean measured air concentration at 1 h of 379 mg/m^3 in the arenas containing bees, and a 0.5 – 6 h mean measured concentration of 115 mg/m^3

B.9.4.2. Bee brood feeding test.

Telone products are applied sub-soil, pre-emergence and, therefore, exposure for bees is unlikely. Furthermore, 1,3-D is not an insect growth regulator. Consequently, a bee brood feeding study has not been conducted.

B.9.4.3. Residue test.

Telone products are applied sub-soil, pre-emergence and, therefore, exposure of bees to residues on plants will not occur.

B.9.4.4. Cage tests.

Telone products are applied sub-soil, pre-emergence and, therefore, oral and contact exposure of bees will not occur. Maximum measured concentrations of 1,3-D in the air are generally 1000-fold less than the bee $NOEC_{inhalation}$, and indicate that the risk to bees via inhalation will also be low. Thus cage tests with bees are not necessary.

B.9.4.5. Field tests.

Telone products are applied sub-soil, pre-emergence and, therefore, oral and contact exposure of bees will not occur. Maximum measured concentrations of 1,3-D in the air are generally 1000-fold less than the bee $NOEC_{inhalation}$, and indicate that the risk to bees via inhalation will also be low. Thus field tests with bees are not necessary.

B.9.4.6. Tunnel tests.

Telone products are applied sub-soil, pre-emergence and, therefore, oral and contact exposure of bees will not occur. Maximum measured concentrations of 1,3-D in the air are generally 1000-fold less than the bee $NOEC_{inhalation}$, and indicate that the risk to bees via inhalation will also be low. Thus tunnel tests with bees are not necessary.

B.9.4.7. Risk assessment to bees

The EFSA highlighted that 1,3-D can be found in the air even at distances of 800 m from the field, and so the risk from inhalation exposure should be assessed.

Subsequently, an inhalation test with bees (*Apis mellifera*) has been conducted with Telone II (95.9% w/w 1,3-D) in which bees were exposed to vapours of the test material for 6 hours and their survival monitored over the remainder of a 48 hour test period (Fussell, S., 2005). During the test the air within the test chambers was sampled to quantify the vapour concentrations to which the bees were exposed. The study resulted in a 48-h inhalation LC_{50} of 1,3-D to worker honeybees of 813 mg/m^3 based on means measured air concentrations at 1h. The nominal concentration at which mortality was not significantly different from controls (i.e. $NOEC_{inhalation}$) was 315 mg/m^3. The mean measured air concentrations were significantly lower than nominal concentrations and gave a 0.5 – 6 h mean measured air concentration at the $NOEC_{inhalation}$ of 115 mg/m^3.

$NOEC_{inhalation}$ of 115 mg/m^3 for Telone II (equivalent to 110 mg 1,3-D $/m^3$), based on mean measured air concentrations, may be used as an estimate of actual air concentrations of 1,3-D which are not acutely toxic to bees.

For the purposes of a Tier I assessment of the potential inhalation risk to bees the $NOEC_{inhalation}$ of 115 mg a.s./m^3 may be compared to the potential exposure concentrations of 1,3-D in the air following typical use of Telone II. The EFSA Scientific Report (2006) List of Endpoints for 1,3-D indicates that mean measured air concentrations of 1,3-D are generally in the range 0.001 - 0.1 mg/m^3. The maximum reported air concentration is 3.415 mg a.s./m^3 (Harquahala Valley, Arizona,US) at 25 m from a field treated with 112 L Telone II/ha (= 132 kg as/ha). This maximum air concentration is equivalent to a *pro rata* concentration of 5.793 mg/m^3 assuming an application rate of 190 L/ha (190/112 x 3.415 = 5.793 mg/m^3). An application rate of 190 L/ha is equivalent to 224 kg as/ha. Based on these measured field data, it is clear that the bee $NOEC_{inhalation}$ is generally more than 1000-fold higher than air concentrations measured under field conditions (0.001 - 0.1 mg/m^3), and 19-fold higher than the calculated maximum measured air concentration in all reported studies ($NOEC_{inhalation}$/maximum PEC_{air} = 115/5.793 = 19).

The approach presented above is expected to be highly conservative, as this compares the $NOEC_{inhalation}$ from a study in which bees were confined to 1,3-D vapours for 6 hours to the maximum

reported concentrations of 1,3-D in air. Under environmentally relevant conditions foraging bees will not be confined to maximum air concentrations for such long periods.

In summary, since measured 1,3-D air concentrations are consistently lower than those demonstrated to be non-toxic to bees, usually by more than 1000-fold, it can be concluded that the risk to bees from 1,3-D vapour following the proposed use of Telone II as a soil fumigant will be acceptable.

B.9.5. Effects on other arthropod species.

The EFSA Scientific Report (2006) highlighted the following areas of concern with regard to risk to non-target arthropods other than bees from 1,3-D:

- Since the extended laboratory studies on soil arthropods (*Folsomia candida*, *Poecilus cupreus*, *Pardosa* spp. and *Aleochara bilineata*) were only evaluated for soil that had been aged for 1 day prior to exposure, the immediate impact at application is not known. Furthermore, given the observed effects on *Folsomia candida* under laboratory test conditions, the risk to non-target arthropods for the outdoor uses should be addressed further.

EFSA concluded that the risk to non-target arthropods for the outdoor uses can only be concluded once additional field data become available. A study has subsequently been conducted to assess the risk to non-target arthropods under typical Southern European field conditions and is summarised in section B.9.5.2.

B.9.5.1. Extended laboratory studies

Telone Injected is applied sub-soil and pre-emergence/planting of crop, therefore, exposure for foliage dwelling non-target arthropods is unlikely at the time of application. As no residues are present in crops planted into pre-treated soil, again there will be no subsequent exposure to foliage dwelling non-target arthropods. The arthropods primarily at risk are those present in or on the soil. Due to the methods of application used for soil treatment with Telone Injected there is no risk to non-target arthropods present in the off-field area, but only to those within the treated area.

Therefore, the relevant soil dwelling non-target arthropods species tested under extended laboratory conditions were a collembolan (*Folsomia candida*) and a soil dwelling predatory mite (*Hypoaspis aculeifer*), for which testing methods were available. In addition to these, three further crop relevant species were tested, *Poecilus cupreus* (carabid beetle), *Aleochara bilineata* (staphylinid beetle) and *Pardosa* spp. (wolf spider).

The results of these studies are summarised below:

Effects on other arthropod species under extended laboratory conditions (as reported in EFSA Scientific Report (2006) list of end points).

Species	Stage	Test Substance	Dose (kg a.s./ha)	End point	Effect (%)
Folsomia candida	Adult	Telone	329	Mortality 1 DAT	78

Hypoaspis aculeifer	Adult	Telone	329	Mortality 1 DAT	18
Poecilus cupreus	Adult	Telone	329	Mortality 1 DAT	3
Pardosa spp.	Adult	Telone	329	Mortality 1 DAT	0
Aleochara bilineata	Adult	Telone	329	Mortality 1 DAT	24

In the study to determine the toxicity of 1,3-D to collembola (*Folsomia candida*), Telone II treated soil aged for approximately 3 weeks was not toxic with no effects on survivorship or fecundity.

B.9.5.2. Field tests.

A field study conducted by Ellis (2001) to determine the incidence of earthworms and microarthropods in soils treated with Telone was not considered valid for the purposes of conducting a risk assessment by the RMS. The RMS considered that the number of animals was too low, hence in the statistical analyses the variability of data is very high and so the results must be treated with caution.

Subsequently a study has been conducted to evaluate the effects of Telone II, applied at 190 L/ha (224 kg a.s./ha), on soil arthropods (and earthworms) under typical conditions of use in Southern Europe. This study is summarized below.

Reference: Small (2006), Study number No 05/09 **GLP statement**: No

Type study: Ground and soil dwelling invertebrates and earthworms field study

Guideline: ISO 11268-3: 1999 and Candolfi et al. (2000)

Year of execution: 2005-2006. **Acceptability**: Acceptable

Test substance: Telone II

Sub-stance	Species	Location	Soil Type	OM (%)	Doses (L/ha)	Time of application	Duration (months)	Criteria	Significant effects	Recovery
Telone II	Earthworm field fauna	Agricultural land of 4ha on the foodplain of the Reno river Bologna	Coarse loamy sand to sandy loam with pH 7.61-7.83	1-0,7	Control		12	Species composition and abundance and biomass of earthworms, collembolan and surface active arthropods (spiders and	N	--
	Macroarthropod field fauna			2-1,52	Control		12		N	--
	Microarthropod field fauna			3-1,09	Control		12		N	--
				4-0,92	Control		12		N	--
				5-1,37	Control	27/05/05	12		Y (earth.)	Yes
				6-0,80	Control	27/05/05	12		Y (earth.)	Yes
				7-1,23	Control	27/05/05	12		Y (earth.)	Yes

8-1,16	199.34 199.34 199.34 199.34	27/05/05	12	beetles)	Y (earth.)	yes

2: Not all data reported, the methodology and/or description are less in accordance with internationally accepted test guidelines.

2. Extended summary

Reference: Small 2006. Telone II: Effects of Field Application on Above ground and Soil-Dwelling Invertebrates and Earthworms.

Guidelines: ISO 11268-3: 1999 and Candolfi et al. (2000). In accordance with Sponsor, this trial is not GLP compliant.With the exception of Telone II application, which will be carried out by the farmer, and the arthropod taxonomy which will be carried out by University experts, and the collembola/earthworm taxonomy wich will be carried out by SynTech Research France, all other aspects of this trial will be carried out according to international GLP guidelines.

Test substance: telone II, batch nr: 2 tanks with SL212920T1, 6 tanks with TC252920T1

Description of field trial and maintenance

The field study was performed from June 2005 until June 2006 on an area of agricultural land of about 4 ha situated on the floodplain of the Reno River near Bologna (Lat. 44° 44' 07.50" N; Long. 11° 36' 48.15" E). The site was under a crop of alfalfa prior to the trial and no pesticides had been applied to it during the previous 5 years. The soil type was loamy sand OM content 0.7-1.52%, pH 7.61-7.83. Not pesticides were applied for crop maintenance during the previous 5 years, during which crops of alfalfa were grown on the field following local agricultural practices, while previously, six and seven years before trial initiation, it had been cultivated respectively with sugar beet and wheat crops.

Tomato plants (*Lycopersicon esculentum* Mill.) were transplanted at 21 DA-A (days after application; 17/06/05). Transplanting was carried out by specialized personnel using a traditional six-row hauled transplanting machine. The plants were of the ALICAN 228F cultivar, this cultivar being commonly grown in the Region Emilia-Romagna and were provided by the nursery HABITAT, at San Vito di Ostellato (FERRARA). Fertiliser, herbicide, fungicide and insecticide application were required to maintain the crop in a good condition, and were performed by using the same tools normally employed by the farm owner for that task. These chemical interventions and their usage are summarised below (Tables 2 and 3).

Table 2. Fertilisers applied during the trial to ensure good tomato crop health.

No.	Date	Elements	Quantity	Unit
1	17/06/05	IRON CHELATE	5	KG/HA
2	29/06/05	IRON CHELATE	5	KG/HA
3	16/07/05	NPK 20-20-20 (AGRIPLANT - Agrimport) + MICROELEMENTS	10+5	KG/HA
4	31/07/05	IRON CHELATE	5	KG/HA
5	21/02/06	AMMONIUM NITRATE (N=19-21%)	150	KG/HA
6	26/04/06	UREA (N=46%)	120	KG/HA

Table 3. Pesticide interventions required for good tomato (from No 1 to No 10) and winter wheat crops (from No 11 to No 14) health and their usage during the trial

No.	Date applied	Maintenance treatment name	Form conc	Form unit	Form type	Rate	Rate unit	Reason for application
1	28/06/05	FORUM R "Dimetomorph+Cu"	46	%	WP	350	G/100 L	Fungus control
2	28/06/05	STRATOS ULTRA "Cicloxidim"	100	g/l	EC	1.2	L/HA	Weed control
3	28/06/05	SENCOR WG "Metribuzin"	35	%	WG	0.8	KG/HA	Weed control
4	28/06/05	TITUS "Rimsulfuron"	25	%	WG	25	G/HA	Weed control
5	07/07/05	CONFIDOR 200 SL "Imidacloprid"	200	g/l	EC	75	ML/100 L	Insect control
6	07/07/05	FORUM R "Dimetomorph+Cu"	46	%	WP	350	G/100 L	Fungus control
7	17/07/05	FORUM R "Dimetomorph+Cu"	46	%	WP	350	G/100 L	Fungus control
8	24/07/05	CURZATE R DF "Cymoxanil+Cu"	43.95	%	WC	300	G/100 L	Fungus control
9	24/07/05	LASER "Spinosad"	480	g/l	SG	30	ML/100 L	Insect control
10	03/08/05	CURZATE R DF "Cymoxanil+Cu"	43.95	%	WG	300	G/100L	Fungus control
11	07/11/05	ROUNDUP BIOFLOW "Glyphosate"	360	G/L	SC	2	L/HA	Weed control
12	28/04/06	HORIZON "Tebuconazolo"	250	G/L	EW	0.8	L/HA	Fungus control
13	10/05/06	BUMINAL "various proteins"	29.7%		WG	0.9	L/HA	Insect control
14	10/05/06	KARATE XPRESS "Lambda-Cyhalothrin"	2.5%		WG	0.4	L/HA	Insect control

Good maintenance also required 12 irrigations (25 mm) executed with a water cannon sprayer or by drip irrigation (from 6/06/05 up to 24/08/2005). The tomato crop was harvested from 09/09/05 to 11/09/05. This was followed by a shallow disc harrowing of the whole trial area on 09/10/05. No further tillage or irrigation was carried out on the field study site between these days and the final arthropod and earthworm samplings, 366-367 days after Telone II treatment. A second crop of winter wheat (*Triticum aestivum* L.) was seeded on 09/11/05. Seeds were of the GUADALUPE 2° variety and which had been pre-treated with PANOCTINE L "Guazatine" 190 g/100 KG seed.

Application, replicates

Application took place on 27/05/2005, using a machine used for application of Telone II (trademark OLIVER – John Blue Co. Huntsville, ALA. US; model FU551, code 704, serial no. 850) hauled by a FIAT 780 tractor. Telone II fumigant was injected into the soil of the four selected trial plots using a dispensing machine (trademark OLIVER – John Blue Co. Huntsville, ALA. US) hauled by a tractor. The actual treatment application rate was 199.34 L/ha compared to the required application rate of 190 L/ha. Therefore, the percentage deviation between the actual quantity of Telone II applied and the quantity which should have been applied was 4.91%. A shallow harrowing was carried out on the untreated plots two days after application of Telone II to the treated plots to replicate the physical harrowing action of the Oliver dispensing machine. This ensured that, as near as was possible, soil invertebrates in both treated and untreated plots experienced the same soil tillage. The OLIVER dispensing machine performs Telone II injection by first cutting furrows into the ground through the ripping action of a rake of 7 blades. The chemical then pours down into the furrows by means of a device consisting of a pump serving many tubes which run down the back of each blade. Finally, a roller at the back of the machine passes over filling in the furrows, thus leaving the Telone II buried below the ground, to a depth of 25-30 cm. The area of land selected for the study measured 320 m in length by 98 m in width. This area was in turn divided into 8 rectangular plots each measuring 40m x 98 m. Four of the plots were randomly selected for treatment with Telone II and the remaining four plots were untreated.

Soil organisms sampling

Seven assessments of the invertebrate fauna (earthworms, macro-arthropods, micro-arthropods) on the trial site were scheduled: 4 days before application; 20 days after application; 5 weeks after application; 3, 6, 9 and 12 months after application. Four earthworm samples were taken from each of Telone II treated and untreated plots by manual digging on selected quadrats of 1 m^2 to a depth of 50 cm. This manual method of worm extraction was employed after the other proposed method of extraction, namely pouring a diluted formaldehyde (0.2%) solution over a selected soil area of 1 m^2 quadrat, proved less effective. The collected worms were transferred alive in containers together with some earth, then they were sent within 48 hours to the identification laboratory, SynTech Research France, Le Bois de Loyse 71570 La Chapelle de Guinchay, France, where they were taxonomically identified, weighed and counted.

Three pitfall traps (plastic pots 8 cm in diameter and 10 cm deep) were set in each replicate plot for the sampling of soil-dwelling macroarthropods. Five samples of soil microarthropods (Collembola) were taken from each replicate plot by soil cores 8 cm in diameter and 8 cm in depth. These plots were sunk into the ground such that the lip of each pot was level with the surface of the soil. To aid in the resetting of the traps, „liner' tubes were inserted into the soil and the plastic pitfall trap pot sat inside this. To set the traps, the cup was placed in the ground and a 1% detergent solution was poured into it to give a depth of 2 cm. A small cover was set up approximately 10 cm above the pitfall trap to prevent rain or irrigation water from entering the trap. The diameter and depth of soil cores was increased to 25 cm diameter and 25 cm deep for the sampling at 3 months and subsequently to increase the chances of obtaining samples containing Collembola. Identification and counting of soil organisms was carried by SynTech Research France and experts at the Agricultural University of Bologna, Italy. Microarthropods were extracted by means of a Berlese apparatus and subsequently identified.

All samples were taken from a zone measuring 20 m x 58 m in the centre of each field trial plot to minimize any possible edge effects associated with plot treatments and with features such as drainage ditches around the outside of the field trial site.

Analysis and statistical analysis of data

The total number of earthworms (*Allolobophora chlorotica*, *Allolobophora caliginosa* and *Allolobophora longa*) and the total weight of earthworms extracted from each replicate soil sample from each of the untreated and Telone II treated plots at each sampling interval was used for statistical analysis. Similarly, the number of beetles, ants, spiders and the total number of arthropods per pitfall trap (which also included the number of crickets and centipedes) in untreated and Telone II treated plots at each sampling interval was used for statistical analysis. The number of Collembola (*Hypogastrura brevis*; species of the family Isotomidae; and species that could not be identified to family or species level) per soil core in untreated and Telone II treated plots was also statistically analysed. Raw data are summarized in the attached file (Appendix 2).

For statistical analysis of all data, residuals of data were first tested for normality using the Kolmogorov-Smirnov test. Data for which residuals were normally distributed were then subjected to a one-way analysis of variance. Simultaneously, a check was run to
obtain confidence intervals for all pairwise differences between level means using the Tukey-Kramer method) with a family error rate of 0.5. Finally, an F-test and Levene's test of equal variance was run. The statistical model held for all data so tested.
For data where the null hypothesis of a normal distribution of residuals was rejected, a Box-Cox transformation was performed and the graphical output used to determine the appropriate data transformation. Having applied the transformation, residuals of data were again tested for normality using the Kolmogorov-Smirnov test. One-way analysis of variance, Tukey-Kramer test and tests of equal variance were then applied. The statistical model held for all data so tested except for the weight of earthworms extracted from soil samples 40 days after Telone II treatment, the number of ants in pitfall traps 6 months after Telone II treatment and the number of Collembola in soil cores 9 months after Telone II treatment as there were too many zero values for a statistically valid test, even when data were transformed. All statistical analyses were carried out using MINITAB statistical software (release 13.31).

RESULTS

Environmental conditions

Maximum and minimum air temperatures and rainfall measurements were obtained from the Regional Meteorological Service at San Pietro Capofiume (BO), Italy which is 4.5 km from the field study site. Maximum and minimum soil temperatures were obtained from a HOBO outdoor data logger buried at a depth of 20 cm on the field study site. During June, there were many days without rainfall and with high temperatures which

necessitated frequent irrigation whilst the transplanted tomato crop became established. Infrequent and low rainfall during July and August required further irrigation. Temperatures during the day reached a peak at the end of July and generally declined thereafter (Figure 9.5.2-1). However, night time temperatures peaked earlier at the end of June.

The mean soil temperatures (Figure 9.5.2-2), recorded by a HOBO outdoor data logger buried 20 cm below the soil surface, reached a peak at the end of June and generally declined thereafter. The profile of mean soil temperature, as would be expected, generally fell between that of the maximum and minimum air temperatures but was much less variable than either.

Figure 9.5.2-1. Meteorological data from the start of the study to date the end of October 2005 supplied by the Regional Meteorological Service at San Pietro Capofiume, 4.5 km from the field site.

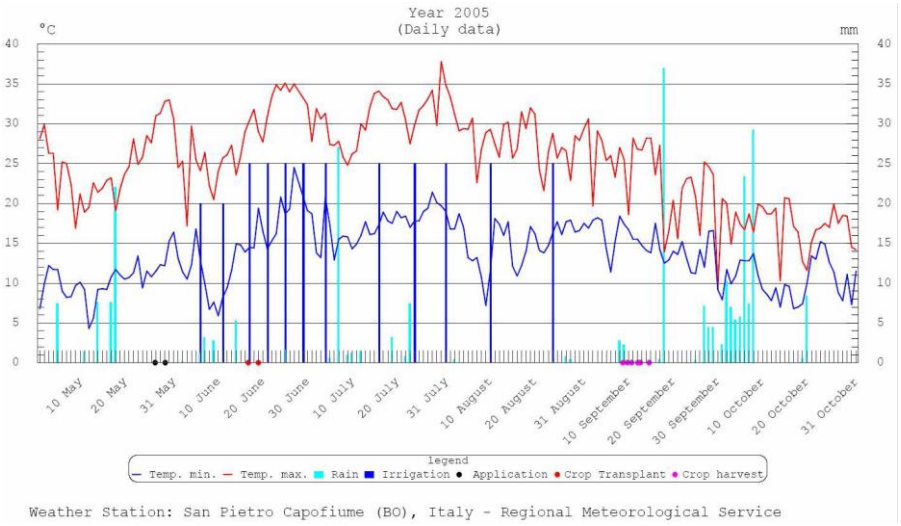
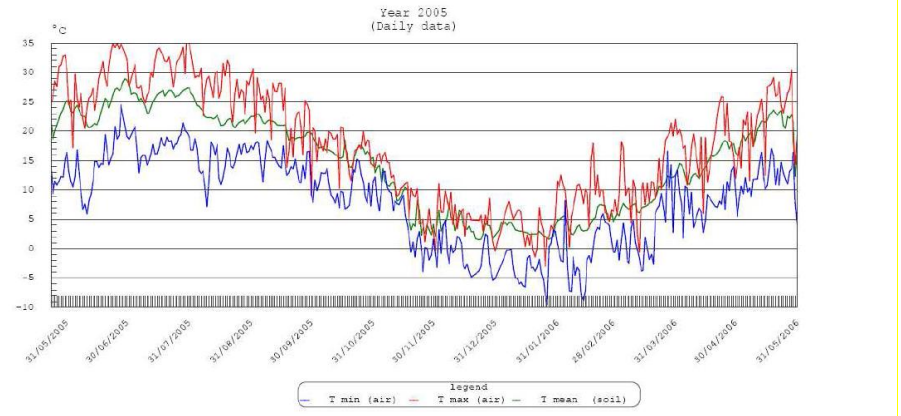


Figure 9.5.2-2. Mean soil temperatures recorded by a HOBO outdoor data logger buried 20 cm below the soil surface of the field site. Maximum and minimum air temperatures, supplied by the Regional Meteorological Service at San Pietro Capofiume, 4.5 km from the field site, are included for ease of comparison.



Biological system

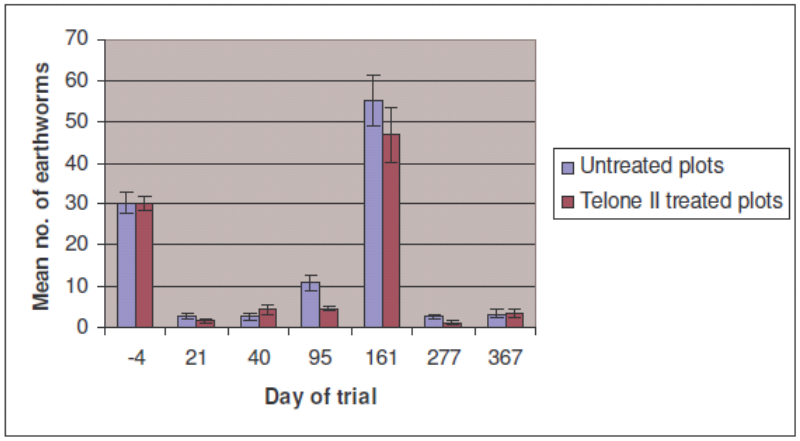
Earthworms

Three earthworm species were found at the site (*Allolobophora chlorotica*, *Allolobophora caliginosa* and *Allolobophora longa*) all of which are common in agricultural soils across Europe. *A. chlorotica* and *A. caliginosa* are endogenic geophagous worms living near the soil surface in sub-surface temporary borrows, *A. longa* is an anecic species which dwells in permanent burrows and feeds on organic matter on the soil surface; thus the species present at the site represented the two key ecological groups present in agricultural soils.

Prior to treatment, the dominant earthworm species present in all plots was the anecic species *A. longa*. Its presence and abundance could have been influenced by alfalfa being the previous crop at the site. Prior and post treatment routine agricultural operations were performed at the site to all plots: these included ploughing and harrowing. *A. longa* is also known to enter obligatory diapause during May to October. This may have also contributed to lower numbers of worms across the whole site as it was initially the most abundant species. *A. chlorotica* and *A. caliginosa* do not enter such diapause and live near the soil surface so would be expected to be influenced by soil moisture changes due to temperature, irrigation and rainfall. In terms of total earthworm abundance the numbers would be expected to naturally decline under typically agricultural conditions when agricultural land is cultivated and a new crop is grown.

A one-way analysis of variance revealed that neither the number of earthworms extracted from replicate samples of soil from untreated plots and from Telone II treated plots, nor the weight of earthworms extracted from untreated plots and from Telone II treated plots, differed significantly at 4 days before treatment or at 21 days or 5 weeks post-treatment. At 3 months post-treatment, significantly more earthworms were extracted from soil samples from untreated plots ($F = 13.99$, $P = 0.001$). However, the weight of earthworms extracted from these samples did not differ significantly from samples extracted from treated plots. At 6 months post-treatment more earthworms were extracted from soil samples from untreated plots than from treated plots but the weight of the samples from the treated plots was higher than from the untreated plots. However, the difference in the number of earthworms extracted and the weight of earthworm extracted at from untreated and Telone II treated plots was not significant. At 9 months post-treatment, a greater number of earthworms were again extracted from soil samples from untreated plots and the weight of the samples from untreated plots was higher, but the difference in the number of earthworms extracted from untreated and Telone II treated plots was not significant. After 12 months more earthworms were extracted from soil samples from Telone II treated plots but a slightly greater weight of earthworms were extracted from untreated plots. However, the difference in the number of earthworms and the weight of earthworms extracted from untreated and Telone II treated plots at 12 months was again not significant (see Figure 9.5.2-3 and Table 9.5.2-4).

Figure 9.5.2-3: Mean number of earthworms (Allolobophora chlorotica, Allolobophora caliginosa and Allolobophora longa) per m^2 in untreated and Telone II treated plots during the course of the field trial



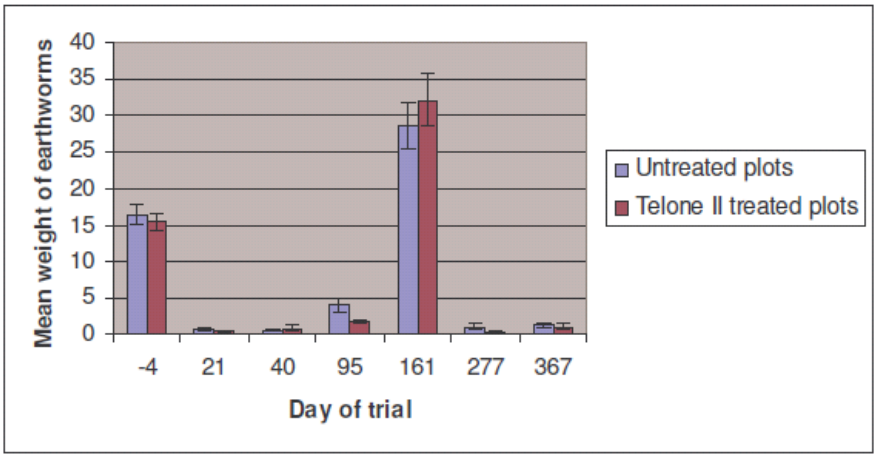


Figure 9.5.2-2: Mean weight (g) of earthworms (Allolobophora chlorotica, Allolobophora caliginosa and Allolobophora longa) per m^2 in untreated and Telone II treated plots during the course of the field trial

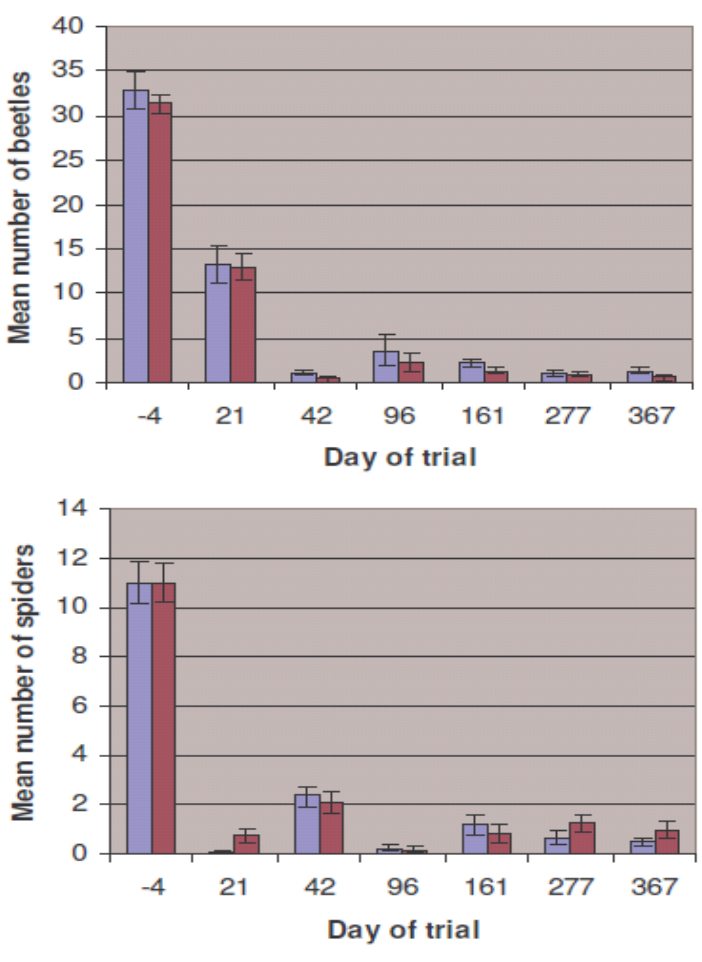
Having increased markedly at 6 months post-treatment, the mean number of earthworms and the mean weight of earthworms sampled decreased again markedly at 9 months and 12 months post-treatment. Therefore, overall trend in earthworm numbers at the site during the field trial can be largely attributed to the normal agricultural practice of growing tomatoes and winter wheat, and to prevailing climatic conditions.

Macroarthropods

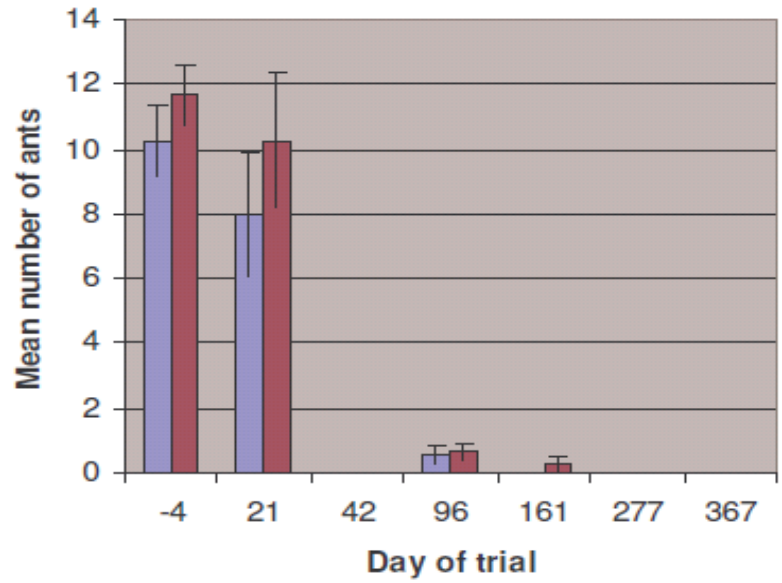
The number of macroarthropods (beetles, spiders, ants, crickets and centipedes) decreased substantially in both Telone II treated and untreated plots post-treatment compared with the numbers obtained pre-treatment. Removal of the previous crop cover, alfalfa, combined with the hot and dry weather conditions which prevail throughout much of the summer in this region of Italy, were likely to have contributed to this natural seasonal decline in numbers. Field tillage could also have contributed. There were no statistically significant differences between the number of macroarthropods (beetles, spiders, ants, crickets and centipedes) in pitfall traps set in Telone II treated and untreated plots at any of the post-treatment sampling intervals (Table 9.5.2-5).

Figure 9.5.2-5:

Upper panel. Mean number of beetles (*Pentodon bidens*, Carabidae; *Rhizotrogus* spp., Scarabeidae; *Drasterius bimaculatus*, Elateridae; *Harpalus* spp., Carabidae; *Pterostichus* spp.,Carabidae) per pitfall trap in untreated and Telone II treated plots during the course of the field trial.



Lower panel 9.5.2-6. Mean number of spiders (*Lycosa* spp., Lycosidae; *Tegenaria agrestis*, Agelenidae) per pitfall trap in untreated and Telone II treated plots during the course of the field trial.



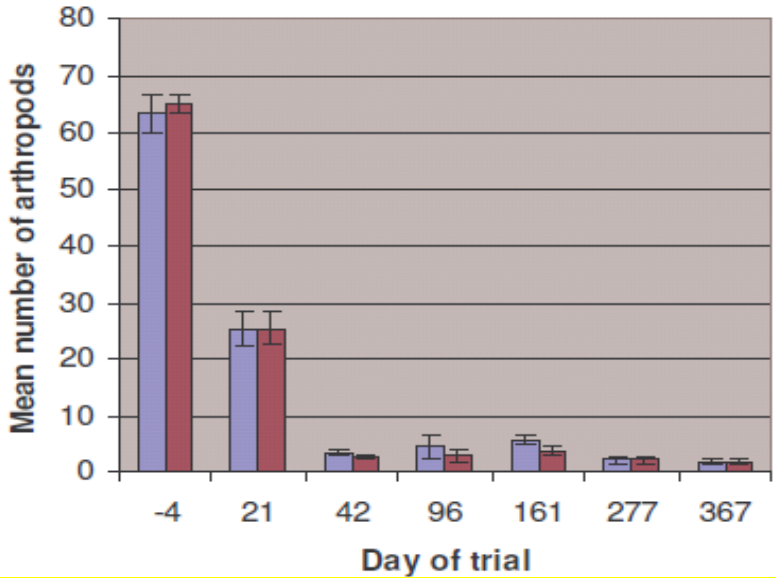


Figure 9.5.2-7:

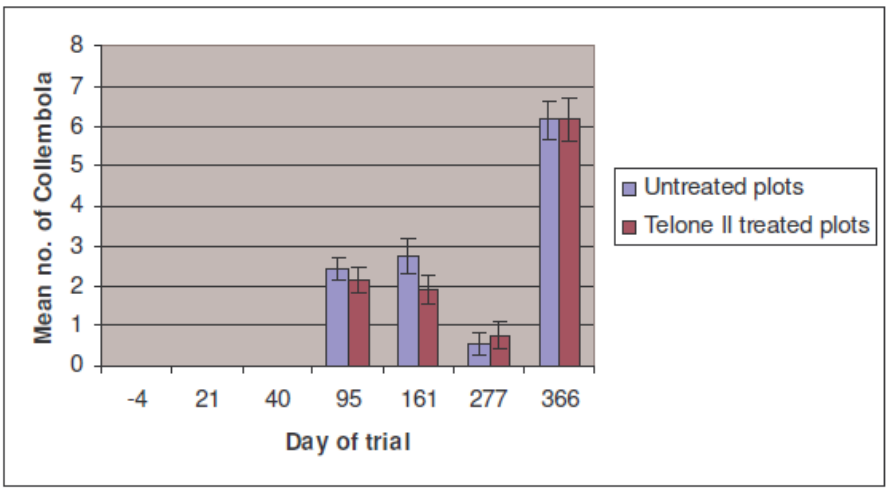
Upper panel: Mean number of ants (species of genus Formicidae) per pitfall trap in untreated and Telone II treated plots during the course of the field trial.

Lower panel: Mean number of arthropods [beetles, spiders, ants, crickets (*Grillus* spp., Orthoptera) and centipedes (*Geophilomorpha* spp., Chilopodae)] per pitfall trap in untreated and Telone II treated plots during the course of the field trial

Microarthropods (Collembola)

Due to the hot and dry conditions experienced during the summer, not Collembola were obtained from soil cores taken 4 days before Telone II treatment. Microarthropods (Collembola) were the greatest affected by these factors and it was not until 3 months post-treatment (and with a change in the soil core sampling method) that any of these organisms were found. However, by the sampling at 12 months post-treatment, the number of Collembola had significantly increased (see figure 9.5.2-8). The mean number of Collembola was higher in samples taken from the four untreated plots than in samples taken from the four Telone II treated plots of the field trial site at 3 months and 6 months post-treatment. However, when tested by one way ANOVA, these differences were not statistically significant.

Figure 9.5.2-8. Mean number of Collembola (*Hypogastrura brevis*; species of the family Isotomidae; and species that could not be identified to family or species level) per soil core in untreated and Telone II treated plots during the course of the field trial. The depth and diameter of soil cores was increased at 3, 6, 9 and 12 months from 8 cm x 8 cm to 25 cm x 25 cm.



In summary, there were no statistically significant differences between the number of macroarthropods (beetles, spiders, ants, crickets and centipedes) in pitfall traps set and microarthropods in Telone II treated and untreated plots at any of the post-treatment sampling intervals.

With the possible exception of earthworms, Telone II fumigant injection did not have any significant adverse effects upon soil dwelling organisms. Effects on earthworms were transient, lasting less than 6 months, with no difference in earthworm abundance between treated and untreated plots detected at 6, 9 or 12 months post-treatment.

Crop growth, yield and phytotoxicity

The tomato crop was transplanted following the 2nd sampling at 21 DA-A (17/06/05) and was present on the trial field at two of the sampling intervals, namely the 3rd sampling at 5 weeks post-treatment (06/07/05) and the 4th sampling at 3 months post-treatment (31/08/05). On 6th July the crop growth stage on the BBCH decimal scale was between 16-18, while on 30th August it was 78-80. The tomato plants grew equally well on Telone II treated and untreated plots.

The crop was harvested over three days from 9th to 11th September 2005 and the average yield was equal to 42 tons/Ha of tomatoes. No signs of phytotoxicity were observed to tomato plants in either the Telone II treated or untreated plots in any of the crop stages and outcomes (growth, time of ripening, yield/Ha) during the entire span of its cycle. The winter wheat crop was seeded on 9th November 2005 following the 5th sampling at 6 months post-treatment (04/11/05) and was present on the trial field at all of the remaining sampling intervals: 6th sampling at 9 months post-treatment (28/02/06); and 7th sampling at 12 months post-treatment (29/05/06). At the time of the final samplings, the growth stage of the winter wheat was 85 BBCH. Harvesting of the winter wheat crop took two days, namely the 10th and 11th July 2006, yielding an average of 7 tons/Ha of grains at 13% of humidity.

RMS assessment: the study was conducted under realistic agronomic conditions following actual practice including the type of site and location, tillage, cropping and the use of selective plant protection products in the South of Europe. Telone II fumigant was injected into the soil of the four selected trial plots using a dispensing machine hauled by a tractor. Telone was applied at maximum application rate (224 kg as/ha) covering the outdoor use. Therefore, the field study is considered to represent a higher tier and it is considered acceptable.

Samples were taken four days before application, and at 20 days post-application, 5 weeks after application, 3, 6, 9 and 12 months after application. For earthworms, the first 50 cm of soil layer was sampled, and for microarthropods and macroarthropods the first 25 and 10 cm, respectively. The abundance of earthworms was low during the study.

Sampling of soil invertebrates (earthworms and macroarthropods) from the field trial site revealed that the number of these organisms decreased substantially in both Telone II treated and untreated plots post-treatment compared with the numbers obtained pretreatment. Hot and dry weather conditions prevailed throughout much of the summer and this likely contributed to this natural decrease in numbers as well as other agricultural operations (e.g. field tillage). Microarthropods (Collembola) were also affected by these factors and it was not until 3 months post-treatment (and with a change in the soil core sampling method) that any of these organisms were found, although they were probably present throughout the study in low numbers or at soil depths greater than those initially sampled. There was very little rainfall during the winter and spring and this likely affected earthworm abundance which fell off markedly following the sampling at 6 months post-treatment.

The mean number of earthworms extracted from soil samples, Collembola in soils cores and arthropods in pitfall traps was higher in samples taken from the four untreated plots than in samples taken from the four Telone II treated plots of the field trial site during several of the post-treatment samplings. However, when the difference in numbers of these organisms was tested by one way ANOVA, the only significant difference was for earthworms sampled at 3 months post-treatment. It is notable that few earthworms were obtained in samples from both treated and untreated plots at this sampling interval and it is possible, therefore, that this difference may have been an artefact. When a much greater number of earthworms were sampled at 6 months post-treatment, no significant difference in the number of earthworms in untreated and Telone II treated plots was found, nor was there any significant difference in the number sampled at 9 months or 12 months post-treatment. There was no significant difference between the mean weight of earthworms in samples taken from the untreated plots and treated plots of the field trial site at any of the sampling intervals.

There were no statistically significant differences between the number of macroarthropods (beetles, spiders, ants, crickets and centipedes) in pitfall traps set in Telone II treated and untreated plots at any of the post-treatment sampling intervals.

A shortcoming of the study was that concentrations of the compound in the soil are not measured, so it is not clear the actual exposure in the study. Not statistical significant effects were observed for macroarthoprods and microarthopods

investigated in Telone II treated and untreated plots at any of the post-treatment sampling intervals for an application rate of 224 kg as/ha. However, effects on earthworms were observed. These effects on earthworms were transient, lasting less than 6 months, with no difference in earthworm abundance between treated and untreated plots detected at 6, 9 or 12 months post-treatment. These results can be used for risk assessment.

B.9.5.3. Risk assessment to non-target arthropods

The extended laboratory studies indicated that soils treated with single application of Telone II at 329 kg a.s./ha may pose a high risk to some soil dwelling arthropods, as indicated by the study with *Folsomia candida*. The application rate evaluated in these studies was 1.5-fold higher than that proposed for Telone II, and so is expected to be an overestimate of the likely risk to soil organisms. On the other hand, due to the nature of the test system (extended laboratory), and typical application method for Telone II by soil injection followed by sealing with a roller, organisms were not present in the test system at the time of soil treatment and this is likely to underestimate the likely risk to soil organisms.

Nevertheless, the studies with all species tested indicated that 1,3-D has low residual toxicity, and that within three weeks of soil treatment there will be no significant toxicity to soil arthropods. Therefore, it is expected that for those species affected during soil treatment, recolonization will be possible within a short period following treatment.

Due to the method of application of Telone II, it is therefore necessary to evaluate the likely impact under normal conditions of use. Therefore the notifier has been submitted a field study recently conducted in South European conditions (in Italy, Small, 2006), in which soil organisms were exposed *in situ* during application of Telone II represents a realistic exposure scenario for soil dwelling arthropods. The results of this field study indicated that soil injection with 1,3-D will not have any detectable adverse effects upon soil dwelling organisms when used in accordance with the proposed GAP for Southern Europe.

In summary, laboratory studies with indicator soil arthropods indicated that 1,3-D has low residual toxicity, and that within a short period of soil treatment there will be no significant toxicity to soil arthropods. Therefore, it is expected that for those species affected during soil treatment, recolonization will be possible within a short period following treatment. This was confirmed in a field study, conducted in accordance with the proposed GAP for Southern Europe for outdoor use, in which soil injection with 1,3-D did not have any detectable adverse effects upon the in-field soil dwelling arthropods.

B.9.6. Effects on earthworms.

The EFSA Scientific Report (2006) highlighted the following critical areas of concern with regard to risk to earthworms from 1,3-D:

- A high acute risk to earthworms was observed in the laboratory and so a study to address this risk for the outdoor uses is required.

A study has subsequently been conducted to assess the risk to earthworms under typical Southern European field conditions and is summarised in section B.9.5.2.

B.9.6.1. Acute toxicity.

The EFSA Scientific Report (2006) lists the acute LC_{50} of 1,3-D for earthworms (*Eisenia fetida*) as 55.6 mg/kg soil. No additional studies have been conducted.

B.9.6.2. Sub lethal effects.

The EFSA Scientific Report (2006) lists the reproductive toxicity NOEC of 1,3-D for earthworms (*Eisenia fetida*) as 770 mg/kg soil (577 kg/ha) from a 1 week aged soil study. No additional reproductive toxicity studies have been conducted.

In the study earthworms were exposed to artificial soil that had been dosed with 0, 770 or 3850 mg Telone II/kg soil (dryweight), one or three weeks earlier. The artificial soil treated with 1,3-D at 770 mg Telone II/kg dry soil or 3850 mg Telone II/kg dry soil, and aged for 3 weeks, did not affect the survival, growth or reproduction of *Eisenia foetida.* When aged for only 1 week, the upper concentration of 3850 mg/kg severely affected survival (95% mortality by day 28) and reproduction (examination at 56 days confirmed an absence of juveniles and cocoons), but treatment at 770 mg/kg did not.

B.9.6.3. Field studies.

A study conducted by Luhrs (2002) to evaluate the effects of 1,3-D on earthworm populations in the field was evaluated by the RMS and summarised in the DAR. The study was considered acceptable by the RMS and showed that earthworm abundance and biomass was substantially decreased 3.5 weeks after treatment with 1,3-D **at 363 kg/ha**. After 4.5 months, however, both earthworm abundance and biomass had recovered to values comparable to those of the "agricultural control". Overall, full recovery of the earthworm populations in 1,3-D treated plots was evident within 4.5 months following application with 1,3-D at 363 kg/ha.

Subsequently, a study has been conducted to evaluate the effects of Telone II, applied at 190 L/ha (224 kg a.s./ha), on earthworms (and soil arthropods) in Southern Europe (Small, 2006), showing that effects on earthworms were transient, lasting less than 6 months, with no difference in earthworm abundance between treated and untreated plots detected at 6, 9 or 12 months post-treatment.

In addition, a survey of earthworm abundance and diversity in soils typically used for growing fruiting vegetable crops in S EU was conducted to provide some context to the potential risk to earthworm populations in soils typically treated with 1,3-D for the control of nematodes in southern Europe.

A summary of the new studies submitted is depicted below.

Small, et al. (2006)

Title: Abundance and diversity of earthworms in soils commonly used for growing vegetable crops in three regions of Sicily. I2L unpublished report No. 05/56, Dow AgroSciences unpublished report 050347-A.

Guidelines: Not guidelines applicable.

Although it was not required by sponsor that this project be GLP compliant, all phases of this study and pheild pahse raw data were carried outh with Agri2000/SynTech Research standard operation precdures. International codes of GLP followed included: OECD principles of good laboratory practices (1997) and The Good laboratory Practice regulations (1999). .Not GLP. The study is considered acceptable.

A survey was conducted to determine the relative abundance and diversity of earthworms (species composition, numbers and biomass) inhabiting field sites in three provinces of Sicily (Italy) typical of sites where vegetable crops are grown, and where frequent or occasional fumigation/sterilisation is required for the control of nematodes.

In each of three provinces of Sicily, Agrigento (AG), Caltanissetta (CL) and Ragusa (RG), 3 farm sites were selected to give a broad range of different situations, particularly in terms of soil type (texture, pH, organic matter etc.), and cropping history. None of the field sites had received a soil fumigant treatment within 2 years of this study. In addition, fields were selected on which any additional irrigation (other than rainfall) would not be used during the period of the trial, as such use would have modified the environmental conditions, potentially influencing the presence and abundance of earthworms. The locations of the 9 selected trial sites are summarised below.

Province	Site Code	Location (Farm, Lattitude and Longitude)
Agrigento	AG08	Leto Michele Farm 37° 07’ 13.35’’ N, 13° 52’ 02.95’’ E
	AG09	Tardino Diego Farm 37° 07’ 07.23’’ N, 13° 57’ 47.10’’ E
	AG10	Russotto Antonino Farm 37° 07’ 31.07’’ N, 13° 55’ 39.49’’ E
Caltanissetta	CL05	Coop Falconara Farm 37° 06’ 28.04’’ N, 14° 02’ 27.42’’ E
	CL06	Maugeri Samuele Farm 37° 08’ 12.31’’ N, 14° 23’ 53.91’’ E
	CL07	Dimodica Giuseppe Farm 37° 08’ 06.73’’ N, 14° 27’ 12.60’’ E
Ragusa	RG02	Ventura Angelo Farm 36° 54’ 57.30’’ N, 14° 24’ 53.23’’ E
	RG03	F.lli Tonino Farm 36° 46’ 49.8’’ N, 14° 35’ 56.04’’ E
	RG11	Seduttore Salvatore Farm 36° 56’ 42.55’’ N, 14° 27’ 49.18’’ E

Earthworms were extracted from soil samples from 15th - 25th November 2005 and from 21st – 25th February 2006 at the selected field sites. Sampling took place after a recent period of rainfall and at soil temperatures ranging between 10 and 15 °C; the time of year, and environmental conditions were selected as being conducive to the presence of earthworms near the soil surface.

On each of the 3 farm sites selected in each province, 20 samples of earthworms were taken at each sampling date. These samples were taken on selected quadrats of 1 m^2 by digging manually the soil to a depth of 50 cm and picking up all earthworms found. The position of quadrats was randomised across the selected field sites. In order to minimise edge effects, sampling was carried out at least 20 - 25 m from the field margin. The collected worms were transferred to a 70% ethanol solution in order to preserve them for subsequent taxonomic identification.

Samples of soil were taken from each trial site and the following characteristics determined: soil type (% sand, % silt, % clay); soil texture; pH; and % organic matter (OM).

Maximum and minimum air temperatures and rainfall measurements were obtained from local weather stations. Mean soil temperatures were obtained from a HOBO outdoor data logger buried at a depth of 15 cm on field study site RG11, Seduttore Salvatore Farm, Vittoria, Ragusa, Sicily. Mean soil temperatures were also obtained from local weather stations where available.

The earthworm abundance data were evaluated using Redundancy Analysis (RDA) to identify whether worm abundance could be associated with any of the environmental (soil) variables measured at the selected sites.

Findings:

No earthworms were obtained in any of the 20 samples taken from each of the 9 sites during the samplings in November 2005. No earthworms were obtained in any of the 20 samples taken from each of 5 sites (AG08, CL06, CL07, RG02, and RG11) during the samplings in February 2006 (see Table 9.6.3-1).

Earthworms were obtained at sites AG09, AG10, CL05 and RG03 during the samplings in February 2006. Two species of earthworm were identified through use of taxonomic keys: *Lumbricus terrestris* and *Allolobophora caliginosa*. Where earthworms were found, total earthworm density varied between 1 and 48 individuals per m^2; the individual species densities were between 1 and 17 *L. terrestris* per m^2, and between 1 and 32 *A. caliginosa* per m^2.

At sites CL05 and RG03 *A. caliginosa* was the only species of earthworm found. *L. terrestris* was also found in samples taken from sites AG09 and AG10, although *A. caliginosa* was present in greater numbers.

Table 9.6.3-1: Earthworm abundance and soil conditions for samples extracted from 9 trial sites in Sicily during February 2006.

Site ID	AG 08	AG 09	AG10	CL 05	CL 06	CL 07	RG 02	RG 03	RG 11
Mean no. worms	0.0	14.9	30.6	4.5	0.0	0.0	0.0	3.0	0.0
S.E. no. worms	0.0	1.5	1.8	0.8	0.0	0.0	0.0	0.7	0.0
Soil type	Sand	Sandy-Clay-Loam	Sandy-Loam	Clay	Loamy-Sand	Sandy-Loam	Sand	Sandy-Clay-Loam	Loamy-sand
Soil temperature at sampling (°C)	12	12	12	10	12	12	12	10	14
%OM	0.32	1.16	1.17	2.48	1.64	1.6	1.17	1.3	1.48
Water holding	27.2	43.6	48.7	77	38.2	44	29.5	42.7	33.5
Rainfall preceding 7 days (mm)	2.4	3.4	2	0.8	0.4	0	20	22.2	25.6
Cultivation*	Cultivated 2002-2005 (harrowing 2005)	Uncultivated 2001-2005 (but ammonium nitrate fertilising 2005)	Uncultivated 2001-2005	Cultivated 2002-2005 (ploughing/ harrowing 2004)	Cultivated 2001-2005 (harrowing 2005)	Cultivated 2001-2005 (ploughing/ harrowing 2005)	Cultivated 2002-2004, uncultivated 2005)	Cultivated 2002-2005 (ammonium nitrate fertilising 2005)	Cultivated 2001-2005 (harrowing + dung fertilising 2005)

* = soil tillage and/or harrowing.

Significant rainfall was recorded (20.4-27.6 mm) during the week preceding the November samplings at trial sites AG08, AG09, AG10, CL05, CL06, CL07 and RG11. The amount of rainfall received during the week preceding the November samplings at trial sites RG02 and RG03 was 8.4 mm and 5.4 mm respectively. Significant rainfall was recorded (20.0-25.6 mm) during the week preceding the February samplings at trial sites RG02, RG03 and RG11. However, little or no rainfall (0-3.4 mm) occurred during the same period at the other trial sites. Mean minimum air temperatures and mean maximum air temperatures were generally higher during the week preceding the November samplings than during the week preceding the February samplings.

Statistical analysis (redundancy analysis) indicated that earthworm diversity and abundance was associated with some of the measured soil variables. For example, the sites containing earthworms at the time of sampling (AG09, AG10, CL05 and RG03) were characterised by lower sand content in the soil and also being richer in organic matter and water holding capacity which are typical requirements for earthworm communities. Conversely, soils with no worms present on either sampling occasion (AG08, CL06, CL06, RG02 and RG11) were typically sandy soils which had been subject to recent cultivation. *A. caliginosa* was found to be more abundant in soils with the lowest sand content (15 and 51% sand) and *L. terrestris* co-existed with *A. caliginosa* in soils with a slightly higher sand content (58 and 63% sand). Worms were not found in soils with sand content of 70% and higher.

In summary, an earthworm survey conducted in different regions and soils in Sicily indicated that variation in the presence or absence of earthworms related primarily to soil type and cultivation history. Two major soil factors were identified that were associated with the presence of earthworms; sand content of soils and the occurrence of recent cultivation. High sand content (thus low organic matter and low water holding capacity) appeared to be the most important factor with earthworms not found in soil of sand content of 70% and above.

1,3-D is typically used on open fields in South Europe, with sandy soils, to control nematode pests of fruiting vegetables. This survey indicates that earthworms will be present in very low densities, in the cultivated zone of such soils.

B.9.6.4. Risk assessment for earthworms

The acute risk assessment for earthworms was estimated by the RMS using the acute toxicity value (LD_{50}) and the initial Predicted Environmental Concentration in soil (PEC_{soil}) when the highest dose in field is injected at 224 kg /ha (worst case for tomatoes crops in Italy, south zone). As Telone is applied injected at 15 - 30 cm depth, two values of PEC_{soil} were calculated. The first one estimated the 1,3-D concentration with a homogeneous distribution within 5 cm of the point of application. The second one estimated the pesticide concentration along the 30 cm depth (from soil surface to 30 cm depth to account for diffusion). These values are 298.66 mg/kg and 49.77 mg/kg respectively. Since the Log K_{ow} of Telone (1,3-D) is lower than 2, it is not necessary to decrease the toxicity endpoints by a factor of 2.

Acute TER values for earthworms

Organism	Substance	LC_{50} (mg/kg soil)	PEC_s (mg/kg soil)	TER_A	Trigger value
Eisenia fetida	Telone 97 (99.3 % 1,3-D)	55.6	5 cm: 298.66	0.18	10
			30 cm: 49.77	1.11	10

The acute TER is below the Annex VI trigger and indicates an acute risk to earthworms.

The long term risk assessment was estimated by the RMS using the NOEC value and the initial PEC_s. In this long-term test with *Eisenia* the earthworms were exposed to two concentrations of Telone, 0.77 g/kg and 3.85 g/kg dry soil, aged for 1 and 3 weeks. Again, two values of PEC at 5 cm and 30 cm were considered for the injected application of 224 kg/ha.

Reproduction TER values for earthworms

Organism	Substance	Aged soil (weeks)	NOEC (mg/kg soil)	PEC_s (mg/kg soil)	TER	Trigger value
Eisenia fetida	Telone 97 (99.3 % 1,3-D)	1	770	5 cm: 298.66	2.6	5
				30 cm: 49.77	15	5
		3	3850	5 cm: 298.66	13	5
				30 cm: 49.77	77	5

Since the earthworms were not present in the soil at the time of treatment it is not possible to assess the long-term risk to a resident population immediately following application of Telone II. However, it is clear that the acute risk is high, and so some effects will occur on earthworm reproduction in laboratory tests with soils treated at typical application rates and above. Nevertheless, based upon the long-term study NOEC, it may be concluded that treated soil will pose a low risk to earthworms within 3 weeks of application, irrespective of whether it is assumed that the 1,3-D will be distributed over a soil depth of 5 cm or 30 cm. Thus, the long-term study with *Eisenia* indicates that 1,3-D has low residual toxicity, and that within three weeks of soil treatment there will be no significant toxicity to earthworms. Therefore, it is expected that even if earthworms are affected during soil treatment, recovery will be possible within a short period following treatment.

Higher Tier

Due to the method of application of Telone II, it was necessary to evaluate the likely impact on earthworm populations under typical conditions of use. Consequently, the field study conducted in Italy (Small, 2006), in which earthworms were exposed *in situ* during application of Telone II represented a realistic exposure scenario. Three earthworm species were found at the site (*Allolobophora chlorotica*, *Allolobophora caliginosa* and *Allolobophora longa*) all of which are common in agricultural soils across Europe. *A. chlorotica* and *A. caliginosa* are endogenic geophagous worms living near the soil surface in sub-surface temporary borrows, *A. longa* is a anecic species which dwells in permanent burrows and feeds on organic matter on the soil surface; thus the species present at the site represented the two key ecological groups present in agricultural soils. Despite declines in earthworm abundance in both control and treated plots which were associated with removal of the

previous crop cover (alfalfa), routine soil tillage and cultivation, and the hot and dry weather conditions typical of Mediterranean regions during spring and summer, the only significant difference for earthworms was detected at 3 months post-treatment. However, the reduction in earthworm abundance at 3 months was not matched by a decrease in earthworm biomass. By 6 months post-treatment earthworm abundance was again greater on the untreated plots, while biomass was greater on the treated plots (the difference was not statistically significant for either endpoint). At 9 and 12 months post-treatment there was also no significant difference between untreated and treated plots for abundance or biomass. Thus, it was concluded from the field study that soil injection with Telone II may have had a transient (lasting no more than 6 months) impact on earthworm abundance (but not biomass) when used in accordance with the proposed GAP for Southern Europe.

When considering the risks posed by 1,3-D to earthworms the laboratory data provided by DAS indicate that earthworm populations may be reduced following soil treatment with 1,3-D (i.e. 1,3-D is hazardous to earthworms). However, the magnitude of any effects, and speed of recovery of populations, will be dependent upon exposure, which is dependent upon a number of factors including climate, landscape and crop cultivation regime. Consequently, the impact of 1,3-D must be considered on a national or regional scale taking into account the agri-environmental conditions that apply. As a guide, earthworm abundance will be higher and populations at greatest risk following late season soil treatments with fumigants in cooler (N EU) climates, where the soil is "capped" and left undisturbed over winter before cropping. In contrast, for those uses of 1,3-D supported for Annex I inclusion, i.e. pre-planting of fruiting vegetables during spring/summer under Southern European conditions, the impact of 1,3-D on earthworm populations (if earthworms are present) will be transient, and recovery of earthworms (if present) is expected to occur within a period of less than 6 months (based on field test results).

In a survey of earthworm presence and abundance in Mediterranean soils typical of those treated with fumigants for the control of nematodes (Small, 2006) only two species were found (*Lumbricus terrestris* and *Allolobophora caliginosa*) in low densities at four of the nine sites sampled. This survey was provided as an illustration that earthworms will either be absent, or present in very low densities, in the cultivated zone of soils likely to be treated with 1,3-D. Statistical analysis indicated that at sites where earthworms were absent the soils were typically sandy (70% or higher sand content) and had been subject to recent cultivation. To put these findings into context, 1,3-D is typically used on sandy soils as these are the type of soils where nematode pests are most prevalent; conversely, this survey indicates that these soils are also those in which earthworms will either be absent, or present in very low densities.

In summary: in South EU agricultural soils, soil injection with Telone II may have a slight transient impact (lasting no more than 6 months) on earthworm abundance when used in accordance with the proposed GAP for Southern Europe (224 kg as/ha). Furthermore, the results of a field survey conducted in inhabiting field sites in three counties of Sicily (Italy), where fumigation/sterilisation may be required for the control of nematodes showed that small numbers of earthworms were found it during November 2005 and February 2006.

B.9.7. Effects on other soil micro-organisms.

The EFSA Scientific Report (2006) highlighted the following critical areas of concern with regard to risk to soil micro-organisms from 1,3-D:

- A high risk to soil micro-organisms was observed in the laboratory and so a field study to address this risk for the outdoor uses is required. This new field study should also cover the concern for the effects from the soil metabolites.

A study has subsequently been conducted to assess the risk to soil micro-organisms under typical Southern European field conditions and is summarised in section B.9.7.1.

B.9.7.1. Field studies: Soil micro-organisms

A study conducted by Forster, 1999 to determine the effects of Telone on soil microflora respiration and nitrogen turnover was evaluated by the RMS, considered acceptable, and summarised in the DAR. The study showed that soil treated with Telone II at 577 kg product/ha or 2885 kg product/ha resulted in reduced microbial respiration and nitrogen transformation for at least 45 days. The addition of a small amount of fresh soil (1% w/w) after 49 days did not stimulate recovery and reduced microbial respiration and nitrogen transformation was still observed at 90 days after soil treatment.

A study conducted by Reis, 2002 to determine the effects of Telone on soil microflora respiration and nitrogen turnover in the field was evaluated by the RMS, considered acceptable, and summarised in the DAR. The study showed that arable soil from N EU treated with Telone II at 300 L/ha (**equivalent to 363 kg 1,3-D/ha, which is more than 1.5-fold higher than the proposed rate supported for Annex I inclusion**) disrupted microbial respiration and nitrogen turnover. Soil respiration rates recovered to within 25% deviation from controls by Day 102 and nitrogen turnover recovered to a level of 25% deviation from control by Day 184. Therefore, the treated soil was considered to have recovered from the 1,3-D application within a period of 184 days.

Subsequently, a study has been conducted to compare the rates of soil respiration and nitrogen transformation in soil samples collected from the field in S EU (Italy) from untreated plots and plots treated with 224 kg Telone II/ha. This study is summarised below.

Mallett, M.J. 2005

Title: Soil microflora activity in soil treated with Telone in the field. CEMAS unpublished report No. CEMR-2824, 28 November 2005.

Soils were sampled in the field and transported to the laboratory to determine respiration and nitrogen transformation in accordance with OECD 216 (2000) and OECD 217 (2000). The study was conducted under GLP. The study is considered acceptable.

The purpose of this study was to determine and compare the rates of soil respiration and nitrogen transformation in soil samples collected from the field from untreated (control) plots and plots previously treated with 190 L/ha Telone (1,3-D). The plots were prepared and the test item applied on 27 May 2005 as part of another study (Small, 2006). Three weeks after treatment, tomato plants were transplanted into the plots in accordance with good agricultural practice. The tomato crop was harvested between 9-11 September 2005.

Soils were collected on 7 September 2005 from untreated (control) plots from a field trials site in Italy and a combined sample from each plot was used to determine the characteristics of the soil including maximum water holding capacity (MWHC) and the optimum glucose concentration.

Eight soil samples (to a depth of 20cm) were collected from the field on 10 October 2005, one sample from each of four control plots and one from each of four treated plots. This represented a period of 136 days (4.5 months) from soil treatment with Telone to soil sampling, and was one month after harvest of the tomato crop. The dry weight of each soil was determined, the moisture content of each soil was adjusted to 45% of the MWHC and the soils were acclimated to the test conditions for 2-3 days before measurement of respiration and nitrogen transformation rates.

To confirm the sensitivity of the soil a positive control consisting of the reference item, dinoseb, was tested against soil from the untreated plots at 10 mg/kg. Separate solvent control and positive control soil samples were prepared from each of the control plot samples. The respiration rate (mg CO_2/kg soil/hour) of one sample from each of the prepared soil samples was measured following acclimation and soon after dosing (within three hours) the solvent control and positive control samples. Further measurement of respiration of the solvent control and positive control samples was made after further seven days.

Samples were also taken for extraction and measurement of inorganic nitrogen content from each of the prepared soil samples following acclimation and after a further seven days to determine the nitrogen transformation rates.

The t-test was used to determine if the mean values for the control and treated plots were significantly different at P = 0.05. The same test was carried out to determine if the means for the solvent control and positive control were significantly different.

Findings:

Analysis of the soil samples taken from the Telone treated and untreated plots showed that the soil was a coarse loamy sand to sandy loam with a slightly alkaline pH of between 7.61 and 7.83. The pH of the soil when tested was between 8.29 and 8.51.

A summary of the nitrogen transformation results is provided below. There was no significant difference (P>0.05) between the mean nitrogen transformation rates for the untreated control and Telone-treated plots indicating that Telone treatment had no residual adverse effect on nitrogen transformation rate in the samples tested. A significant difference of +91% (P≤ 0.05) was seen between the solvent control and positive control (10 mg/kg dinoseb) for nitrogen transformation rate confirming the sensitivity of the soil to the reference substance dinoseb.

Nitrate nitrogen transformation rates (0 – 7 days)

	Control plots	Treated plots
Mean (mg N/kg/day)	1.08	1.13
Range (mg N/kg/day)	0.831 – 1.40	0.534 – 1.71
Difference from control (%)	-	+ 4.6%

A summary of the respiration rate results is provided below. A significant difference (P≤ 0.05) was seen between the treated and control plots for soil respiration, however as this difference (-17.7%) was below the Annex VI trigger of 25% effects for soil microflora, this reduction was not considered to be biologically significant. A significant difference of -19.8% (P≤ 0.05) was seen between the solvent control and positive controls after seven days exposure to the positive control.

Respiration rates (Day 0)

	Control plots	Treated plots
Mean (mg N/kg/day)	13.95	11.49*
Range (mg N/kg/day)	13.24 – 14.55	10.04 – 12.56
Difference from control (%)	-	-17.7%

* = statistically significant ($p \leq 0.05$) from solvent control

In summary, soil treated with 190 L/ha (= 224 kg/ha injected to the soil) Telone II did not have any significant long lasting effects on soil respiration or nitrogen turnover. Recovery was showed within 4.5 months of treatment. Soil function was not significantly different to that of untreated soils (less than 25% deviation) after 4.5 months post-treatment.

B.9.7.2. Risk assessment

A laboratory study showed that soil treated with Telone II **at 577 kg product/ha or 2885 kg product/ha** (i.e. 2.5 – 12.5x higher rates than proposed) and assuming distribution within a 5 cm soil profile will reduce microbial respiration and nitrogen transformation, and that under laboratory conditions recovery is unlikely to occur within 100 days after soil treatment.

Since long-term effects were observed in this laboratory study, it is appropriate to consider data from additional studies carried out on samples collected from the field. Two field studies have been conducted; the first conducted in northern EU with soil treated at 363 kg as/ha showed that soil respiration rates recovered after 102 days post treatment and nitrogen turnover recovered (less than 25% deviation from control) within 184 days.

In a second study, conducted in southern EU, soil was treated with 190 L/ha Telone (224 kg a.s./ha) and showed that soil respiration and nitrogen turnover did not deviate significantly from untreated soil (less than 25% deviation from control) within 4.5 months. The soil evaluated in this new study was sampled long after metabolites of 1,3-D will have formed within the soil, and as such any residual toxicity due to the metabolites was also assessed as part of this study.

In summary, treatment with 1,3-D will result in a temporary disruption of soil function, particularly in terms of nitrogen transformation processes. However, under field conditions these effects are not long-lived, and in a S EU field study it was illustrated that any effect on soil treated with 190 L/ha **Telone (224 kg /ha injected into the soil) will not be detectable after 4.5 months of soil treatment.**

B.9.8. Effects on other non-target organisms (flora and fauna) believed to be at risk.

The EFSA Scientific Report (2006) highlighted the following critical area of concern with regard to risk to non-target terrestrial plants from 1,3-D:

- 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.

Specifically, the EPCO Expert's meeting required that the risk to non-target plants should be quantified and TER values at a few metres from the field should be calculated. The EFSA highlighted also that this assessment should be based on an ER_{50} value, not the NOEC as provided in the list of endpoints.

A study to investigate the phytotoxicity of 1,3-D, 3-chloroallyl alcohol (3-3-CAA) and 3-chloroacrylic acid (3-3-CACAA) to non-target terrestrial plants has previously been conducted following a request by the USEPA, and was specifically designed to address potential exposure of (crop) plants via contaminated irrigation water. The results of the vegetative vigor study may be used in a simple Tier I assessment as irrigation water containing 1,3-D was applied directly to the leaf surfaces of the seedlings, and the plants would have been exposed to any volatile gas released from the soil in which the plants were cultivated.

B.9.8.1. Effects on non-target terrestrial plants

A study to investigate the phytotoxicity of 1,3-D, 3-chloroallyl alcohol (3-3-CAA) and 3-chloroacrylic acid (3-3-CACAA) to non-target terrestrial plants has previously been conducted following a request by the USEPA, and was specifically designed to address potential exposure of (crop) plants via contaminated irrigation water. The results of the vegetative vigor study may be used in a simple Tier I assessment as irrigation water containing 1,3-D was applied directly to the leaf surfaces of the seedlings, and the plants would have been exposed to any volatile gas released from the soil in which the plants were cultivated.

McCormick and Schwab (1999)

Title: Effect of 1,3-D Dichloropropene, 3-chloroallyl alcohol, and 3-chloroacrylic acid on the emergence and vegetative vigor of non-target terrestrial plants. Dow Agrosciences unpublished report No. GH-C5032 (December 3, 1999). U.S. EPA Pesticide Assessment Guidelines, Subdivision J, Series 122-1 and 123-1, OPPTS 850.4150 Terrestrial Plant Toxicity, Tier I (Vegetative Vigor), and OPPTS 850.4250 Vegetative Vigor, Tier II. GLP.

Test substance: Telone (1,3-dichloropropene; TSN 101723; Lot No. MD16164901; 97.8 %), 3-3-CAA (3-chloroallyl alcohol; TSN 101692; Lot No. 199801576-46; 100 %) and 3-3-CACAA (3-chloroacrylic acid; TSN 101767; Lot No. B1044-59; 99.5 %).

Tier I and Tier II seedling emergence and vegetative vigor studies were conducted for 1,3-D (as Telone II), and the two metabolites 3-CAA and 3-CACA using 10 plant species (4 monocotyledons and 6 dicotyledons), representing seven different families.

Monocot species tested were corn (*Zea mays*), wheat (*Triticum aestivum*), barnyard grass (*Echinochloa crus-galli*) and onion (*Allium cepa*). The dicot species tested were sugarbeet (*Beta vulgaris altissima*), cucumber (*Cucumis sativus*), sunflower (*Helianthus annus*), radish (*Raphanus sativus*), soybean (*Glycine max*) and tomato (*Lycopersicon esculentum*).

Since 1,3-D is applied in a drip irrigation or injected into soil, the study was specifically designed to evaluate phytotoxicity of 1,3-D and the two metabolites in irrigation water. Tier I seedling emergence and vegetative vigor tests were conducted using the maximum expected concentrations of each of the compounds in irrigation water (assuming the worst-case GAP registered in the U.S.) for all 10 species. The test substances were applied to the pots and plants to simulate a 0.75-inch irrigation event.

Tier II testing was conducted for those species which showed more than 25% detrimental effects for at least one test parameter in the Tier I test. Only the Tier II studies will be reviewed in greater detail in this summary. The Tier II seedling emergence and vegetative vigor studies were conducted with the following test substances and species:

Telone

Emergence: corn, onion, radish, sugarbeet, tomato

Vegetative vigor: corn, cucumber, onion, sugarbeet, sunflower, tomato, wheat.

3-CAA

Emergence: onion

Vegetative vigor: onion, sugarbeet, wheat.

3-CACA

Emergence: onion

Vegetative vigor: none

In the Tier II tests plants were grown in environmentally regulated greenhouses in plastic pots (6.5 inch diameter, 5 inch depth) containing a sandy loam soil (54% sand; 32% silt; 14% clay; organic carbon content 1.2%; pH 6.4). The soil was filled to 4 inch depth, at which level the diameter of the pots was 6 inch giving a treated soil surface area ($\prod r^2$) of 28.3 $inch^2$ (= 1.826 x 10^{-6} ha), and the volume ($\prod r^2$xdepth) is estimated at 113 $inch^3$ (= 1853 cm^3). The reported soil bulk density was 1.41 g/cm^3, and so the mass of soil in each pot was approximately 2.6 kg/pot.

The study was conducted in glasshouses at ABC Laboratories in Columbia, Missouri USA apart from one Tier II emergence and vegetative vigor test for onion which was conducted in a walk-in growth chamber with artificial light (16 h light: 8 h dark). Natural light was used in the greenhouses for all species except in an onion re-test conducted in a greenhouse with natural lighting supplemented with 600 watt high pressure sodium Gro-lights.

In the tests for all species except onion, temperature ranged from a 14.4 - 38.7°C and humidity was 14.8 - 99%. Onions were tested in the environmental chamber at 23.2 – 29.8°C and 37.3 – 93.2% humidity, and in the greenhouse re-test at 21.3 – 36.9°C and 4.6 - 62% humidity.

For the emergence tests four replicates with 10 seeds per replicate were tested for each control and treatment level, except for the onion emergence re-test which consisted of six replicates. Because the test species differ in their size and growth requirements, numbers of seeds per pot were adjusted accordingly. The number of seeds per pot and number of pots per replicate were as follows: barnyard grass, onion and wheat – 10 seeds per pot / 1 pot per replicate; corn, cucumber, radish, soybean, sugarbeet, sunflower and tomato: 5 seeds per pot / 2 pots per replicate.

Following planting, the test substance treatments were applied in 350 mL water onto the soil surface to simulate an irrigation event of approximately 0.75 inch (1.9 cm) water. In the onion re-test with Telone, ethanol was used as a co-solvent and a solvent blank (4.5 mL ethanol/L) also tested.

The in-life phase of each test was terminated after 22 days (onion re-test terminated after 20 days). Observations of phytotoxicity and emergence were recorded for all species. At the end of the in-life phase shoot lengths were determined and shoots were harvested and fresh weight was determined. Statistical analysis was conducted on the emergence, survival, shoot length and shoot weight data to determine NOEC (no-observable effect concentration), EC_{25} and EC_{50} values.

For the vegetative vigor tests six replicates with 6 seedlings per replicate were tested for each control and treatment level. The number of seedlings per pot and number of pots per replicate were as follows: onion and wheat – 6 seedlings per pot / 1 pot per replicate; corn, cucumber, sugarbeet, sunflower and tomato: 3 seedlings per pot / 2 pots per replicate. Barnyard grass, radish and soybean were not evaluated in Tier II vegetative vigor tests because less than 25% effects were observed in the Tier I tests.

The test substance treatments were applied in 350 mL water onto the foliage and soil to simulate an irrigation event of approximately 0.75 inch (1.9 cm) water. The in-life phase of each species was terminated after 22 days for sugarbeet, and after 21 days for corn, cucumber, onion, sunflower, tomato and wheat. Observations of phytotoxicity, shoot length, and shoot weight were recorded for all species as in the emergence tests, and statistical analysis was conducted to determine NOEC, EC_{25} and EC_{50} values.

Samples of the treatment solutions used for the emergence and vegetative vigor studies were collected pre- and post-application and analyzed to quantify the concentrations of the test substances in solution.

Findings:

Mean measured concentrations of 3-CAA and 3-CACA in the irrigation solutions ranged from 93 to 105% of nominal, indicating that actual concentrations of the metabolites in the irrigation solutions were in good agreement with the target levels. The recovery of 1,3-D showed more variability, ranging from 55-133% of nominal in the Tier I tests and 51-96% nominal in the Tier II tests (22-132% in onion emergence re-test). The poor recovery of 1,3-D was attributed to its volatility. Nevertheless, since recoveries were low, the treatment rates were based on mean recovered 1,3-D values rather than nominal values. Therefore, for the Tier II emergence tests the concentrations (and corresponding dose per pot), of the test substances were as follows:

Telone: 81, 49, 28, 15 µg/mL (= 28.35, 17.15, 9.8, 5.25 mg/pot)

3-CAA: 12, 6, 3 µg/mL (= 4.2, 2.1, 1.05 mg/pot)

3-CACA: 4, 2, 1 µg/mL (= 1.4, 0.7, 0.35 mg/pot)

In the onion re-test with Telone, the rates were 80, 40, 20, 10, 5, 2.5, 1.25 µg/mL (= 28, 14, 7, 3.5, 1.75, 0.875, 0.4375 mg/pot).

For the vegetative vigor studies the concentrations of the test substances in the irrigation water, and the resulting doses per pot, were as follows:

Telone; 81, 49, 28, 15, 9 µg/mL (= 28.35, 17.15, 9.8, 5.25, 3.15 mg/pot)

3-CAA: 12, 6, 3, 1.5 µg/mL (= 4.2, 2.1, 1.05, 0.525 mg/pot)

For 3-CACA no Tier II vegetative vigor tests were triggered.

Results at the conclusion of the in-life phase of the seedling emergence and vegetative vigor tests with Telone are summarized in Tables 9.8.1-1 and 9.8.1-2. For the purpose of this summary only the EC_{50} values are presented, and these are summarised in terms of irrigation water concentration (µg/mL), treatment rate per pot (mg/pot) and treatment rate per hectare (kg/ha) based on the treated soil surface area of 28.3 $inch^2$ (= 1.826 x 10^{-6} ha).

Table 9.8.1-1. Effect of 1,3-D on Percent emergence, Shoot Length and Shoot Weight of Terrestrial Non-Target Plants in a Seedling Emergence Study

	Percent Emergence EC_{50}			Shoot Length EC_{50}			Shoot Weight EC_{50}		
Species[a]	(µg/mL)	(mg/pot)	(kg/ha)	(µg/mL)	(mg/pot)	(kg/ha)	(µg/mL)	(mg/pot)	(kg/ha)
Corn	>81	>28.35	>15.5	>81	>28.35	>15.5	>81	>28.35	>15.5
Onion	>81	>28.35	>15.5	>81	>28.35	>15.5	>81	>28.35	>15.5
Radish	>81	>28.35	>15.5	>81	>28.35	>15.5	>81	>28.35	>15.5
Soybean	63	22.05	12.1	55	19.25	10.5	>81	>28.35	>15.5
Sugarbeet	>81	>28.35	>15.5	>81	>28.35	>15.5	>81	>28.35	>15.5
Tomato	70	24.50	13.4	78	27.3	15.0	60	21.00	11.5

[a] In the Tier I test less than 25% effect was recorded for cucumber, sunflower, wheat and barnyard grass at the rate tested (152 µg/mL in irrigation water; equivalent to 53.2 mg/pot, and 29.1 kg/ha).

Table 9.8.1-2. Effect of 1,3-D on Shoot Length and Shoot Weight of Terrestrial Non-Target Plants in a Vegetative vigor Study

	Shoot Length EC_{50}			Shoot Weight EC_{50}		
Species	(µg/mL)	(mg/pot)	(kg/ha)	(µg/mL)	(mg/pot)	(kg/ha)
Corn	>81	>28.35	>15.5	>81	>28.35	>15.5
Cucumber	59	20.65	11.3	57	19.95	10.9
Onion	38	13.30	7.3	28	9.80	5.4
Sugarbeet	80	28.00	15.3	72	25.20	13.8
Sunflower	>81	>28.35	>15.5	>81	>28.35	>15.5
Tomato	68	23.80	13.0	59	20.65	11.3
Wheat	>81	>28.35	>15.5	>81	>28.35	>15.5

[a] In the Tier I test less than 25% effect was recorded for radish, soybean and barnyard grass at the rate tested (152 µg/mL in irrigation water; equivalent to 53.2 mg/pot, and 29.1 kg/ha).

In the seedling emergence tests, soybean and tomato were the most sensitive species tested with EC_{50} values equivalent to 10.5 kg/ha (shoot length) and 11.5 kg/ha (shoot weight), respectively. Less than 50% effects were reported for corn, onion, radish and sugarbeet at the maximum rate tested in the Tier II study (15.5 kg/ha), while less than 25% effects were reported for cucumber, sunflower, wheat and barnyard grass in the Tier I test treated at 29.1 kg/ha.

In the vegetative vigor tests onion was the most sensitive species tested with an EC_{50} value equivalent to 7.3 kg/ha (shoot length) and 5.4 kg/ha (shoot weight). Less than 50% effects were reported for corn, sunflower and wheat at the maximum rate tested in the Tier II study (15.5 kg/ha), while less than 25% effects were reported for radish, soybean and barnyard grass in the Tier I test treated at 29.1 kg/ha.

Results of the seedling emergence and vegetative vigor tests with 3-CAA are summarized in Tables 8.6-3 and 8.6-4, and results of the seedling emergence tests with 3-CACA are summarized in Table 8.6-5.

Table 9.8.1-3. Effect of 3-CAA on Percent emergence, Shoot Length and Shoot Weight of Terrestrial Non-Target Plants in a Seedling Emergence Study

	Percent Emergence EC_{50}			Shoot Length EC_{50}			Shoot Weight EC_{50}		
Species	(µg/mL)	(mg/pot)	(kg/ha)	(µg/mL)	(mg/pot)	(kg/ha)	(µg/mL)	(mg/pot)	(kg/ha)
Onion	>12	>4.2	>2.3	>12	>4.2	>2.3	>12	>4.2	>2.3

[a] In the Tier I test less than 25% effect was recorded for barnyard grass, radish, corn, soybean, cucumber, sugarbeet, sunflower, tomato and wheat at the rate tested (12 µg/mL in irrigation water; equivalent to 4.2 mg/pot, or 2.3 kg/ha).

Table 9.8.1-4. Effect of 3-CAA on Shoot Length and Shoot Weight of Terrestrial Non-Target Plants in a Vegetative vigor Study

	Shoot Length EC_{50}			Shoot Weight EC_{50}		
Species	(µg/mL)	(mg/pot)	(kg/ha)	(µg/mL)	(mg/pot)	(kg/ha)
Onion	>12	>4.2	>2.3	>12	>4.2	>2.3
Sugarbeet	>12	>4.2	>2.3	>12	>4.2	>2.3
Wheat	>12	>4.2	>2.3	>12	>4.2	>2.3

[a] In the Tier I test less than 25% effect was recorded for barnyard grass, radish, corn, soybean, cucumber, sunflower and tomato at the rate tested (12 µg/mL in irrigation water; equivalent to 4.2 mg/pot, or 2.3 kg/ha).

Table 9.8.1-5. Effect of 3-CACA on Percent emergence, Shoot Length and Shoot Weight of Terrestrial Non-Target Plants in a Seedling Emergence Study

	Percent Emergence EC_{50}			Shoot Length EC_{50}			Shoot Weight EC_{50}		
Species	(µg/mL)	(mg/pot)	(kg/ha)	(µg/mL)	(mg/pot)	(kg/ha)	(µg/mL)	(mg/pot)	(kg/ha)
Onion	>4	>1.4	>0.8	>4	>1.4	>0.8	>4	>1.4	>0.8
Radish	>4	>1.4	>0.8	>4	>1.4	>0.8	>4	>1.4	>0.8

[a] In the Tier I test less than 25% effect was recorded for barnyard grass, corn, cucumber, soybean, sugarbeet, sunflower, tomato and wheat at the rate tested (4 µg/mL in irrigation water; equivalent to 1.4 mg/pot, or 0.8 kg/ha).

In the Tier II seedling emergence test with onion, 3-CAA had less than 50% effect at the rate tested (equivalent to 2.3 kg/ha). Less than 25% effects were reported for the other nine species in the Tier I tests treated at 2.3 kg/ha. Similarly, in the Tier II test with 3-CACA there were less than 50% effects on onion and radish at the rate tested (equivalent to 0.8 kg/ha), while less than 25% effects were reported for the other eight species in the Tier I tests treated at 0.8 kg/ha. In the Tier II vegetative vigor tests with 3-CAA there were less than 50% effects on onion, sugarbeet and wheat at the rate tested (equivalent to 2.3 kg/ha), while less than 25% effects were reported for the other seven species in the Tier I tests treated at 2.3 kg/ha.

In summary, based on EC_{50} values, soybean and tomato were the most sensitive species tested with 1,3-D in seedling emergence tests, with the minimum EC_{50} values equivalent to an irrigation concentration of 55 mg/L (shoot length) and 60 mg/L (shoot weight), respectively. These irrigation concentrations were equivalent to application of 10.5 kg/ha (shoot length) and 11.5 kg/ha (shoot weight) to soybean and tomato respectively in this study.

Less than 50% effects were reported for corn, onion, radish and sugarbeet irrigated with 81 mg/L 1,3-D (equivalent to applying 15.5 kg/ha) in the Tier II test, and less than 25% effects were reported for irrigation with 152 mg/L the equivalent of 29.1 kg/ha for cucumber, sunflower and barnyard grass in the Tier I test.

In vegetative vigor tests onion was the most sensitive species with an EC_{50} for irrigation water of 28 mg/L (equivalent to 5.4 kg/ha) for the most sensitive parameter (shoot weight). Less than 50% effects were reported for corn, sunflower and wheat irrigated with 81 mg/L (the equivalent of 15.5 kg/ha) in the Tier II study, while less than 25% effects were reported for radish, soybean and barnyard grass in the Tier I test treated at 152 mg/L (the equivalent of 29.1 kg/ha).

The soil metabolites, chloroallyl alcohol (3-CAA) and chloroacrylic acid (3-CACA) had less than 50% effect in both seedling emergence and vegetative vigor studies at the maximum concentrations tested, 12 and 4 mg/L (equivalent to 2.3 kg/ha and 0.8 kg/ha) respectively for all species tested.

B.9.8.2 Risk Assessment

Telone II is a soil fumigant applied by injection into the soil, typically at a depth of 20-30 cm, followed by compaction of the topsoil to help seal the soil in order to maximize the efficacy of the material and minimize volatility losses of 1,3-D. Considering the combination of an injected product and the capping of the soil, drift and run-off of 1,3-D and its metabolites are negligible.

Exposure calculations

The average 1,3-D PEC_{soil} has been calculated by Wang *et al* (2005) for the upper 30-cm soil profile in untreated soil adjacent to 1,3-D treated-fields for distances of 0.1m, 1m, 3m, 5m and 10m from the field edge. The model was used to simulate treatment of a field with 1,3-D by open field shank injection under two temperature conditions typical of northern (15 ºC) and southern (30 ºC) zones in the EU. Lateral transport was simulated for up to 120 days following application of 1,3-D at a rate of 230 kg a.i./ha, which is similar to the maximum supported outdoor use in the EU of 224 kg a.i./ha being considered for Annex I inclusion. The metabolite 3-chloroallyl alcohol is transient in soil (half-life: 0.2 – 0.3 days), while the metabolite 3-chloroacrylic acid is significantly less volatile than 1,3-D and therefore not likely to exhibit lateral flow. Therefore, lateral movement of the metabolites from the field will be negligible and has not been considered.

For the purposes of this assessment, only the use of Telone II in S. EU has been considered. At the higher environmental temperatures typical of S. EU conditions diffusion of 1,3-D in the soil is fast, with higher volatilization losses and less available for lateral transport. The predicted total 1,3-D soil concentration averaged over the upper 30 cm soil profile showed decreasing concentrations at increasing distances from the application site.

Average total 1,3-D concentrations (mg/kg-soil) in the top 30-cm soil at 0.1, 1, 5, 14, and 28 days after injection at selected locations from the field edge, T = 30 ºC.

Time	**Distance from Field Edge**				
(day)	**0.1 m**	**1 m**	**3 m**	**5 m**	**10 m**
0.1	221.0	<0.001	<0.001	<0.001	<0.001
1	106.0	0.052	<0.001	<0.001	<0.001
5	15.10	1.600	<0.001	<0.001	<0.001
14	2.320	0.783	0.006	<0.001	<0.001

28	0.348	0.174	0.010	<0.001	<0.001
0 - 28 day maximum	**221.0**	**1.600**	**0.006**	**<0.001**	**<0.001**

Due to faster movement of 1,3-D at higher environmental temperatures the maximum PEC_{soil} at 1 m from the treated field occurred after 5 days and was 1.6 mg/kg soil. Concentrations did not exceed 0.006 mg/kg soil at 3 m and beyond. Since the model simulated application of 1,3-D at 30 cm depth, the average soil concentration in the 30 cm depth is considered to be worst-case when considering the off-field plant root zone.

Toxicity endpoints

The EC_{50} values estimated for the plants tested in the vegetative vigour and seedling emergence tests with 1,3-D are summarised above and indicate shoot dry weight as the most sensitive end-point. The most sensitive species in the vegetative vigour test was onion with an EC_{50} of 28 µg a.s./mL; in the seedling emergence test soybean was most sensitive with an EC_{50} of 55 µg a.s./mL. Since each pot was irrigated with 350 mL of test solution, and each pot contained approximately 2.6 kg_{soil}, these EC_{50} values are equivalent to 3.8 mg a.s./kg_{soil} (= 0.028 mg a.s./mL x 350 mL / 2.6 kg_{soil}) and 7.4 mg a.s./kg_{soil} (= 0.055 mg a.s./mL x 350 mL / 2.6 kg_{soil}) respectively.

Toxicity ratio exposures

Based on the lowest EC_{50}, and the PEC_{soil} values provided above the worst-case TER can be calculated deterministically at different distances from the treated soil in accordance with the guidance provided in SANCO/10329/2002 for non-target terrestrial plants. However, in the case of 1,3-D the use of the vegetative vigor EC_{50} for risk assessment will be misleading since exposure of plant foliage to a soil injected fumigant will not occur via irrigation (or spraying) under field conditions. Therefore, in this situation, comparison of the lowest EC_{50} of 7.4 mg a.s./kg soil (soybean) from the seedling emergence test to the PEC_{soil} values is more appropriate.

If the TER based on the most sensitive species exceeds 5 then the guidance document states that effects on non-target plants are considered acceptable. The calculated TER values are summarised below and illustrate that the TER exceeds 5 at distances of 3 m from the field edge. Thus, the assessment indicates that the risk to non-target plants will be acceptable at 3 m from the treated field.

TER values for non-target plants at different distances from the treated field using the deterministic approach (SANCO/10329/2002) with the lowest seedling emergence EC_{50} for non-target plants of 7.4 mg a.s./kg soil.

Region	**Distance from field edge**								
	1 m			**3 m**			**5 m**		
	EC_{50}	PEC_{soi}	TE	EC_{50}	PEC_{soi}	TER	EC_{50}	PEC_{soi}	TER

	[1]	[1]	R	[1]	[1]		[1]	[1]	
Souther n EU	7.4	1.6	4.6	7.4	0.006	123 3	7.4	<0.00 1	>740 0

[1] EC_{50} for soybean (seedling emergence test).

The off-field TER for non-target plants exceeded the trigger value of 5 at 3 m from the treated field indicating that 1,3-D will not pose an unacceptable risk to non-target plants adjacent to treated fields.

Soil metabolites

The soil metabolites, chloroallyl alcohol (3-CAA) and chloroacrylic acid (3-CACA) had less than 50% effect in both seedling emergence and vegetative vigor studies at the maximum concentrations tested, 12 and 4 mg/L. Since each pot was irrigated with 350 mL of test solution, and each pot contained approximately 2.6 kg_{soil}, the EC_{50} values are **greater than** 1.6 mg 3-CAA/kg_{soil} (= 0.012 mg a.s./mL x 350 mL / 2.6 kg_{soil}) and 0.53 mg a.s./kg_{soil} (= 0.004 mg a.s./mL x 350 mL / 2.6 kg_{soil}) respectively. Therefore, at 3 m even assuming that the maximum metabolite concentrations are similar to those of the parent 1,3-D (i.e. 0.006 mg/kg soil), and that the EC_{50} is not much greater than the maximum concentration tested in the studies, the TER values will exceed 88 and indicate a low risk to non-target plants.

In summary, the off-field TER for non-target plants exceeded the trigger value of 5 at 3 m from the treated field indicating that 1,3-D will not pose an unacceptable risk to non-target plants adjacent to treated fields. The soil metabolites, chloroallyl alcohol (3-CAA) and chloroacrylic acid (3-CACA) had less than 50% effect in seedling emergence studies at the maximum concentrations tested, 12 and 4 mg/L (equivalent to 1.6 and 0.53 mg/kg_{soil}) respectively for all species tested.

Conclusion: buffer zones of 3 m are needed to protect non target plants of application of Telone II.

B.9.9. Effects on biological methods of sewage treatment.

The EFSA Scientific Report (2006) highlighted the following critical areas of concern with regard to risk to sewage treatment organisms from 1,3-D:

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

A study conducted by Kennedy, 2001 to determine the effects of Telone on activated sewage sludge respiration was evaluated by the RMS and summarised in the DAR. The 3 h EC50 estimated from the study results was 325.4 µL/L (equivalent to 384 mg 1,3-D/L); though the RMS raised concern that because actual concentrations of the test solution were not determined this may be an underestimate of toxicity since the dosing solution was stirred overnight prior to exposing the sewage sludge to ensure complete dissolving of the test material.

Nevertheless, due to the volatility of 1,3-D, the tine injection technology and application of Telone Drip in greenhouses, movement of 1,3-D in runoff and resultant contamination of biological treatment processes via surface water contamination is unlikely as indicated by the low PEC_{sw} values. However, since it is at least theoretically possible that Telone could be released as result of washing tools employed for the application of 1,3-D in greenhouses, it is recommended that waste water used for cleaning equipment is not released directly into drains leading to sewage treatment plants.

In summary, the sewage organism 3 h EC_{50} for 1,3-D was 384 mg/L. Following the outdoor use of 1,3-D by injection or indoor use as a drip treatment in greenhouses, movement of 1,3-D and contamination of biological treatment processes is unlikely. However, since it is at least theoretically possible that Telone could be released as result of washing tools employed for the application of 1,3-D in greenhouses, it is recommended that waste water used for cleaning equipment is not released directly into drains leading to sewage treatment plants.

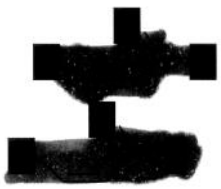
B.9.10. Other/ Special studies

Ecotoxicological profile of impurities in 1,3-D technical

The EFSA Scientific Report (2006) raised a general concern related to the high application rates of 1,3-D and consequently the potential for significant amounts of poly chlorinated impurities in the technical material to be added to the environment. The EFSA requested further clarification of the content, nature and potential hazard of the impurities in the technical 1,3-D, as well as further information on their potential hazard to non-target organisms. The EFSA specifically requested that the ecotoxicological relevance of the impurity 1,2-dichloropropane be addressed, its levels confirmed in the ecotoxicological studies, and any implications to the ecotoxicology risk assessments be evaluated. These concerns are addressed below.

For completeness, all the impurities identified in technical 1,3-D from Dow (and summarized in the table below) have been considered further. All are short chain (3- or 6- carbon) chlorinated alkanes, alkenes, dienes or oxirane, which have similar molecular weights and structures to the parent 1,3-D.

Impurities specified in technical 1,3-D from Dow (active substance, minimum content of 96.5% is included for information on comparative structure and molecular weight)

Compound	Structure	Molecular formula and weight	Content in technical material (%)
Parent active substance (chlorinated alkene)			
1,3-dichloropropene		$C_3H_4Cl_2$ 110.97	Min. 96.5
Chlorinated alkene impurities			
[redacted]		[redacted]	Max. 0.1 < 1 g/kg
[redacted]		[redacted]	Max.0.1 **< 1 g/kg**
[redacted]		[redacted]	Max.0.1 **< 1 g/kg**
[redacted]		[redacted]	Max.0.1 **< 1g/kg**
[redacted]		[redacted]	Max.0.3 **3 g/kg max**
Chlorinated alkane impurities			
1,2-dichloropropane	Cl	$C_3H_6Cl_2$ 112.99	Max 0.01 **Max. 0.1**
[redacted]		[redacted]	Max.0.2 **2 g/kg** Max.**0.3** **Max 3 g/kg** Max.**0.2** **Max 2 g/kg** Max.0.1 **< 1g/kg** Max.0.1 **1 g/kg** Max.0.1 **< 1g/kg**

Compound	Structure	Molecular formula and weight	Content in technical material (%)
[redacted]	[redacted]	[redacted]	Max.0.1
			< 1g/kg
[redacted]	[redacted]	[redacted]	Max.0.1
			< 1 g/kg
[redacted]	[redacted]	[redacted]	Max.0.1
			< 1g/kg
[redacted]	[redacted]	[redacted]	Max.0.1
			< 1g/kg
[redacted]			Max. 01
			< 1 g/kg

Additional impurities can be found in batches from Kanesho (see Annex C, addendum 3). From a toxicological point of view these impurities have been assessed and the conclusion was these impurities are not relevant (Addendum IV, to B6, March 2009). According to last technical specifications in the five batches analysis from Kanesho and DOW it was showed that levels of 1,2-dichloropropane are always below 0.01%.

Levels of 1,2-dichloropropane on batches used in ecotoxicological studies

The following statement was submitted by the notifier (Dow Agrosciences): "*All impurities identified in batches of technical 1,3-D (minimum purity: 96.5 %w/w) are at levels below 0.3 % (w/w) and there is no reason to believe that these impurities would not have been present in 1,3-D at the time of ecotoxicity testing. The levels of 1,2-Dichloropropane in 1,3-D Technical has been controlled at Dow AgroSciences to levels below 0.1% since 1991 and has been controlled to a maximum of 0.01% since 1997. Therefore, the toxicity end-points determined for technical 1,3-D will account for the toxicity and content of these impurities*".

Levels of all impurities were not measured in batches of 1,3-D used for the ecotox studies. A copy of all the available data on the key batches used in the Ecotoxicology tests is summarised in the table below. Only information about purity is depicted.

Characterisation of key batches used in Ecotoxicological tests.

STUDY	BATCH DETAILS
Fink, R. et al. (1982): Acute Oral LD_{50} - Bobwhite Quail. Telone II Soil Fumigant - Final Report. Dow	**AGR 190428** Purity 92.0%

AgroSciences, unpublished report No. 103-207, 5 May 1982. **MJ01**	
Gallagher, S.P., Grimes, J. & Beavers, J.B. (1999): Telone II: A dietary LC50 study with the Northern bobwhite. Dow AgroSciences, unpublished report No. 103-432, 26 August 1999. **MJ18**	Telone II microcapsules. Lot No. M102698 Prepared from 1,3-D (**Lot No. KA10162771**, 96 % purity)
Gallagher, S.P., Grimes, J. & Beavers, J.B. (1999): Telone II: A dietary LC50 study with the Mallard. Dow AgroSciences, unpublished report No. 103-433, 26 August 1999. **MJ19**	
Diana L. Temple, Kathy H. Martin, Joann B. Beavers, Mark Jaber. (2006): 1,3-DICHLOROPROPENE: A REPRODUCTION STUDY WITH THE NORTHERN BOBWHITE	Telone II microcapsules, Lot No.: M021805. Prepared from 1,3-D TSN104897 (**Lot No. SA27292OT**, 95.9 % purity)
Marino, T.A., M^{c}Clymont, E.L. & Yaroch, A.M. (2001): Telone II: An acute toxicity study with the rainbow trout, *Oncorhynchus mykiss* Walbaum.. Dow AgroSciences, unpublished report No. 011153, 23 October 2001. **MJ22**	**TSN102629** **Lot No. PE1716281A** Purity 100% 1,3-dichloropropene (51.5% *cis* and 49.4% *trans*)
Marino, T.A., McClymont, E.L., Hales, C.A. & Yaroch, A.M. (2001). Telone II: An acute toxicity study with the daphnid, *Daphnia magna,* Straus. Dow AgroSciences, unpublished report No. 011154, 05 October 2001. **MJ23**	
Drottar, K.R. & Krueger, H.O. (1999): Telone II: A 96-hour flow-through acute toxicity test with the Sheepshead minnow (*Cyprinodon variegatus*). Dow AgroSciences, unpublished report No. 103A-110, 8 April 1999. **MJ07**	**Lot No. KA10162771**. Purity: 96% 1,3-D.
Drottar, K.R. & Krueger, H.O. (1999): Telone II: A 96-hour flow-through acute toxicity test with the saltwater mysid (*Mysidopsis bahia).* Dow AgroSciences, unpublished report No. 103A-109, 8 April 1999. **MJ06**	
Drottar, K.R. & Krueger, H.O. (1999) Telone II: A 96-hour shell deposition test with the Eastern oyster (*Crassotrea virginica*): Dow AgroSciences, unpublished report No. 103A-111, 8 April 1999. **MJ08**	
Marino, T.A., Kirk, H.D., Hugo, J.M. & McFadden, L.G. (2000): Telone* II Soil Fumigant: Toxicity to the early life stages of the Fathead Minnow, *Pimephales promelas* Rafinesque. Dow AgroSciences, unpublished report No. 991081, 27 January 2000. **MJ21**	**AGR295646** Lot No. TA901221 Dow Registry No. M-003993. Purity 96% 1,3-D
Kirk, H.D., Hugo, J.M. & Marino, T.A. (1999): Telone II Soil Fumigant: An acute toxicity study with the bluegill sunfish, *Lepomis macrochirus* Rafinesque. Dow AgroSciences, unpublished report No. 981185, 7 May 1999. **MJ10**	
Kirk, H.D., Gilles, M.M., Marino, T.A., Hugo, J.M. & McFadden, L.G. (1999): Evaluation of the chronic toxicity of Telone II soil fumigant to the daphnid, *Daphnia magna* Straus. Dow AgroSciences, unpublished report No. 991086, 21 December 1999. **MJ20**	
Kirk, H.D., Gilles, M.M., Hugo, J.M. & McFadden, L.G. (1999): Phytotoxicological evaluation of Telone II soil fumigant exposed freshwater green alga, *Selenastrum capricornutum* Printz. Dow AgroSciences, unpublished report No. 981159, 10 June 1999. **MJ15**	
Kirk, H.D., Gilles, M.M., Rick, D.L. & McFadden, L.G. (1999): Phytotoxicological evaluation of Telone II soil fumigant exposed freshwater diatom, *Navicula pelliculosa*. Dow AgroSciences, unpublished report No. 981178, 24	

March 1999. **MJ11**	
Kirk, H.D., Gilles, M.M., Rick, D.L. & McFadden, L.G. (1999): Phytotoxicological evaluation of Telone II soil fumigant exposed bluegreen alga, *Anabaena flos-aquae.* Dow AgroSciences, unpublished report No. 981177, 24 March 1999. **MJ13**	
Kirk, H.D., Gilles, M.M., Rick, D.L. & McFadden, L.G. (1999): Phytotoxicological evaluation of Telone II soil fumigant exposed saltwater diatom, *Skeletonema costatum*. Dow AgroSciences, unpublished report No. 981168, 24 March 1999. **MJ12**	
Kirk, H.D., Gilles, M.M., Rick, D.L. & McFadden, L.G. (1999): Phytotoxicological evaluation of Telone II soil fumigant exposed aquatic plant, Duckweed, *Lemna gibba* L. G-3. Dow AgroSciences, unpublished report No. 981165, 4 May 1999. **MJ14**	
Bakker, F. (2001). An extended laboratory study to evaluate the effect of Telone II treated soil on the springtail *Folsomia candida* (Collembola: Isotomidae). Dow AgroSciences unpublished report number DA016FCE, 30th November 2001. **MJ27**	Batch No.**PC19292061.** Purity 97.9% 1,3-D.
Bakker, F. (2001). An extended laboratory study to evaluate the effect of Telone II treated soil on the predaceous mite *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae). Dow AgroSciences unpublished report number DA015HAE, 30th November 2001. **MJ28**	
Kennedy, S.H. (2001). The effects of Telone II on activated sewage sludge respiration. Dow AgroSciences, unpublished report No. CEMR-1624, 6 September 2001. **MJ25**	
Bakker, F. (2001). Potential effects of Telone II treated soil on the carabid beetle *Poecilus cupreus* determined in an extended laboratory assay. Dow AgroSciences unpublished report number DA001PCE, 2nd October 2001. **MJ31**	**Batch reference: TSN 101035** Purity 95.4% 1,3-D w/w C of A = AD/1335
Bakker, F. (2001). Potential effects of TELONE II applications in the soil on the staphylinid beetle *Aleochara bilineata* determined in an extended laboratory assay. Dow AgroSciences unpublished report number DA003ABE, 2nd October 2001. **MJ29**	
Bakker, F. (2001). Potential effects of TELONE II treated soil on female spiders of the genus *Pardosa* determined in an extended laboratory assay. Dow AgroSciences unpublished report number DA002PSE, 2nd October 2001. **MJ30**	
Mallett, M.J. (1999): Sub-acute toxicity of Telone II to the earthworm Eisenia foetida Dow AgroSciences, unpublished report No. CEMR-881, 17 March 1999. **MJ09**	
Forster, J. (1999): A laboratory assessment of the effects of Telone II on soil microflora respiration ad nitrogen transformations according to BBA Guidelines V1 1-1 (1990). Dow AgroSciences, unpublished report No. ENV 4010, 6 August 1999. **MK26**	
Rodger, M. & Cameron, D. (1997): Telone 97: Acute toxicity (LC_{50}) to the earthworm (Eisenia foetida). Dow AgroSciences, unpublished report No. DWC 780/962073, 9 January 1997. **MJ05**	**Batch No. EB951012**. Purity 99.3% w/w 1,3-D C of A = KL/188

RMS opinion is that according to last technical specifications (see addendum C and table below) levels of 1, 2-Dichloropropane are expected to decrease at levels of 0.01 % since 1991. This statement is supported for information depicted in the DAR and in the EFSA report where is indicated that there are toxicological studies performed with batches containing 1, 2-Dichloropropane in the range of 1.4%-2%.

Under RMS opinion and taking into account all the available information such as manufacturing and time of ecotoxicity testing can be assumed that the ecotoxicity endpoints determined for technical 1,3-D account for the toxicity and content of all impurities.

Because the levels of impurities on the different ecotox batches are not available, the notifier has provided information on the structures and the measured, or estimated, toxicities of the identified impurities; which illustrates that all are expected to have similar or lower toxicity to non-target organisms than 1,3-D (see table below).

Also, the notifier has provided estimates of the likely exposure of non-target organisms to the impurities which illustrates that the maximum environmental loading of any individual impurity following application of technical 1,3-D will be more than 350-fold lower (and as much as 9650-fold lower) than that of the active substance 1,3-D. Therefore, a semi-quantitative risk assessment can be made with the information provided, and this shows that if the impurities are no more toxic than 1,3-D, while exposure of non-target organisms is at least 350-fold lower, then the risk associated with the impurities is addressed by the risk assessments conduced for 1,3-D.

Furthermore, this is in agreement with the conclusion reached in the section of Toxicology and metabolism (addendum IV, March 2009). In this addendum was conclude that the impurities which occur in 1,3-dichloropropene products do not contribute toward the potential toxicity of these products.

Tier I screening for 1,2-dichloropropane

A Tier I screening assessment have been conducted using publicly available toxicity data (e.g. literature search, Manufacturers Safety Data Sheets (MSDS) and Pesticide Action Network Database) (see Table below). In the case of 1,2-dichloropropane, which is used as a raw material in the production of many other chemicals, in a variety of non-agricultural applications, as well as historically being co-formulated with 1,3-D as a component of D-D Mix, an extensive summary of its environmental and human health endpoints have been published by the World Health Organisation (1993) and OECD (2003).

OECD (2003) concluded that 1,2-dichloropropane has "*low acute hazard toward fish, invertebrates, and alga with EC_{50} values in a range 15-140 mg/l, and with chronic aquatic NOEC values of 4.1-11 mg/l in these same species*." and overall that "*The chemical is currently of low priority for further work because of its low [environmental] hazard profile.*"

Furthermore, the notifier using the methodology outlined in the Manual on development and use of FAO and WHO specifications for pesticides, Feb 2006 revision of the First edition was employed to estimate the potential contribution of 1,2-dichloropropane to the overall toxicity of Dow AgroSciences 1,3-dichloropropene. The toxicity of an impurity is considered "relevant" if it is calculated to increase

the potential hazard of the product by greater than 10%, and it is considered to be "not-relevant" if it increases the potential hazard of the product by less than 10%.

Aquatic organisms

Estimates were calculated using experimental-derived toxicity data for fish (*fathead minnow*, LC50 =140 mg/L), Daphnia (48h-EC50 = 55.9 mg/L), algae (*Skeletonema*, 72hEC50 = 15.5) and using the maximum potential of impurity levels outlined in the Specification of Dow AgroSciences and Kaseho (maxim 0.01%). The "relative hazard" estimates are 0.0322, 0.0293 and 0.0645 for daphnia, fish and algae, respectively. The "Maximum Theoretical Increase in Hazard" estimates are 1 for the three taxonomic groups, thus not increase in the potential hazard is calculated.

Mammals

In the addendum IV to B6 (March 2009), the maximum Theoretical increase in hazard estimates is 1 for 1,2-dichloropropane. Not increase in the potential hazard is calculated.

In this case, for 1,2-Dichloropropane can be concluded that this impurity do not contribute toward the potential toxicity of 1,3-dichloropropene products. Using the approach of developing manual of FAO and taking into account all available information under RMS opinion 1,2-dichloropropane should be considered as not ecotoxicological relevant.

Furthermore, ecotoxicity data for 1,2-dichloropropane were compiled by the notifier (see table below), and these data agrees with experimental data used for relative hazard according to FAO specifications.

In summary: according to ecotoxicological profile of 1,2-dichloropropane from data used in FAO specifications, and the fact that the maximum proportion in the technical product is 0.01%, it can be concluded that 1,2-dichloropropane should be considered as not ecotoxicological relevant.

Moreover, according to assessment in toxicology section 1,2-dichloropropane should be considered as not toxicological relevant.

Tier I screening for other impurities

Toxicity assessment

For those impurities where no data were available, estimated toxicity end-points were derived using Quantitative Structure Activity Relationships (QSAR) using the USEPA ECOSAR database (USEPA, 2003, EPI Suite v3.12; http://www.epa.gov/oppt/exposure/docs/episuitedl.htm). From the ECOSAR database the relevant ecotoxicological end-points (i.e. EC/LC_{50} for freshwater fish, *Daphnia*, algae and earthworms) estimated using the most appropriate QSAR class (SARs for neutral organics or vinyl/allyl halides) were taken. These end-points were chosen to allow an assessment of the relative toxicity of the impurities to be compared to that of the active substance. The available toxicity end-points for the impurities for aquatic and soil organisms are summarized below. For the fish acute toxicity end-point (96 h LC_{50}) the lowest predicted value for freshwater or saltwater fish was used.

To assess the reliability of the QSAR estimates, the predicted toxicity for 1,3-D was also estimated using the same USEPA ECOSAR database and is summarised in the following table for comparison with the lowest reliable end-points referenced in the draft DAR. For fish, *Daphnia* and algae the predicted end-points were within a factor of 1.7 – 10.7 of the lowest end-points reported in the draft DAR. Therefore, it may be assumed that the predicted end-points for the impurities have a similar magnitude of error and that, as a reasonable worst-case, they may underestimate toxicity by a factor of 10.

Toxicity to non-target organisms of impurities identified in technical 1,3-D

Impurity	Acute Toxicity (mg/L or mg/kg$_{soil}$)			
	Fish (96 h LC_{50})	*Daphnia* (48 h EC_{50})	Algae (96 h EC_{50})	Earthworms (14 d LC_{50})
1,3-D (active substance)[1]	**0.87**	**3.58**	**2.35**	**55.6**
1,3-D (active substance)[2]	1.49	38.37	13.50	NA
[redacted]	1.96	63.6	18.6	NA
[redacted]	1.95	5.12	3.47	272
[redacted]	2.3	6.3	4.3	292
[redacted]	2.15	5.81	3.92	NA
[redacted]	1.5	30.4	12.8	NA
Chlorinated alkanes				
1,2-dichloropropane	≥ 61[3,4]	52[5]	14.7[6]	4240[6]
[redacted]	111[4]	280[5]	61.1[5]	554
[redacted]	1.9	4.8	3.3	269
[redacted]	2.0	5.2	3.5	277
[redacted]	2.0	5.2	3.5	277
[redacted]	2.1	5.5	3.7	283
[redacted]	3.5	10.1	6.7	396
[redacted]	0.25	1.32	1.61	NA
[redacted]	0.40	3.14	2.80	NA
[redacted]	31.9	NA	47.9	NA
[redacted]	NA	NA	NA	NA

[1]Lowest reliable end-points referenced in the draft DAR;
[2]EPI Suite, ECOSAR v0.99g. For fish the lowest 96 h LC_{50}, freshwater or saltwater, is reported;
[3]WHO (1993);
[4]Data referenced for fathead minnow 96 h LC_{50} in Russom *et al*, 1997. Predicting modes of toxic action from chemical structure: acute toxicity in the fathead minnow (*Pimephales promelus*). Env. Toxicol. Chem. 16(5). pp. 948-967
[5]PAN database (www.pesticideinfo.org);

[6]OECD SIDS (2003);
[7]Data are available for the similar compound 1,2,3-trichloropropane - fish LC50 = 42 mg/L, *Daphnia* EC50 = 20 mg/L, algal EC50 = 46.9 mg/L (www.inchem.org/documents/cicads/cicads/cicad56.htm#10.1). In addition, data are referenced for fathead minnow 96 h LC_{50} of 57.7 mg/L in Russom *et al*, 1997; NA = No data available

These data indicate that in all cases where toxicity data are available, or can be estimated, the impurities have similar or lower toxicity to aquatic and soil organisms than the active substance 1,3-D.

RMS assessment: Notifier has been used the ECOSAR (Ecological Structure Activity Relationships) personal computer software program to estimate the toxicity of impurities of 1,3-Dichloropropene. The program predicts the toxicity of industrial chemicals to aquatic organisms such as fish, invertebrates, and algae by using Structure Activity Relationships (SARs). The estimates of acute (short-term) toxicity for fish, *Daphnia* and algae and the predicted end-points were within a factor of 1.7 – 10.7 of the lowest end-points reported in the draft DAR for 1,3-Dichloropropene. Therefore, the notifier assumed that the predicted end-points for the impurities have a similar magnitude of error and that, as a reasonable worst-case, they may underestimate toxicity by a factor of 10. The approach is considered acceptable for aquatic organisms, but RMS question the validation of the ECOSAR program to estimate the toxicity on earthworms because the program is developed and validated for aquatic toxicity.

According with the endpoints estimated for the different aquatic organisms, all the impurities have a lower toxicity that the active substance 1,3-Dichloropropene.

Exposure assessment

In addition to the ecotoxicological end-points provided above, the environmental loading, fate and behaviour characteristics of the same impurities should be considered. All impurities listed above are present at less than 0.30 % (w/w), most are present at less than 0.1 % (w/w), and in the case of 1,2-dichloropropane less than 0.01 %; i.e. the maximum environmental loading of any individual impurity following application of technical 1,3-D will be at least 322-fold lower (and as much as 9650-fold lower) than that of the active substance 1,3-D.

The environmental fate and behaviour characteristics of typical impurities in 1,3-D have been considered in Mackay *et al.*, 2006. Fugacity modelling of the chlorinated alkane, alkene, hexadiene and oxirane impurities, assuming soil injection of Telone, illustrated that for most of the impurities the levels will rapidly decline. Indeed, by 14-days after soil treatment all impurities, with the exception of [redacted] and [redacted] are expected to decline by more than 90%, with volatilization or degradation as the major routes of loss.

Percentage loss of impurities from soil by evaporation and degradation (taken from Mackay et al, 2006 summarised in addendum).

Impurity	Amount Lost by 14 days		
	Total (%)	via evaporation (%)	via degradation (%)

1,3-D (active substance)	**94.75**	**60.40**	**30.30**
1,2-dichloropropane	96.19	64.05	28.57
[redacted]	69.66	11.54	56.68
[redacted]	98.37	73.61	23.18
[redacted]	84.21	37.47	44.27
[redacted]	100	93.41	6.33
[redacted]	100	92.01	7.71
[redacted]	98.48	74.81	22.83
[redacted]	99.95	86.62	12.91
[redacted]	100	85.93	13.82
[redacted]	100	89.56	10.30
[redacted]	99.95	73.78	25.79
[redacted]	90.72	3.61	74.07
[redacted]	No data have been submitted		

Two impurities, [redacted] and [redacted] were not evaluated in Mackay *et al.,* 2006. However, both of these volatile impurities are expected to behave similarly to 1,3-D, and are not expected to persist in soil.

Consequently, the maximum concentration of any of the impurities in soil will always be at least 386-fold lower than the active substance, and all but two of the impurities, [redacted] will be no more persistent than the active substance. The fugacity model indicated that for these two impurities, losses will be greater than 90% by 28 days after soil treatment (see Mackay *et al*., 2006), illustrating that they are not persistent and will not accumulate between seasons.

Since losses of the impurities are primarily by volatilization and degradation, there are no reasons to believe that lateral movement of the impurities to surface waters will be any greater than for the active substance. Furthermore, from the fate section was showed that chlorinated alkene and hexadiene impurities were rapidly hydrolysed ($DT_{50} \leq 0.41$ days), while the chlorinated propane impurities had similar hydrolysis rates to 1,3-D (DT_{50} of chlorinated propane impurities ≤ 9.2 days). Thus, there is no reason to believe that these impurities will be any more persistent in the environment than the active substance.

In conclusion, the impurities in technical 1,3-D are chemically similar to the active substance (simple short chain chlorinated hydrocarbons), but are applied to soil at rates significantly lower (386 – 9650 fold), are expected to have similar or lower toxicity than 1,3-D, and are not significantly more persistent. Where laboratory toxicity studies have been conducted with 1,3-D, it is reasonable to assume that the measured toxicity takes into account any contribution from impurities present at the relevant relative quantities to those that will be applied in the environment.

Where higher-tier (field) studies have been conducted, the assessment of effects will take into account any impact from the impurities as well as that of 1,3-D since their fate and behaviour is similar.

Therefore all risk assessments performed for 1,3-D should adequately address any potential risk associated with the impurities.

In summary, the measured or predicted toxicity end-points for the impurities in technical 1,3-D are similar or lower than the measured endpoints for 1,3-D for indicator non-target organisms. In addition, the magnitude of exposure of non-target organisms to the impurities is significantly (at least 386-fold) lower than 1,3-D, and the duration of exposure will not differ appreciably from that of 1,3-D. Therefore, where the risk from 1,3-D is determined to be acceptable, it is reasonable to assume that the risk from the impurities will also be acceptable.

B.9.11. Pesticidal screening data for (EZ)-3-chloroacrylic acid

The EFSA opinion (page 48) stated: *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). This data gap was proposed during the last evaluation meeting (see Evaluation table rev 2-1 (6-03-2006): Applicant to submit data on the pesticidal activity of the groundwater metabolite acrylic acid).*

All the relevant information available for *(EZ)-3-chloroacrylic acid* (see below) indicates that this metabolite is toxicologically relevant, it is not genotoxic and is ecotoxicological relevant (has a higher toxicity to aquatic plants and non target plants). According to SANCO/221/2000 rev. 10, and from a regulatory point of view, it is necessary to know if the metabolite has a comparable or higher biological activity than the parent.

Compound (name and/or code)	**Mobility in soil**	**> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological relevance**
(*EZ*)-3-chloroacrylic acid	K_{doc} <1-17.5mL/g Very high mobility	Yes all 5 pertinent FOCUS groundwater scenarios (concentrations 0.4-144µg/L, 3 of the 5 scenarios > 10 µg/L) Monitoring data available	No data available.	Relevant Toxic (R25) oral LD_{50} 91 mg/kg bw Not genotoxic	Relevant because of higher toxicity to algae and *Lemna gibba*.

To address this data gap the notifier submitted the following information:

Activity of 3-Chloroacrylic acid as a nematicide

Notifier statement: *The product 1,3-Dichloropropene acts effectively as a soil fumigant because it is able to dissipate rapidly (primarily as a vapour) after injection into the soil thus cleanse the soil in the root zone of crops (5 – 50 cms) of soil borne pests. No significant label claims are made for 1,3-D in control of weeds and disease and in reality the prime use by EU vegetable growers is to apply before*

planting and free the soil of nematodes and allow the crop the best starting conditions for growth. Therefore one of the key reasons why 1,3-D is an effective soil fumigant nematacide is because of its highly volatile nature which allows it to dissipate rapidly as a gas, move through the soil profile, and reach the pests surrounding the root zone of crops.

The vapour pressures of 1,3-D and the 3-Chloroacrylic acid are shown in the Table below:

Physical Property	*1,3-Dichloropropene*	*3-Chloroacrylic acid*
Vapour Pressure at 20ºC	*Cis – 3520 Pa*	*Cis – 2.84 Pa*
	Trans – 2319 Pa	*Trans – 4.12 Pa*

Therefore based on the fact that 1,3-Dichloropropene is a volatile liquid with a high vapour pressure and the acid metabolite is a solid with at least a 500 fold difference in vapour pressure we could not expect the 3-chloroacrylic acid metabolite to be an effective nematacide, and dissipate rapidly in the soil to root depth as seen with 1,3-Dichloropropene.

RMS assessment: the statement submitted by the notifier indicates that the 3-chloriacrylic acid is less volatile than the parent 1,3-D suggesting that this metabolite is not an effective nematacide. However, not real data support this statement was submitted.

Activity of 3-Chloroacrylic acid as a herbicide

The notifier has been submitted data available in the literature relating to relating to the effectiveness of 3-chloroacrylic acid as a plant dessicant (foliar applications) (Zakirov and Kadraliev, 1973). Spraying cotton with 3.5 kg acrofol (cis-chloracrylic acid) [Cas n. 1609-93-4]/ha induced 70-75% defoliation without decreasing yield.

Zakirov and Kadraliev (1973). Studies on cotton defoliation
Uzb. 50 Let (1973), 302-10, 405-20 Publisher:"Fan" Uzb. SSR, Tashkent, USSR.
Results: Spraying cotton with 3.5 kg acrofol (cis-chloracrylic acid) [Cas n. 1609-93-4]/ha induced 70-75% defoliation without decreasing yield.

Furthermore, the notifier has provided some additional information (see summary below) showing that 3-chlorycid has herbicide activity in soybeans when is applied in a composition containing 1.2% cis-3-chloroacrylic acid, 0.1% Triton X-100 and water at 5.6kg/ha in soybeans (Kurtz and Herrett , 1963). In another study (Weimer, from DOW-summary, not GLP, not date) has been showed that the 3-chlroacrylic aid has a greater growth reduction that 1,3-D on both soybean and shorgum at 30 kg/ha.

Kurtz and Herret, 1963. Patents BE 631083. FR 1360887.

Summary: Hindered plant growth is obtained from compns. prepared from a haloacrylate-producing Compound, such as an acid of the general formula XCH:C(R)CO2H, where X is a halogen, R is H or a C1-4 alkyl group. The compound may be in the form of a metal or organometallic salt of the acid, an ester, a polyethylene glycol alkylphenyl ether, or a Na alkyl- arenesulfonate. A composition containing 1.2% cis-3-chloroacrylic acid, 0.1% Triton X-100, and H2O, at 5.6 kg./ha., was herbicidally effective without phytotoxicity to soybeans.

Weimer M. Dow AgroSciences. Comparison of the Efficacy of 1,3 Dichlorpropene and 3-Chloroacrylic acid Against Two Weed Species in the Lab

Protocol: Protocol based on guidance document (Sanco/221/2000-rev.10-final; 25 February, 2003) provided by European Commission: Health & Consumer Protection Directorate-General.

Objective: To fulfill Annex I data requirements comparing efficacy of the 3-chloroacrylic acid metabolite of 1,3-dichloropropene to the parent compound against two weed species in the lab.

Key Question: What is the biological activity of 3-chloroacrylic acid relative to 1,3-dichloropropene against two weed species?

Test Materials:

1,3-dichloropropene	(i.e. parent material)
3-chloroacrylic acid	(i.e. acid metabolite)

Treatments:

1.	1,3-dichloropropene	283 Kg/Ha
2.	1,3-dichloropropene	94.3 Kg/Ha
3.	1,3-dichloropropene	31.4 Kg/Ha
4.	3-chloroacrylic acid	272 Kg/Ha
5.	3-chloroacrylic acid	90.6 Kg/Ha
6.	3-chloroacrylic acid	30.2 Kg/Ha
7.	Untreated	

Replications: 6

Weeds Tested:

Soybean	*Glycine max*
Sorghum	*Sorghum bicolor*

Materials and Methods:

10.2 cm pots were used, with six replicate pots per treatment. For each pot, approximately 1.3 cm of a mineral soil mixture (80% loam/20% silt) was placed at the bottom and then a clear drinking straw approximately 10 cm long was placed vertically in the soil in the middle of the pot. The pot was then filled approximately 2/3 full with additional soil, leaving the straw in place in the middle of the pot. Three soybean (*Glycine max*) and eight sorghum (*Sorghum bicolor*) seeds were placed in each pot and an additional 2-cm of soil was placed on top of the seeds. Next, either 1,3-D or it's metabolite was applied to soil at the base of the straw by adding the sample to the open top of the straw, followed by washing with 1 ml of water to ensure all sample was applied to the soil and no residue was trapped on the inner wall surface of the straw. The application was performed in a laboratory fume hood to avoid exposure to the fumigants. After compound application, the top of the straw was then pushed down into the soil approximately 1 cm deep. Three days after application of the sample, the straws were removed

from the pots and the pots then removed from the hood and taken to a greenhouse (maintained at 26°C) for an additional four days. The pots were initially sub-irrigated and soil moisture maintained by top watering for the remainder of the experiment. At 19 days after introduction of the parent or metabolite, percent visual growth reduction of the soybeans and sorghum were determined (Table 1). 6 grams of metabolite was placed in 24 ml of water to dissolve for a concentration of 250 mg/ml.

Results: The results of this assay are depicted below:

Growth response (% growth reduction) of soybean and sorghum to pre-plant soil application of 1,3-D or a 1,3-D metabolite. Evaluations made 19 days after application.

Treatment	Rate	Percent Growth Reduction	
	Kg/ha	Soybean	Sorghum
1,3-D	31	0	0
1,3-D	94	93.8	12.5
1,3-D	283	100	81.3
3-chloroacrylic acid	30	100	50
3-chloroacrylic acid	91	97.5	82.5
3-chloroacrylic acid	272	100	100
Untreated	-	0	0

Summary and conclusions: soybean and sorghum growth was reduced by both 1,3-D and it's metabolite. Soybean was more sensitive to both the parent and metabolite than sorghum. The 3-chloracrylic acid metabolite demonstrated greater growth reduction than 1,3-D on both soybean and sorghum.

RMS assessment: The data provided by the notifier (literature and statements) indicates that the 3-chloroacrylic acid have an impact on germinated weed seeds, suggesting that this metabolite has herbicidal activity higher than 1,3-D. Therefore, based on the guidance document of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000-rev. 10), this metabolite is considered "relevant" for regulatory aspects and the levels in groundwater must not exceed the level of 0.1 µg as/L.

B.9.12. Indoor uses of 1,3-D.

According to EFSA report "*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*".

Notifiers Response:

*The supported indoor uses of 1,3-D by drip irrigation is for **permanent indoor uses** and so earthworms, soil micro-organisms, F. candida and other soil non-target arthropods are unlikely to come into contact with 1,3-dichloropropene. Furthermore, under these conditions DAS believe that the function of the soil is to grow fruiting vegetables - in such cases the soil "function" is as a substrate for the crop, and not to be preserved as a viable natural soil ecosystem.*

RMS assessment. The supported indoor uses of 1,3-D by drip irrigation is for permanent indoor uses in artificial sandy soil. The use of artificial sandy soil is the most important way of cultivation in the greenhouses area of South-eastern Spain. Several fruiting vegetables (tomatoes, peppers, etc) are cultivated in these permanent greenhouses. The soil in these cases is a substrate for the crop. Not further information is needed.

B.9.13 References relied on.

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
ECOTOXICOLOGY					
IIA 9.1.3 DAR Reference B9.1.3	Temple D.L et al	2006	1,3-DICHLOROPROPENE: A REPRODUCTION STUDY WITH THE NORTHERN BOBWHITE Wildlife International DAS Report No.: DECO-HET K-006409-074 (Masterfile Number): J29 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIIA 10.4.1 DAR Reference 8.3.1.1/01	Fussell, S	2005	An inhalation toxicity test to determine the effect of Telone II on adults of the honeybee, *Apis mellifera*, under laboratory conditions Mambo-Tox Ltd / CEMAS DAS Report No.: DECO-HET K-006409-072 (Masterfile Number): J28 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIA 10.1.4 DAR Reference 10.1.4/02	Small G	2007	Determination of residues of 1,3-Dichloropropene in arthopds communities and earthworms following Telone II soil injection in Italy Insect Investigations Limited DAS Report No.: 15015038-5155-3 (Masterfile Number): MJ41 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIIA 10.6.1.3 DAR Reference 10.6.1/03	Small G	2006	Abundance and diversity of earthworms in soils commonly used for growing vegetable crops in 3 regions of Sicily Insect Investigations Limited DAS Report No.: 050347-A (Masterfile Number): MJ43 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIA 10.5.2 DAR Reference 10.5.2/02	Small G	2006	Telone II: effects of field application on above ground arthropods and earthworms Insect Investigations Limited DAS Report No.: 15015038 /05116E (Masterfile Number): MJ44 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
IIIA 10.3 DAR Reference 10.3/01	Blanckenhagen F.V	2006	Presence of small mammalson fields treated with Telone II – Italy RIFCon GmbH DAS Report No.: deco-het k-006409-077 (Masterfile Number): MJ45 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIIA 10.7.2 DAR Reference 10.7.2/03	Mallet, MJ	2005	Soil Microflora activity in soil treated with Telone in the field CEMAS DAS Report No.: CEMR-2824 (Masterfile Number): MJ40 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIIA 9.2.2.2 DAR Reference B 9.2.2.2/02	Marino, T.A., Carr, M.S., Yaroch, A.M.	2007	3-chloroacrylic acid: Toxicity to the early life stages of the Fathead Minnow, Pimephales promelas. Dow Midland DAS Report No.: deco het dr-0125-7869-022 (Masterfile Number): MJ47 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIIA 9.2.5 DAR Reference B 9.2.5/02	Marino, T.A., Currie, R.J., Carr, M.S., Yaroch, A.M.	2007	3-chloroacrylic acid (1:1 cis/trans): A 21 day chronic toxicity study with the daphnid Daphnia magna. Dow Midland DAS Report No.: 071106, (Masterfile Number): MJ48 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIA 9.6 DAR Reference 8.6/01 (Submitted previously to RMS – and reported in DAR Addendum 1 B9 Ecotox-icology	McCormick, R.W., Schwab, D.	1999	Effect of 1,3-D Dichloropropene, 3-Chloroallyl Alcohol, and 3-Chloroacrylic Acid on the Emergence and Vegetative Vigor of Non-Target Terrestrial Plants Dow AgroSciences DAS Report No.: GH-C-5032 (990043) (Masterfile Number): NS02 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS

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APPENDIX 2: Raw data

Earthworm data

Insect Code		1 WORM	1 WORM	2 WORM	2 WORM	3 WORM	3 WORM	WORMS	WORMS
Crop Code		LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES
Part Rated		INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P
Rating Data Type		COUINS	WEIFRE	COUINS	WEIFRE	COUINS	WEIFRE	COUINS	WEIFRE
Rating Unit		NUMBER	G	NUMBER	G	NUMBER	G	NUMBER	G
Rating Date		23/05/2005	23/05/2005	23/05/2005	23/05/2005	23/05/2005	23/05/2005	23/05/2005	23/05/2005
Crop Stage		0	0	0	0	0	0	0	0
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Insect Stage		ADULT	ADULT	ADULT	ADULT	ADULT	ADULT	JUVEN	JUVEN
Footnote No.		1	2	3	4	5	6	7	8
Trt-Eval Interval		-4 DA-A	-4 DA-A	-4 DA-A	-4 DA-A	-4 DA-A	-4 DA-A	-4 DA-A	-4 DA-A
Plot No.	Sample No.								
1	1	4	0.6	0	0	17	15.1	4	0.8
1	2	0	0	4	0.6	15	13.4	8	1.7
1	3	3	0.4	0	0	20	15.9	8	1.9
1	4	0	0	0	0	18	13.8	6	1.3
2	13	0	0	3	0.7	22	16.2	4	0.6
2	14	9	0.9	0	0	14	10.1	4	0.6
2	15	0	0	1	0.1	14	9.1	0	0
2	16	0	0	5	1	18	12.2	5	1.1
3	25	0	0	3	0.9	13	11.9	3	0.3
3	26	0	0	0	0	27	19.3	7	1.9
3	27	2	0.2	2	0.3	20	13.2	4	0.4
3	28	2	0.2	6	0.8	42	28.4	12	2.7
4	37	5	0.8	0	0	25	15.8	7	1.7
4	38	8	1.9	0	0	22	13.1	10	2.2
4	39	7	0.6	2	0.5	8	6.5	8	1.7
4	40	0	0	7	1.7	20	15.9	7	1.5
5	49	0	0	12	3.1	21	13.1	5	0.6
5	50	0	0	2	0.5	18	13.3	5	1.1
5	51	0	0	3	0.4	18	10.3	7	0.8
5	52	9	1.4	0	0	14	9.6	6	1.1
6	61	2	0.2	1	0.1	14	10.9	6	1.4
6	62	0	0	4	0.7	24	14.8	14	2.6
6	63	0	0	10	2.7	15	13.1	3	0.2
6	64	1	0.1	1	0.1	17	13.8	14	3.3
7	73	1	0.2	1	0.1	19	15.4	7	1.5
7	74	0	0	10	4	20	15	7	2
7	75	0	0	3	0.2	11	8.9	14	2.6
7	76	0	0	0	0	40	29.2	6	1.4
8	85	6	0.8	1	0.2	15	10.1	1	0.2
8	86	0	0	7	0.4	10	6	7	1.5
8	87	3	0.3	1	0.2	20	13.3	1	0.1
8	88	0	0	3	0.4	16	12	7	1.6

Insect Code		1 WORM	1 WORM	2 WORM	2 WORM	3 WORM	3 WORM	WORMS	WORMS
Crop Code		LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES
Part Rated		INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P
Rating Data Type		COUINS	WEIFRE	COUINS	WEIFRE	COUINS	WEIFRE	COUINS	WEIFRE
Rating Unit		NUMBER	G	NUMBER	G	NUMBER	G	NUMBER	G
Rating Date		17/06/2005	17/06/2005	17/06/2005	17/06/2005	17/06/2005	17/06/2005	17/06/2005	17/06/2005
Crop Stage		12	12	12	12	12	12	12	12
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Insect Stage		ADULT	ADULT	ADULT	ADULT	ADULT	ADULT	JUVEN	JUVEN
Footnote Number		1	2	3	4	5	6	7	8
Trt-Eval Interval		21 DA-A	21 DA-A	21 DA-A	21 DA-A	21 DA-A	21 DA-A	21 DA-A	21 DA-A
Plot No.	Sample No.								
1	1	0	0	0	0	4	1.4	1	0.1
1	2	0	0	0	0	1	0.2	0	0
1	3	0	0	2	0.2	0	0	1	0.1
1	4	0	0	0	0	0	0	0	0
2	13	0	0	0	0	3	1.1	1	0.1
2	14	0	0	0	0	0	0	0	0
2	15	2	0.2	1	0.5	1	1.3	6	1.1
2	16	0	0	0	0	2	0.9	1	0.1
3	25	0	0	0	0	0	0	0	0
3	26	0	0	0	0	0	0	0	0
3	27	0	0	2	0.4	0	0	0	0
3	28	0	0	0	0	1	0.4	2	0.4
4	37	0	0	0	0	1	0.4	1	0.2
4	38	0	0	0	0	2	1	4	0.6
4	39	0	0	0	0	0	0	0	0
4	40	1	0.1	0	0	2	0.9	2	0.5
5	49	0	0	2	0.2	1	0.2	0	0
5	50	0	0	0	0	1	0.4	4	0.7
5	51	0	0	1	0.1	1	0.3	1	0.2
5	52	0	0	0	0	0	0	0	0
6	61	0	0	0	0	1	0.4	0	0
6	62	0	0	0	0	0	0	0	0
6	63	0	0	0	0	0	0	0	0
6	64	0	0	0	0	0	0	0	0
7	73	0	0	2	0.3	0	0	0	0
7	74	0	0	3	0.7	1	0.1	0	0
7	75	0	0	0	0	0	0	0	0
7	76	0	0	0	0	0	0	0	0
8	85	0	0	0	0	2	1.2	0	0
8	86	0	0	0	0	0	0	2	0.1
8	87	0	0	0	0	2	1	1	0.1
8	88	0	0	0	0	0	0	0	0

Insect Code		1 WORM	1 WORM	2 WORM	2 WORM	3 WORM	3 WORM	WORMS	WORMS
Crop Code		LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES
Part Rated		INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P
Rating Data Type		COUINS	WEIFRE	COUINS	WEIFRE	COUINS	WEIFRE	COUINS	WEIFRE
Rating Unit		NUMBER	G	NUMBER	G	NUMBER	G	NUMBER	G
Rating Date		06/07/2005	06/07/2005	06/07/2005	06/07/2005	06/07/2005	06/07/2005	06/07/2005	06/07/2005
Crop Stage		12							
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Insect Stage		ADULT	ADULT	ADULT	ADULT	ADULT	ADULT	JUVEN	JUVEN
Footnote Number		1	2	3	4	5	6	7	8
Trt-Eval Interval		21 DA-A	40 DA-A	40 DA-A	40 DA-A	40 DA-A	40 DA-A	40 DA-A	40 DA-A
Plot	Sample								
No.	No.								
1	1	0	0	0	0	0	0	0	0
1	2	0	0	0	0	0	0	0	0
1	3	0	0	0	0	2	1.7	1	0.3
1	4	0	0	0	0	1	0.8	0	0
2	13	0	0	1	0.1	0	0	0	0
2	14	0	0	0	0	0	0	0	0
2	15	0	0	0	0	1	0.7	0	0
2	16	0	0	0	0	1	0.9	0	0
3	25	0	0	0	0	0	0	0	0
3	26	0	0	0	0	0	0	0	0
3	27	0	0	0	0	2	1.4	0	0
3	28	0	0	0	0	0	0	0	0
4	37	0	0	0	0	0	0	1	0.1
4	38	0	0	0	0	6	2.4	3	0.4
4	39	0	0	0	0	2	1.1	0	0
4	40	0	0	0	0	0	0	0	0
5	49	0	0	0	0	0	0	0	0
5	50	0	0	0	0	1	0.5	0	0
5	51	0	0	0	0	1	1	0	0
5	52	1	0.2	0	0	1	1.1	0	0
6	61	0	0	0	0	0	0	0	0
6	62	0	0	0	0	1	0.7	0	0
6	63	0	0	0	0	0	0	0	0
6	64	9	1.3	0	0	2	1.8	2	0.4
7	73	0	0	0	0	0	0	0	0
7	74	0	0	0	0	0	0	0	0
7	75	0	0	0	0	0	0	0	0
7	76	0	0	3	0.5	4	2.2	2	0.6
8	85	0	0	0	0	0	0	0	0
8	86	0	0	0	0	0	0	0	0
8	87	0	0	0	0	0	0	0	0
8	88	0	0	3	0.5	4	2.2	2	0.6

Insect Code		1 WORM	1 WORM	2 WORM	2 WORM	3 WORM	3 WORM	WORMS	WORMS
Crop Code		LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES
Part Rated		INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P
Rating Data Type		COUINS	WEIFRE	COUINS	WEIFRE	COUINS	WEIFRE	COUINS	WEIFRE
Rating Unit		NUMBER	G	NUMBER	G	NUMBER	G	NUMBER	G
Rating Date		30/08/2005	30/08/2005	30/08/2005	30/08/2005	30/08/2005	30/08/2005	30/08/2005	30/08/2005
Crop Stage									
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Insect Stage		ADULT	ADULT	ADULT	ADULT	ADULT	ADULT	JUVEN	JUVEN
Footnote Number		1	2	3	4	5	6	7	8
Trt-Eval Interval		95 DA-A	95 DA-A	95 DA-A	95 DA-A	95 DA-A	95 DA-A	95 DA-A	95 DA-A
Plot	Sample								
No.	Plot								
1	1	0	0	3	0.4	0	0	1	0.2
1	2	0	0	3	0.6	3	2.2	1	0.4
1	3	0	0	0	0	1	1	2	0.1
1	4	0	0	4	0.4	0	0	4	0.6
2	13	0	0	5	0.5	2	0.8	6	0.8
2	14	0	0	2	1.2	3	2.5	0	0
2	15	0	0	4	0.2	0	0	3	0.3
2	16	0	0	5	0.2	1	0.9	4	0.9
3	25	0	0	1	0.1	2	2.2	3	0.4
3	26	0	0	2	0.4	1	0.8	6	2.2
3	27	1	0.1	0	0	6	5.1	4	0.3
3	28	0	0	11	1.8	3	3.2	3	0.3
4	37	0	0	0	0	5	3	7	1.8
4	38	0	0	6	1.1	10	6.4	2	0.6
4	39	0	0	2	0.2	5	3.3	2	0.3
4	40	0	0	9	1.2	16	11.6	9	2.6
5	49	0	0	0	0	1	0.6	0	0
5	50	0	0	0	0	4	2.3	1	0.2
5	51	0	0	0	0	2	1.2	2	0.2
5	52	0	0	0	0	2	1.7	1	0.1
6	61	0	0	2	0.3	1	0.2	1	0.1
6	62	0	0	0	0	2	1.2	7	1.5
6	63	0	0	2	0.3	2	1.2	0	0
6	64	0	0	3	0.2	3	1.5	2	1.1
7	73	0	0	1	0.1	0	0	0	0
7	74	0	0	0	0	0	0	9	3.1
7	75	0	0	0	0	2	2	0	0
7	76	0	0	4	0.7	1	1.5	0	0
8	85	0	0	0	0	0	0	1	0.4
8	86	0	0	2	0.2	2	2.2	1	0.3
8	87	0	0	5	0.8	0	0	1	0.2
8	88	0	0	5	0.8	0	0	1	0.2

Insect Code		1 WORM	1 WORM	2 WORM	2 WORM	3 WORM	3 WORM	WORMS	WORMS
Crop Code		LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES
Part Rated		INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P
Rating Data Type		COUINS	WEIFRE	COUINS	WEIFRE	COUINS	WEIFRE	COUINS	WEIFRE
Rating Unit		NUMBER	G	NUMBER	G	NUMBER	G	NUMBER	G
Rating Date		04/11/2005	04/11/2005	04/11/2005	04/11/2005	04/11/2005	04/11/2005	04/11/2005	04/11/2005
Crop Stage									
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Insect Stage		ADULT	ADULT	ADULT	ADULT	ADULT	ADULT	JUVEN	JUVEN
Footnote Number		1	2	3	4	5	6	7	8
Trt-Eval Interval		161 DA-A	161 DA-A	161 DA-A	161 DA-A	161 DA-A	161 DA-A	161 DA-A	161 DA-A
Plot	Sample								
No.	No.								
1	1	0	0	16	5	13	15.2	17	3.5
1	2	0	0	13	2.9	10	6	31	5.6
1	3	0	0	15	5.3	19	25	12	3.1
1	4	0	0	16	4.9	24	31.4	10	1.8
2	13	0	0	24	7.5	14	17.3	26	4.3
2	14	0	0	2.5	11	27	37.9	25	5.8
2	15	0	0	20	6.6	10	15.7	25	4.2
2	16	0	0	21	5.2	16	17.5	26	5.4
3	25	0	0	4	0.8	2	1.6	1	0.8
3	26	0	0	12	4.3	23	25.8	31	6.6
3	27	0	0	40	15.2	16	18.2	16	5.7
3	28	0	0	10	2.1	7	8	0	0
4	37	0	0	42	16.3	21	16.5	48	11.4
4	38	0	0	17	6.5	15	10.1	19	6.7
4	39	0	0	8	3.1	18	12.8	6	2
4	40	0	0	25	7.4	21	20.8	26	7
5	49	0	0	11	3.1	18	23.9	8	2
5	50	0	0	2	0.9	23	37.5	0	0
5	51	0	0	12	4.2	27	40.6	4	1.4
5	52	0	0	5	2.1	29	43.7	5	2.6
6	61	0	0	40	10.1	17	25.6	24	6.8
6	62	0	0	44	12.7	18	27.1	20	4.1
6	63	0	0	19	6.8	11	18.2	9	2.4
6	64	0	0	23	9.1	7	10.3	16	5.2
7	73	1	0.1	6	1.8	5	5.4	5	1.2
7	74	0	0	0	0	2	3	1	0.5
7	75	0	0	32	10.5	18	14.8	26	6
7	76	1	0.1	39	17.2	9	10.2	19	5.7
8	85	0	0	9	3.9	22	23.6	4	1.3
8	86	1	0.1	29	10.7	17	21.9	6	2.1
8	87	0	0	16	9.8	32	37.6	45	9.9
8	88	0	0	3	0.6	10	15	1	0.6

Insect Code		1 WORM	1 WORM	2 WORM	2 WORM	3 WORM	3 WORM	WORMS	WORMS
Crop Code		TRZAW	TRZAW	TRZAW	TRZAW	TRZAW	TRZAW	TRZAW	TRZAW
Part Rated		INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P	INSECT P
Rating Data Type		COUINS	WEIFRE	COUINS	WEIFRE	COUINS	WEIFRE	COUINS	WEIFRE
Rating Unit		NUMBER	G	NUMBER	G	NUMBER	G	NUMBER	G
Rating Date		28/02/2006	28/02/2006	28/02/2006	28/02/2006	28/02/2006	28/02/2006	28/02/2006	28/02/2006
Crop Stage									
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Insect Stage		ADULT	ADULT	ADULT	ADULT	ADULT	ADULT	JUVEN	JUVEN
Footnote Number		1	2	3	4	5	6	7	8
Trt-Eval Interval		277 DA-A	277 DA-A	277 DA-A	277 DA-A	277 DA-A	277 DA-A	277 DA-A	277 DA-A
Plot	Sample	S05	S05	S05	S05	S05	S05	S05	S05
No.	No.	1	1	1	1	1	1	1	1
1	1	1	0	0	0	0	4	1	1.4
1	2	2	0	0	0	0	1	0	0.2
1	3	0	0	2	0.2	0	0	1	0.1
1	4	0	0	0	0	0	0	0	0
2	13	0	0	0	0	3	1.1	1	0.1
2	14	0	0	0	0	0	0	0	0
2	15	2	0.2	1	0.5	1	1.3	6	1.1
2	16	0	0	0	0	2	0.9	1	0.1
3	25	0	0	0	0	0	0	0	0
3	26	0	0	0	0	0	0	0	0
3	27	0	0	2	0.4	0	0	0	0
3	28	0	0	0	0	1	0.4	2	0.4
4	37	0	0	0	0	1	0.4	1	0.2
4	38	0	0	0	0	2	1	4	0.6
4	39	0	0	0	0	0	0	0	0
4	40	1	0.1	0	0	2	0.9	2	0.5
5	49	0	0	2	0.2	1	0.2	0	0
5	50	0	0	0	0	1	0.4	4	0.7
5	51	0	0	1	0.1	1	0.3	1	0.2
5	52	0	0	0	0	0	0	0	0
6	61	0	0	0	0	1	0.4	0	0
6	62	0	0	0	0	0	0	0	0
6	63	0	0	0	0	0	0	0	0
6	64	0	0	0	0	0	0	0	0
7	73	0	0	2	0.3	0	0	0	0
7	74	0	0	3	0.7	1	0.1	0	0
7	75	0	0	0	0	0	0	0	0
7	76	0	0	0	0	0	0	0	0
8	85	0	0	0	0	2	1.2	0	0
8	86	0	0	0	0	0	0	2	0.1
8	87	0	0	0	0	0	0	0	0
8	88	0	0	0	0	0	0	0	0

Insect Code		WORMS	WORMS	WORMS	1 WORM
Crop Code		TRZAW	TRZAW	TRZAW	TRZAW
Part Rated		INSECT P	INSECT P	INSECT P	INSECT P
Rating Data Type		COUINS	WEIFRE	COUINS	COUINS
Rating Unit		NUMBER	G	NUMBER	NUMBER
Rating Date		28/02/2006	28/02/2006	29/05/2006	29/05/2006
Crop Stage					
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH
Insect Stage		MIXED	MIXED	ADULT	ADULT
Footnote Number		9	10	1	1
Trt-Eval Interval		277 DA-A	277 DA-A	367 DA-A	367 DA-A
Plot	Sample	T11	T12	S05	S05
No.	No.	1	1	1	1
1	1	2	5	0	0
1	2	2	1	0	0
1	3	3	0.3	0	0
1	4	0	0	0	0
2	13	4	1.2	0	0
2	14	0	0	0	0
2	15	10	3.1	0	0
2	16	3	1	0	0
3	25	0	0	0	0
3	26	0	0	0	0
3	27	2	0.4	0	0
3	28	3	0.8	0	0
4	37	2	0.6	0	0
4	38	6	1.6	0	0
4	39	0	0	0	0
4	40	5	1.5	0	0
5	49	3	0.4	0	0
5	50	5	1.1	0	0
5	51	3	0.6	0	0
5	52	0	0	0	0
6	61	1	0.4	0	0
6	62	0	0	0	0
6	63	0	0	0	0
6	64	0	0	0	0
7	73	2	0.3	0	0
7	74	4	0.8	0	0
7	75	0	0	0	0
7	76	0	0	0	0
8	85	2	1.2	0	0
8	86	2	0.1	0	0
8	87	0	0	0	0
8	88	0	0	0	0

Insect Code		WORMS	WORMS	WORMS	WORMS
Crop Code		TRZAW	TRZAW	TRZAW	TRZAW
Part Rated		INSECT P	INSECT P	INSECT P	INSECT P
Rating Data Type		COUINS	WEIFRE	COUINS	WEIFRE
Rating Unit		NUMBER	G	NUMBER	G
Rating Date		29/05/2006	29/05/2006	29/05/2006	29/05/2006
Crop Stage					
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH
Insect Stage		JUVEN	JUVEN	MIXED	MIXED
Footnote Number		7	8	9	10
Trt-Eval Interval		367 DA-A	367 DA-A	367 DA-A	367 DA-A
Plot No.	Sample No.	S05 BBCH	S05 BBCH	T13 BBCH	T14 BBCH
1	1	3	0.7	5	1.9
1	2	2	1	5	3
1	3	0	0	4	2
1	4	0	0	0	0
2	13	9	2.4	10	2.9
2	14	2	0.6	4	1.7
2	15	0	0	0	0
2	16	0	0	0	0
3	25	13	2.8	16	4.6
3	26	3	0.8	5	1.4
3	27	0	0	0	0
3	28	0	0	0	0
4	37	1	0.1	1	0.1
4	38	2	0.3	3	0.9
4	39	0	0	1	1
4	40	0	0	0	0
5	49	2	0.5	5	2
5	50	1	0.1	5	2.3
5	51	4	0.5	9	3
5	52	2	0.4	3	0.9
6	61	6	1.5	6	1.5
6	62	2	0.4	2	0.4
6	63	0	0	1	0.2
6	64	0	0	0	0
7	73	2	0.3	4	0.8
7	74	2	0.3	3	0.9
7	75	0	0	0	0
7	76	0	0	0	0
8	85	7	1.4	13	4.1
8	86	2	0.2	4	1.2
8	87	0	0	0	0
8	88	0	0	0	0

Footnotes to earthworm data:

Footnote Nr 1: Average Nr of *Allolobophora chlorotica* individuals/sample/plot
Footnote Nr 2: Total Weight of *Allolobophora chlorotica* individuals/sample/plot
Footnote Nr 3: Average Nr of *Allolobophora caliginosa* individuals/sample/plot
Footnote Nr 4: Total Weight of *Allolobophora caliginosa* individuals/sample/plot
Footnote Nr 5: Average Nr of *Allolobophora longa* individuals/sample/plot
Footnote Nr 6: Total Weight of *Allolobophora longa* individuals/sample/plot
Footnote Nr 7: Total Nr of earthworms juveniles/sample/plot
Footnote Nr 8: Total Weight of earthworm juveniles/sample/plot

Glossary:

Crop Code
LYPES = Tomato / Lycopersicon esculentum Mill.
TRZAW = Wheat, Winter / *Triticum aestivum* L.

Insect Code
1 WORM, 2 WORM, 3 WORM = the Nr refers to each of the three species of earthworms found, and it is meant solely for visually differentiating the tab columns.
WORMS = overall amounts of earthworms (1 worm + 2 worm +3 worm), in terms of number and weight separately.
P = Pest is Part Rated

Rating Data Type
COUINS = Count - Insect
WEIFRE = Weight - Fresh

Rating Unit
G = GRAM

Crop Stage Scale
BBCH = BBCH uniform plant stages. Phenological stadium indication following "Biologische Bundesanstalt, Bundessortenamt and Chemical industry" code.

ARM Action Codes
S05 = Perform 5% Student-Newman-Keuls
n DA-*A* = *n* days after application *A*

Microarthropod, soil core data

Insect Code		COLL	COLL	COLL	1 COLL	2 COLL	3 COLL	4 COLL	COLL
Crop Code		LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES
Rating Unit		NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER
Rating Date		23/05/2005	17/06/2005	17/06/2005	31/08/2005	31/08/2005	31/08/2005	31/08/2005	31/08/2005
Crop Stage		0	12	12					
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Footnote No.		1	1	1	2	3	4	5	1
Trt-Eval Interval		-4 DA-A	21 DA-A	21 DA-A	96 DA-A	96 DA-A	96 DA-A	96 DA-A	96 DA-A
# Sub samples, Dec.		0	0	0	1	1	1	1	1
Plot No.	Sample No.								
1	5	0	0	0	0	2	0	0	2
1	6	0	0	0	0	2	0	0	2
1	7	0	0	0	0	3	0	0	3
1	8	0	0	0	0	0	0	0	0
1	9	0	0	0	2	1	0	0	3
2	17	0	0	0	0	3	0	0	3
2	18	0	0	0	1	2	0	0	3
2	19	0	0	0	1	2	0	0	3
2	20	0	0	0	2	1	0	0	3
2	21	0	0	0	1	1	0	0	2
3	29	0	0	0	0	0	0	0	0
3	30	0	0	0	0	0	0	0	0
3	31	0	0	0	1	2	0	0	3
3	32	0	0	0	0	3	0	0	3
3	33	0	0	0	1	1	1	0	3
4	41	0	0	0	2	0	3	0	5
4	42	0	0	0	1	2	0	0	3
4	43	0	0	0	1	2	0	0	3
4	44	0	0	0	0	3	0	0	3
4	45	0	0	0	0	2	0	0	2
5	53	0	0	0	1	3	0	0	4
5	54	0	0	0	0	4	0	0	4
5	55	0	0	0	0	1	0	0	1
5	56	0	0	0	1	1	0	0	2
5	57	0	0	0	1	2	0	0	3
6	65	0	0	0	0	1	0	0	1
6	66	0	0	0	0	2	0	0	2
6	67	0	0	0	1	1	0	0	2
6	68	0	0	0	2	2	0	0	4
6	69	0	0	0	0	2	0	0	2
7	77	0	0	0	0	0	0	0	0
7	78	0	0	0	0	3	0	0	3
7	79	0	0	0	0	1	0	0	1
7	80	0	0	0	0	2	0	0	2
7	81	0	0	0	1	3	0	0	4
8	89	0	0	0	0	0	0	0	0
8	90	0	0	0	0	0	0	0	0
8	91	0	0	0	1	3	0	0	4
8	92	0	0	0	0	2	0	0	2
8	93	0	0	0	0	2	0	0	2

Insect Code		1 COLL	2 COLL	3 COLL	4 COLL	COLL
Crop Code		LYPES	LYPES	LYPES	LYPES	LYPES
Rating Unit		NUMBER	NUMBER	NUMBER	NUMBER	NUMBER
Rating Date		04/11/2005	04/11/2005	04/11/2005	04/11/2005	04/11/2005
Crop Stage						
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH	BBCH
Footnote Number		2	3	4	5	1
Trt-Eval Interval		161 DA-A	161 DA-A	161 DA-A	161 DA-A	161 DA-A
ARM Action Codes		S05	S05	S05	S05	T2 S05
# Subsamples, Dec.		1	1	1	1	1
Trt						
No.	Plot					
1	5	3	3	0	0	6
1	6	2	5	0	1	8
1	7	0	2	0	1	3
1	8	0	3	0	0	3
1	9	0	3	0	0	3
2	17	0	3	0	0	3
2	18	0	0	0	0	0
2	19	0	3	0	0	3
2	20	0	1	0	0	1
2	21	0	1	0	0	1
3	29	0	3	0	0	3
3	30	0	3	0	2	5
3	31	1	3	0	0	4
3	32	0	3	0	0	3
3	33	0	2	0	0	2
4	41	0	1	0	0	1
4	42	0	2	0	0	2
4	43	0	1	0	0	1
4	44	1	1	0	0	2
4	45	0	1	0	0	1
5	53	0	0	2	2	4
5	54	0	0	2	0	2
5	55	0	0	0	0	0
5	56	0	0	1	1	2
5	57	0	1	1	1	3
6	65	0	1	0	0	1
6	66	0	1	1	0	2
6	67	0	2	0	1	3
6	68	0	0	0	0	0
6	69	1	1	0	0	2
7	77	3	3	0	0	6
7	78	1	1	0	0	2
7	79	0	0	1	0	1
7	80	0	2	0	0	2
7	81	0	0	0	0	0
8	89	1	1	0	0	2
8	90	2	1	0	0	3
8	91	0	0	0	0	0
8	92	0	1	0	0	1
8	93	1	1	0	0	2

Insect Code		COLL	COLL	COLL	COLL	COLL	COLL
Crop Code		TRZAW	TRZAW	TRZAW	TRZAW	TRZAW	TRZAW
Rating Unit		NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER
Rating Date		28/02/2006	28/02/2006	29/05/2006	29/05/2006	29/05/2006	29/05/2006
Crop Stage		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Crop Stage Scale		2	4	2	3	4	5
Footnote Number		277 DA-A	277 DA-A	366 DA-A	366 DA-A	366 DA-A	366 DA-A
Trt-Eval Interval		S05	S05	S05	S05	S05	S05
ARM Action Codes		1	1	1	1	1	1
# Subsamples, Dec.		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Trt							
No.	Plot						
1	5	0	0	2	1	0	0
1	6	0	0	1	2	2	1
1	7	0	0	2	4	1	0
1	8	0	0	4	2	5	1
1	9	4	0	1	1	1	1
2	17	0	0	1	3	2	0
2	18	0	0	2	2	3	0
2	19	2	0	1	1	2	0
2	20	0	0	2	4	1	1
2	21	0	0	2	1	4	0
3	29	0	0	1	2	1	0
3	30	0	0	4	1	1	0
3	31	3	1	2	5	2	0
3	32	0	0	1	3	1	0
3	33	0	0	5	2	1	1
4	41	0	0	3	1	1	0
4	42	1	0	2	1	2	0
4	43	0	0	1	2	2	0
4	44	0	0	2	1	1	1
4	45	0	0	2	4	0	0
5	53	0	0	1	1	2	0
5	54	0	0	3	1	1	1
5	55	1	0	2	1	1	0
5	56	1	0	1	5	1	0
5	57	0	0	2	2	3	0
6	65	0	1	1	2	2	1
6	66	0	0	2	1	1	0
6	67	1	0	5	4	1	1
6	68	0	1	2	2	1	0
6	69	0	0	1	1	1	0
7	77	1	0	1	6	2	0
7	78	1	6	2	1	1	0
7	79	0	0	3	2	2	0
7	80	0	0	4	2	2	0
7	81	0	0	2	1	1	0
8	89	0	0	1	1	2	0
8	90	0	0	6	4	1	1
8	91	1	0	2	2	2	0
8	92	0	0	2	3	2	1
8	93	1	0	1	2	1	0

Footnotes to pitfall trap data:

Footnote Nr 1: Total Number of Microarthropods (Springtails, Collembola) individuals/100 g soil.
Footnote Nr 2: Average Number of Unidentified nr 1, Collembola individuals/100 g soil.
Footnote Nr 3: Average Number of Unidentified nr 2, Collembola individuals/100 g soil.
Footnote Nr 4: Average Number of Isotomidae family individuals/100 g soil.

Footnote Nr 5: Average Number of *Hypogastrura brevis* individuals/100 g soil.

Glossary:

Crop Code
LYPES = Tomato / Lycopersicon esculentum Mill.
TRZAW = Wheat, Winter / *Triticum aestivum* L.

Insect Code
1 COLL, 2 COLL, 3 COLL, 4 COLL = the Nr refers to each of the four species of Microarthropods found, and it is meant solely for visually differentiating the tab columns.
COLL = overall amounts of Microarthropods, in terms of number of individuals.
P = Pest is Part Rated

Rating Data Type
COUINS = Count - Insect

Crop Stage Scale
BBCH = BBCH uniform plant stages. Phenological stadium indication following "Biologische Bundesanstalt, Bundessortenamt and Chemical industry" code.

ARM Action Codes
S05 = Perform 5% Student-Newman-Keuls mean separation on Standardized Summary
n DA-*A*= *n* days after application *A*

Macroarthropods, pitfall trap data

Insect Code		ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP
Crop Code		LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES
Rating Unit		NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER
Rating Date		23/05/2005	23/05/2005	23/05/2005	23/05/2005	23/05/2005	23/05/2005	17/06/2005	17/06/2005	17/06/2005	17/06/2005	17/06/2005	17/06/2005	17/06/2005
Crop Stage		0	0	0	0	0	0	12	12	12	12	12	12	12
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Infestation Unit		PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL
Footnote Number		1	2	3	4	5	6	7	8	6	9	3	5	10
Trt-Eval Interval		-4 DA-A	-4 DA-A	-4 DA-A	-4 DA-A	-4 DA-A	-4 DA-A	21 DA-A	21 DA-A	21 DA-A	21 DA-A	21 DA-A	21 DA-A	21 DA-A
# Subsamples, Dec.		1	1	1	1	1	1	1	1	1	1	1	1	1
Plot No.	Sample No.	Centipede	Drasterius	Formicidae	Lycosa	Harpalus	Pterostichus	Pentodon	Grillus	Pterostichus	Tegenaria	Formicidae	Harpalus	Rhizotrogus
1	10	8	3	1	5	7	5	0	13	5	0	3	0	0
1	11	9	11	14	8	11	8	1	8	4	1	3	0	0
1	12	12	12	14	13	10	11	0	5	1	0	3	0	0
2	22	7	9	11	13	13	16	0	4	5	0	20	0	0
2	23	6	6	9	10	17	14	0	3	5	0	18	0	0
2	24	5	10	10	12	11	11	0	1	4	0	7	0	0
3	34	8	6	15	12	15	12	0	4	6	0	5	0	2
3	35	11	7	9	13	14	10	0	0	3	0	4	0	0
3	36	17	12	12	11	11	10	0	1	0	0	1	0	0
4	46	9	18	7	16	11	10	0	4	15	0	16	0	1
4	47	7	13	10	8	15	17	0	2	9	0	12	0	1
4	48	12	11	11	11	8	9	0	2	11	0	4	0	0
5	58	13	12	12	10	9	10	0	0	10	2	18	0	0
5	59	8	7	10	9	11	10	0	1	7	0	10	0	1
5	60	14	11	12	10	13	10	0	1	6	1	12	0	0
6	70	10	8	17	16	15	11	0	4	10	1	25	0	0
6	71	12	9	10	9	5	11	0	2	2	0	20	0	0
6	72	12	10	12	15	10	11	0	0	0	0	5	0	0
7	82	9	14	12	7	12	9	1	3	9	3	8	0	0
7	83	11	10	12	13	10	11	1	2	6	0	2	0	0
7	84	13	10	11	12	10	8	0	1	3	0	5	1	0
8	94	7	5	17	11	15	7	2	1	10	0	9	0	0
8	95	14	13	5	8	16	10	0	1	8	2	4	0	0
8	96	10	9	10	12	13	11	0	0	5	0	5	0	0

Insect Code		ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP
Crop Code		LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES
Rating Unit		NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER
Rating Date		08/07/2005	17/06/2005	17/06/2005	08/07/2005	08/07/2005	08/07/2005	08/07/2005	08/07/2005	08/07/2005	08/07/2005	08/07/2005
Crop Stage			12	12								
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Infestation Unit		PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL
Footnote Number		8	11	10	8	6	9	3	5	10	12	13
Trt-Eval Interval		42 DA-A	21 DA-A	21 DA-A	42 DA-A	42 DA-A	42 DA-A	42 DA-A	42 DA-A	42 DA-A	42 DA-A	42 DA-A
# Subsamples, Dec.		1	1	1	1	1	1	1	1	1	1	1
Plot No.	Sample No.	Grillus	Total	Rhizotrogus	Grillus	Pterostichus	Tegenaria	Formicidae	Harpalus	Rhizotrogus	Noctuid	Staphylinidae
1	10	0	21	0	0	0	3	33	0	0	0	4
1	11	0	17	0	0	0	4	7	0	0	0	1
1	12	0	9	0	0	0	2	11	1	0	1	0
2	22	0	29	0	0	1	1	89	0	0	0	0
2	23	0	26	0	0	0	5	13	0	0	0	3
2	24	0	12	0	0	1	3	17	0	0	0	0
3	34	0	17	2	0	0	2	34	0	0	0	0
3	35	1	7	0	1	0	1	65	0	0	0	0
3	36	0	2	0	0	1	1	15	0	0	1	0
4	46	1	36	1	1	1	2	13	0	0	1	0
4	47	0	24	1	0	0	3	40	0	0	0	0
4	48	0	17	0	0	0	1	9	0	0	1	0
5	58	1	30	0	1	0	1	13	0	0	0	0
5	59	1	19	1	1	0	3	20	0	0	0	0
5	60	0	20	0	0	0	4	5	0	0	0	0
6	70	0	40	0	0	1	2	41	0	0	0	0
6	71	0	24	0	0	0	0	37	0	0	0	0
6	72	0	5	0	0	0	0	6	0	0	0	3
7	82	0	24	0	0	0	2	20	0	0	0	0
7	83	0	11	0	0	0	3	12	0	0	0	0
7	84	0	10	0	0	0	1	10	0	0	0	0
8	94	0	22	0	0	0	4	1	0	0	0	0
8	95	0	15	0	0	0	1	10	0	0	0	0
8	96	0	10	0	0	0	4	6	0	0	0	0

Insect Code		ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP
Crop Code		LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES	LYPES
Rating Unit		NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER
Rating Date		31/08/2005	31/08/2005	31/08/2005	31/08/2005	04/11/2005	04/11/2005	04/11/2005	04/11/2005	04/11/2005	04/11/2005	04/11/2005
Crop Stage												
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Infestation Unit		PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL
Footnote Number		6	9	3	5	1	3	6	8	13	14	15
Trt-Eval Interval		96 DA-A	96 DA-A	96 DA-A	96 DA-A	161 DA-A	161 DA-A	161 DA-A	161 DA-A	161 DA-A	161 DA-A	161 DA-A
# Subsamples, Dec.		S05	S05	S05	S05	S05	S05	S05	S05	S05	S05	S05
Plot	Sample											
No.	No.	Pterostichus	Tegenaria	Formicidae	Harpalus	Geophilomorpha	Formicidae	Pterostichus	Grillus	Staphylinidae	Spider	Insect larvae
1	10	9	0	0	0	0	0	1	0	0	0	0
1	11	22	0	3	0	0	0	5	0	0	0	2
1	12	3	1	1	0	0	0	3	0	1	0	3
2	22	0	1	0	0	2	0	1	0	0	0	0
2	23	0	0	0	0	2	0	1	0	0	0	0
2	24	0	0	0	0	2	0	2	0	0	1	0
3	34	1	0	0	1	1	0	5	0	0	2	0
3	35	0	1	0	0	1	0	4	0	0	2	1
3	36	1	0	2	0	1	0	2	0	0	3	3
4	46	2	0	0	0	0	0	0	0	0	2	1
4	47	0	0	1	0	1	0	0	2	1	4	2
4	48	4	0	0	0	1	0	1	0	0	0	1
5	58	3	0	1	0	0	0	0	0	0	0	0
5	59	4	1	1	0	0	0	0	0	0	0	1
5	60	13	0	1	0	0	0	0	0	0	0	0
6	70	0	1	0	0	1	0	1	0	0	2	0
6	71	1	0	0	0	1	0	2	0	0	0	0
6	72	1	0	2	0	0	0	1	0	0	4	0
7	82	1	0	0	0	0	0	1	0	0	1	1
7	83	0	0	3	0	0	0	3	0	1	1	3
7	84	3	0	0	0	4	3	1	0	0	0	0
8	94	1	0	0	0	0	0	2	0	0	2	3
8	95	1	0	0	0	1	0	1	0	0	0	0
8	96	0	0	0	0	0	0	3	0	0	0	0

Insect Code		ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP	ARTHROP
Crop Code		TRZAW	TRZAW	TRZAW	TRZAW	TRZAW	TRZAW	TRZAW
Rating Unit		NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER	NUMBER
Rating Date		28/02/2006	28/02/2006	28/02/2006	29/05/2006	29/05/2006	29/05/2006	29/05/2006
Crop Stage								
Crop Stage Scale		BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH
Infestation Unit		PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL	PIT-FALL
Footnote Number		5	14	18	1	4	4	13
Trt-Eval Interval		277 DA-A	277 DA-A	277 DA-A	367 DA-A	367 DA-A	367 DA-A	367 DA-A
# Subsamples, Dec.		S05	S05	S05	S05	S05	S05	S05
Plot	Sample							
No.	No.	Harpalus	Spider	Collembola	Geophilomorpha	Lycosa	Harpalus	Staphylinidae
1	10	1	1	0	0	0	0	1
1	11	0	0	0	0	0	0	1
1	12	2	0	0	0	1	1	1
2	22	1	0	0	0	0	1	0
2	23	0	0	0	0	1	0	0
2	24	4	0	1	0	0	3	0
3	34	0	1	0	0	0	1	0
3	35	3	0	4	1	0	0	0
3	36	1	0	0	0	1	1	0
4	46	0	1	0	0	2	4	0
4	47	1	2	0	0	1	0	0
4	48	0	3	0	0	0	2	0
5	58	1	1	0	0	0	0	0
5	59	1	0	0	0	2	0	0
5	60	3	0	0	0	1	4	0
6	70	1	3	0	0	1	0	0
6	71	0	1	0	0	0	0	0
6	72	0	2	0	3	0	1	0
7	82	0	1	0	0	0	0	0
7	83	0	2	0	0	2	1	0
7	84	0	0	0	0	0	0	0
8	94	2	0	0	0	3	0	0
8	95	2	3	0	0	2	0	0
8	96	0	2	0	1	1	1	0

Footnotes to pitfall trap data:

Insect	Common Name	Scientific Name
Footnote Nr 1. =	Scarab beetle	*Pentodon bidens*, Carabidae
Footnote Nr 2. =	Cricket	*Grillus* spp., Orthoptera
Footnote Nr 3. =	Wolf spider	*Lycosa* spp., Lycosidae
Footnote Nr 4. =	Hobo spider	*Tegenaria agrestis*, Agelenidae
Footnote Nr 5. =	Ants	Speciae variae, Formicidae
Footnote Nr 6. =	Chafer	*Rhizotrogus* spp., Scarabeidae
Footnote Nr 7. =	Centipede	*Geophilomorpha* spp., Chilopodae
Footnote Nr 8. =	Coleopteran	*Drasterius bimaculatus*, Elateridae
Footnote Nr 9. =	Ground beetle	*Harpalus* spp., Carabidae
Footnote Nr 10. =	Ground beetle	*Pterostichus* spp.,Carabidae
Footnote Nr 11. =	Coleoptera	Staphylinidae
Footnote Nr 12. =	Insect larvae, various spp.	
Footnote Nr 13. =	Collembola spp.	

Glossary:

Crop Code
LYPES = Tomato / *Lycopersicon esculentum* Mill.
TRZAW = Wheat, Winter / *Triticum aestivum* L.

Insect Code
ARTHROP = Arthropods
P = Pest is Part Rated

Rating Data Type
COUINS = Count - Insect

Crop Stage Scale
BBCH = BBCH uniform plant stages. Phenological stadium indication following "Biologische Bundesanstalt, Bundessortenamt and Chemical industry" code.

ARM Action Codes
S05 = Perform 5% Student-Newman-Keuls mean separation on Standardized Summary
n DA-*A* = *n* days after application *A*

APPENDIX 5: Analysed data

Abundance and wet weight of earthworms and arthropods sampled from Site 4 prior to Telone II application, on the day of application and then 3, 5, 7, 14 and 21 days after application (n= number of samples taken).

Sampling interval	preA		0 DA-A		3 DA-A		5 DA-A		7 DA-A		14 DA-A		21 DA-A	
Date	8-9/04/06		11-12/04/06		14-15/04/06		16-17/04/06		18-19/04/06		25-26/04/06		2-3/05/06	
Units	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)
Earthworms														
Totals	0	0.00	12	6.30	2	1.10	4	1.30	1	0.3	2	2.10	8	6.28
Mean ± SD	0.0 ± 0.0 (n=16)	0.00 ± 0.00 (n=16)	0.9 ± 2.0 (n=14)	0.63 ± 1.06 (n=14)	0.1 ± 0.5 (n=16)	0.07 ± 0.28 (n=16)	0.3 ± 0.6 (n=13)	0.10 ± 0.21 (n=13)	0.1 ± 0.3 (n=14)	0.02 ± 0.08 (n=14)	0.1 ± 0.5 (n=15)	0.14 ± 0.54 (n=15)	0.7 ± 0.9 (n=13)	0.52 ± 0.81 (n=13)
Dead earthworms														
Totals	0	0	0	0	0	0	3	2.6	1	0.3	0	0	0	0
Spiders														
Totals	9	0.50	4	0.19	2	0.1	0	0	0	0	6	0.1	1	0.22
Mean ± SD	2.3 ± 2.1 (n=5)	0.13 ± 0.17 (n=5)	1.0 ± 0.8 (n=5)	0.05 ± 0.04 (n=5)	0.4 ± 0.9 (n=5)	0.02 ± 0.04 (n=5)	0.0 ± 0.0 (n=5)	0.0 ± 0.0 (n=5)	0.0 ± 0.0 (n=5)	0.0 ± 0.0 (n=5)	1.2 ± 0.8 (n=5)	0.05 ± 0.07 (n=5)	0.2 ± 0.4 (n=5)	0.04 ± 0.10 (n=5)
Dead spiders														
Totals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Beetles														
Totals	11	0.30	6	0.64	2	0.11	7	0.30	2	0.05	48	0.50	71	2.61
Mean ± SD	2.8 ± 3.8 (n=5)	0.08 ± 0.12 (n=5)	1.5 ± 1.3 (n=5)	0.16 ± 0.13 (n=5)	0.4 ± 0.5 (n=5)	0.02 ± 0.04 (n=5)	1.4 ± 1.1 (n=5)	0.06 ± 0.04 (n=5)	0.4 ± 0.9 (n=5)	0.01 ± 0.02 (n=5)	9.6 ± 5.3 (n=5)	0.13 ± 0.05 (n=5)	14.2 ± 6.1 (n=5)	0.52 ± 0.20 (n=5)
Dead beetles														
Totals	0	0	0	0	0	0	3	0.1	0	0	0	0	0	0
Other arthropods														
Totals	11	0.28	1	0.10	0	0.00	2	0.06	9	0.35	3	0.10	4	0.52
Mean ± SD	2.8 ± 1.0 (n=5)	0.07 ± 0.04 (n=5)	0.5 ± 0.7 (n=5)	0.03 ± 0.05 (n=5)	0.0 ± 0.0 (n=5)	0.00 ± 0.00 (n=5)	0.4 ± 0.9 (n=5)	0.01 ± 0.03 (n=5)	1.8 ± 1.5 (n=5)	0.07 ± 0.04 (n=5)	0.6 ± 0.9 (n=5)	0.03 ± 0.05 (n=5)	0.8 ± 0.8 (n=5)	0.10 ± 0.10 (n=5)
Dead other arthropods														
Totals	0	0	0	0	0	0	1	0.20	0	0	0	0	0	0

Abundance and wet weight of earthworms and arthropods sampled from Site 7 prior to Telone II application, on the day of application and then 3, 5, 7, 14 and 21 days after application (n= number of samples taken).

Sampling interval	preA		0 DA-A		3 DA-A		5 DA-A		7 DA-A		14 DA-A		21 DA-A	
Date	8-9/04/06		11-12/04/06		14-15/04/06		16-17/04/06		18-19/04/06		25-26/04/06		2-3/05/06	
Units	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)
Earthworms														
Totals	9	5.89	9	8.22	17	10.8	12	5.9	44	21.17	16	4.58	29	25.05
Mean ± SD	0.6 ± 1.0 (n=14)	0.4 ± 0.7 (n=14)	0.9 ± 1.6 (n=10)	0.8 ± 1.4 (n=10)	1.7 ± 2.3 (n=10)	1.1 ± 1.6 (n=10)	1.2 ± 1.3 (n=10)	0.6 ± 0.8 (n=10)	4.4 ± 5.6 (n=10)	2.1 ± 2.1 (n=10)	1.3 ± 1.9 (n=12)	0.4 ± 0.5 (n=12)	2.9 ± 2.4 (n=10)	2.5 ± 2.1 (n=10)
Dead earthworms														
Totals	0	0	0	0	7	3.1	1	0.01	2	0.83	0	0	0	0
Spiders														
Totals	38	2.20	22	0.98	5	0.15	2	0.09	7	0.2	2	0.15	7	0.37
Mean ± SD	9.5 ± 2.6 (n=5)	0.55 ± 0.17 (n=5)	5.5 ± 2.1 (n=5)	0.25 ± 0.14 (n=5)	1.0 ± 1.7 (n=5)	0.03 ± 0.04 (n=5)	0.4 ± 0.5 (n=5)	0.02 ± 0.03 (n=5)	1.4 ± 1.7 (n=5)	0.04 ± 0.04 (n=5)	0.4 ± 0.5 (n=5)	0.03 ± 0.05 (n=5)	1.4 ± 0.9 (n=5)	0.07 ± 0.06 (n=5)
Dead spiders														
Totals	0	0	0	0	6	0.12	0	0	0	0	0	0	0	0
Beetles														
Totals	13	1.70	66	1.67	10	0.40	15	1.23	3	0.40	6	0.40	28	1.56
Mean ± SD	3.3 ± 2.6 (n=5)	0.43 ± 0.26 (n=5)	16.5 ± 4.0 (n=5)	0.42 ± 0.26 (n=5)	2.0 ± 1.9 (n=5)	0.08 ± 0.09 (n=5)	3.0 ± 3.3 (n=5)	0.25 ± 0.38 (n=5)	0.6 ± 1.3 (n=5)	0.08 ± 0.18 (n=5)	1.2 ± 1.1 (n=5)	0.08 ± 0.08 (n=5)	5.6 ± 3.6 (n=5)	0.31 ± 0.15 (n=5)
Dead beetles														
Totals	0	0	0	0	5	0.1	0	0	0	0	0	0	0	0
Other arthropods														
Totals	2	0.70	11	1.07	0	0.00	3	0.06	3	0.16	30	0.67	5	0.51
Mean ± SD	0.5 ± 1.0 (n=5)	0.18 ± 0.35 (n=5)	2.8 ± 1.7 (n=5)	0.27 ± 0.21 (n=5)	0.0 ± 0.0 (n=5)	0.00 ± 0.00 (n=5)	0.6 ± 1.3 (n=5)	0.01 ± 0.03 (n=5)	0.6 ± 0.5 (n=5)	0.03 ± 0.04 (n=5)	6.0 ± 8.0 (n=5)	0.13 ± 0.13 (n=5)	1.0 ± 0.7 (n=5)	0.13 ± 0.15 (n=5)
Dead other arthropods														
Totals	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Abundance and wet weight of earthworms and arthropods sampled from Site 8 prior to Telone II application, on the day of application and then 3, 5, 7, 14 and 21 days after application (n= number of samples taken).

Sampling interval	preA		0 DA-A		3 DA-A		5 DA-A		7 DA-A		14 DA-A		21 DA-A	
Date	8-9/04/06		11-12/04/06		14-15/04/06		16-17/04/06		18-19/04/06		25-26/04/06		2-3/05/06	
Units	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)
Earthworms														
Total	6	4.10	48	36.20	21	12.70	4	2.20	12	9.11	8	3.40	15	10.81
Mean ± SD	0.5 ± 1.2 (n=13)	0.32 ± 0.83 (n=13)	4.8 ± 9.2 (n=10)	3.62 ± 7.54 (n=10)	2.1 ± 4.0 (n=10)	1.27 ± 2.34 (n=10)	0.3 ± 1.1 (n=14)	0.16 ± 0.59 (n=14)	1.2 ± 1.7 (n=10)	0.91 ± 1.29 (n=10)	0.6 ± 1.2 (n=14)	0.24 ± 0.58 (n=14)	1.5 ± 1.5 (n=10)	1.08 ± 1.12 (n=10)
Dead earthworms														
Totals	0	0	0	0	0	0	3	0.9	2	1.27	0	0	0	0
Spiders														
Totals	28	0.70	6	0.80	16	0.38	9	0.11	7	0.05	2	0.01	6	0.32
Mean ± SD	5.6 ± 3.2 (n=5)	0.14 ± 0.12 (n=5)	1.2 ± 1.3 (n=5)	0.16 ± 0.18 (n=5)	3.2 ± 1.3 (n=5)	0.08 ± 0.04 (n=5)	1.8 ± 1.8 (n=5)	0.02 ± 0.02 (n=5)	1.4 ± 1.7 (n=5)	0.01 ± 0.01 (n=5)	0.4 ± 0.9 (n=5)	0.00 ± 0.00 (n=5)	1.2 ± 1.3 (n=5)	0.06 ± 0.09 (n=5)
Dead spiders														
Totals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Beetles														
Totals	16	0.71	34	1.40	19	0.30	10	1.76	3	0.24	8	0.45	33	1.73
Mean ± SD	3.2 ± 2.2 (n=5)	0.14 ± 0.15 (n=5)	6.8 ± 7.2 (n=5)	0.28 ± 0.27 (n=5)	3.8 ± 4.3 (n=5)	0.08 ± 0.05 (n=5)	2.0 ± 1.6 (n=5)	0.35 ± 0.65 (n=5)	0.6 ± 1.3 (n=5)	0.05 ± 0.11 (n=5)	1.6 ± 1.7 (n=5)	0.09 ± 0.08 (n=5)	6.6 ± 4.1 (n=5)	0.35 ± 0.50 (n=5)
Dead beetles														
Totals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other arthropods														
Totals	12	1.37	3	0.75	24	0.73	210	0.35	3	0.20	4	0.32	7	0.94
Mean ± SD	2.4 ± 2.2 (n=5)	0.27 ± 0.20 (n=5)	0.6 ± 0.5 (n=5)	0.15 ± 0.27 (n=5)	4.8 ± 3.4 (n=5)	0.15 ± 0.12 (n=5)	42.0 ± 88.4 (n=5)	0.07 ± 0.04 (n=5)	0.6 ± 0.9 (n=5)	0.04 ± 0.05 (n=5)	0.8 ± 1.1 (n=5)	0.06 ± 0.09 (n=5)	1.4 ± 1.5 (n=5)	0.19 ± 0.17 (n=5)
Dead other arthropods														
Totals	0	0	0	0	0	0	1	0.2	0	0	0	0	0	0

Abundance and wet weight of earthworms and arthropods sampled from Site 9 prior to Telone II application, on the day of application and then 3, 5, 7, 14 and 21 days after application (n= number of samples taken)

Sampling interval	preA		0 DA-A		3 DA-A		5 DA-A		7 DA-A		14 DA-A		21 DA-A	
Date	8-9/04/06		11-12/04/06		14-15/04/06		16-17/04/06		18-19/04/06		25-26/04/06		2-3/05/06	
Units	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)	Number	Weight (g)
Earthworms														
Totals	0	0.00	0	0.00	0	0	0	0	0	0	0	0.00	0	0
Mean ± SD	0.0 ± 0.0 (n=16)	0.0 ± 0.0 (n=16)	0.0 ± 0.0 (n=16)	0.0 ± 0.0 (n=16)	0.0 ± 0.0 (n=15)	0.0 ± 0.0 (n=15)	0.0 ± 0.0 (n=14)	0.0 ± 0.0 (n=14)	0.0 ± 0.0 (n=13)	0.0 ± 0.0 (n=13)	0.0 ± 0.0 (n=15)	0.0 ± 0.0 (n=15)	0.0 ± 0.0 (n=13)	0.0 ± 0.0 (n=13)
Dead earthworms														
Totals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Spiders														
Totals	1	0.02	2	0.40	0	0	2	0.02	2	0.05	2	0.07	6	0.85
Mean ± SD	0.2 ± 0.4 (n=5)	0.00 ± 0.01 (n=5)	0.4 ± 0.5 (n=5)	0.08 ± 0.13 (n=5)	0.0 ± 0.0 (n=5)	0.00 ± 0.00 (n=5)	0.4 ± 0.5 (n=5)	0.00 ± 0.01 (n=5)	0.4 ± 0.9 (n=5)	0.01 ± 0.02 (n=5)	0.4 ± 0.5 (n=5)	0.01 ± 0.02 (n=5)	1.2 ± 0.8 (n=5)	0.17 ± 0.25 (n=5)
Dead spiders														
Totals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Beetles														
Totals	63	1.99	46	3.80	6	0.70	6	0.12	40	4.30	19	0.30	34	0.25
Mean ± SD	12.6 ± 7.2 (n=5)	0.40 ± 0.31 (n=5)	9.2 ± 3.7 (n=5)	0.76 ± 0.21 (n=5)	1.2 ± 1.3 (n=5)	0.14 ± 0.21 (n=5)	1.2 ± 1.3 (n=5)	0.02 ± 0.02 (n=5)	8.0 ± 2.9 (n=5)	0.86 ± 0.42 (n=5)	3.8 ± 3.3 (n=5)	0.06 ± 0.06 (n=5)	6.8 ± 2.9 (n=5)	0.05 ± 0.04 (n=5)
Dead beetles														
Totals	0	0	0	0	1	0.01	0	0	0	0	0	0	0	0
Other arthropods														
Totals	1	0.05	4	1.30	0	0.00	13	0.15	40	0.65	8	0.50	4	0.15
Mean ± SD	0.2 ± 0.4 (n=5)	0.01 ± 0.02 (n=5)	0.8 ± 1.1 (n=5)	0.26 ± 0.37 (n=5)	0.0 ± 0.0 (n=5)	0.00 ± 0.00 (n=5)	2.6 ± 2.7 (n=5)	0.03 ± 0.02 (n=5)	8.0 ± 4.8 (n=5)	0.13 ± 0.10 (n=5)	1.6 ± 1.1 (n=5)	0.10 ± 0.15 (n=5)	0.8 ± 1.8 (n=5)	0.03 ± 0.07 (n=5)
Dead other arthropods														
Totals	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANNEX B

1,3-DICHLOROPROPENE

ADDENDEUM 4

B - 8 : ENVIRONMENTAL FATE AND BEHAVIOUR

THIS ADDENDUM WAS PREPARED UNDER THE RESPONSIBILITY OF:

Mr. García - Baudín, J. Mª. Ph. D. (Co-ordinator).

Mr. Alonso - Prados, J. L. Ph D. (Scientific Co-ordinator).

Unidad de Productos Fitosanitarios I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FROM THE DOSSIERS SUBMITTED BY:

Task Force: Dow AgroScience & Kanesho Soil Treatment SPRL/BVBA

WITH THE ASSISTANCE OF THE FOLLOWING EXPERTS:

Environmental fate and behaviour

Ms. Alonso-Prados, Elena

Unidad de Productos Fitosanitarios I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FOREWORD

The following addendum has been done in order to answer the concerns arisen during the peer review and collected in the evaluation table rev. 0-0 (17.07.2009) and reporting table rev. 1-1 (17.07.2009) for the active substance 1,3-dichloropropene.

B.8 Environmental fate and Behaviour.

B.8.6.2 Estimation of concentrations in surface water.

B.8.6.2.1 Drainage /lateral flow

a) Shank use. Field conditions

Data GAP 4.1: Applicant to provide an explicit description of the relationship used to describe the 3 phase partition as utilised in the DripFume model.

RMS has checked again in the report Nº: GH-C 5358 (Masterfile:MK 42) for any evidence of these relationships and they are described in the second paragraph of the page 41 of the report. Therefore this Data Gap can be considered addressed

Additionally, RMS contacted with the corresponding author of the article published in Computers and Electronics in Agriculture 56 (2): 111-119 who confirmed that the linear phase partition was computed as:

Cg=Kh*Cl
Cs=Kd*Cl
Cl =Cf

where Cg is gas phase concentration, Cl is liquid phase concentration, Cs is solid phase (adsorbed) concentration Cf is concentration of 1,3-D in the drip system during the time of application

Kh is the dimensionless Henry's constant

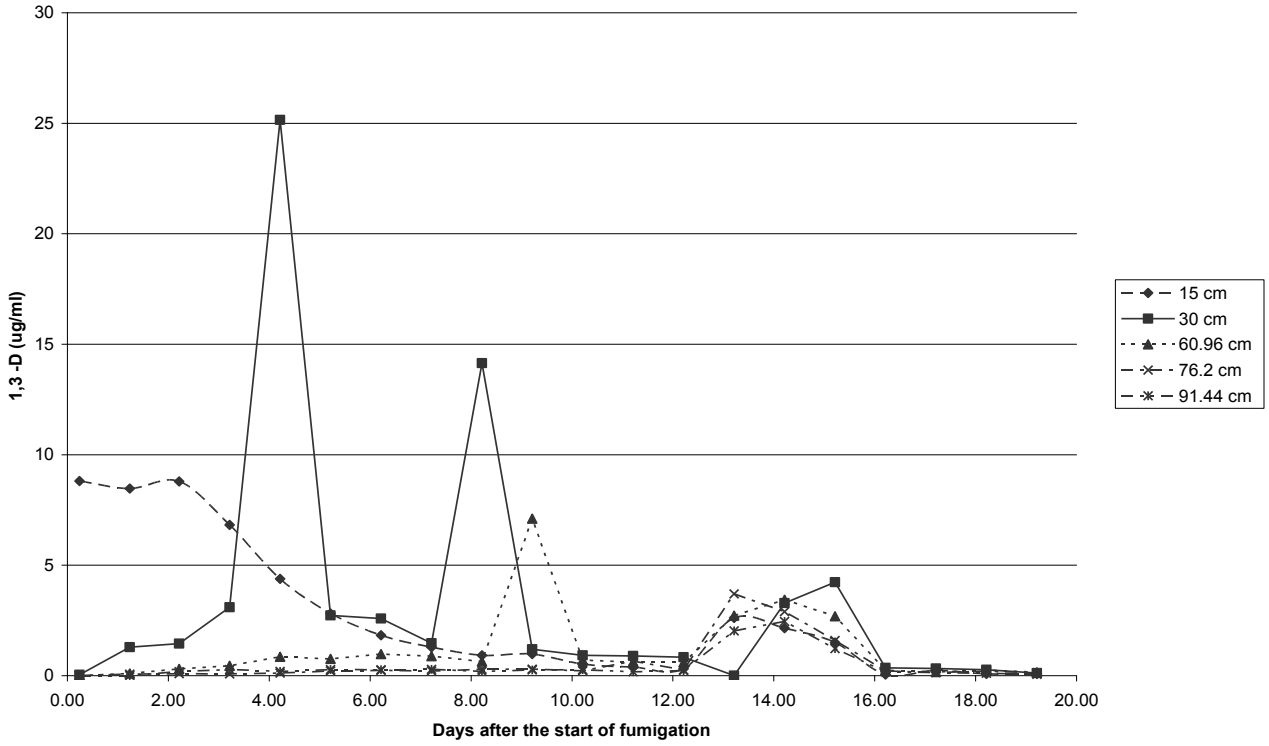
Kd is the adsorption coefficient

b) Drip irrigation. Experimental evidences of limited lateral transport o 1,3-D.

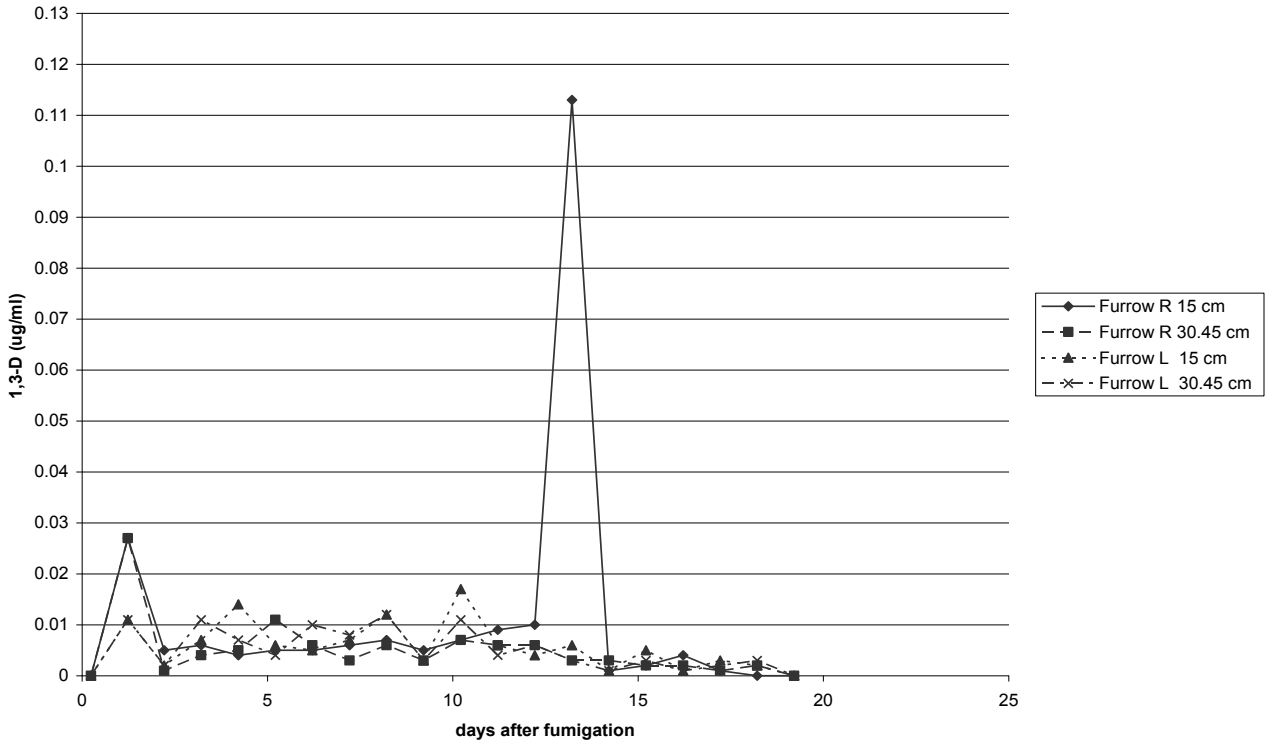
Open point 4.1: RMS to provide the additional detail attached to the reporting table in relation to figure 8.6.2.1-3 in an addendum.

Figure 8.6.2.1-3: 1,3-D Soil gas in the Beds and in the furrows

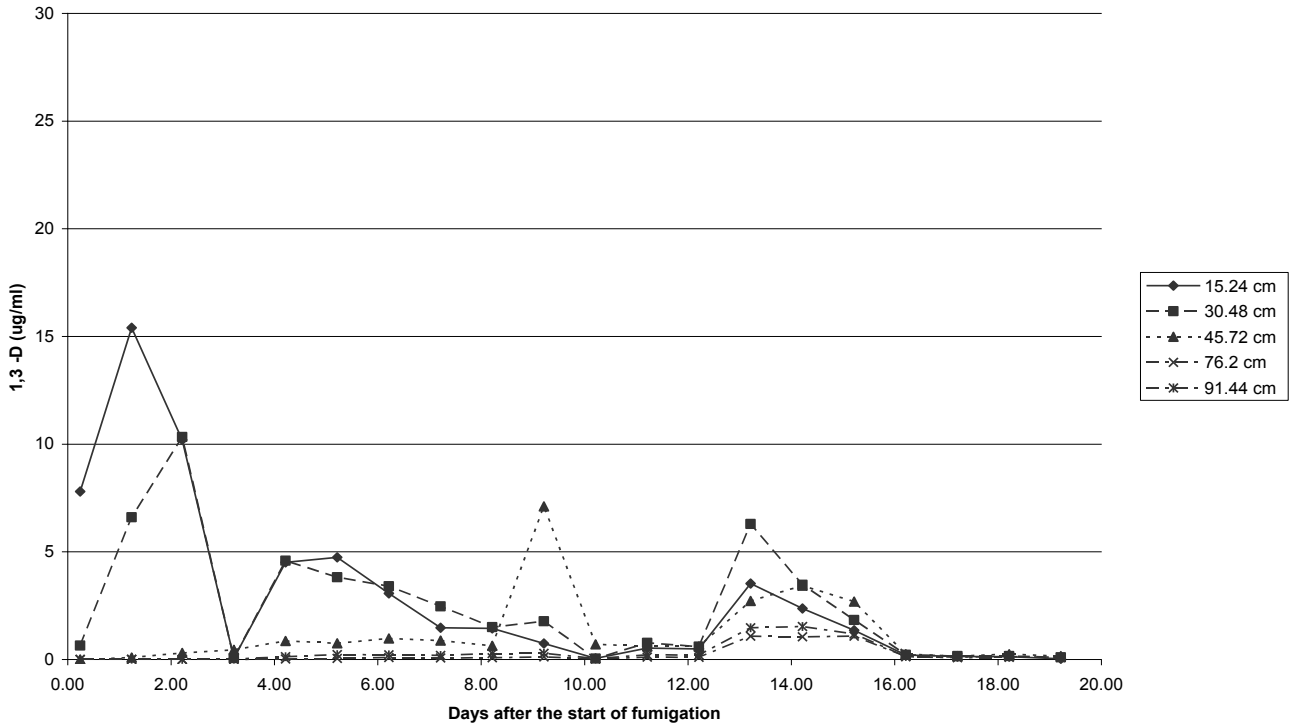
A) Bed A



B) Furrow A



C) Bed B



D) Furrow B

B.8.10 Monitoring Data

B.8.10.1 Groundwater

B.8.10.1.2 Evidence of 1,3-D Use in the areas of monitoring

Open point: 4.4: RMS to update table 8.10.1.2-1 to include the units for the sales figures for Italy, France and the UK where the the units are missing, in an adendum, if this information is available.

Table 8.10.1.2-1: Information on 1,3-D Sales, length of use, and proximity to Groundwater Monitoring wells

Country	Distributor	Amount per year	Region	Locality	Application Proximity to Wells	Years Used	Relevant Well Monitored (code)
ITALY	Galanti	250000 l/y	Lazio	Sabaudia	Selva Piana	10	SAB02
	SIS	0.16%	Lazio	Latina	Aprilia		CAR, CAM02, GIA03
	SIS	0.13%	Lazio	Latina	Sabaudia		SAB02
	SIS	0.06%	Lazio	Latina	Fondi		FON07
	SIS	9.2%	Veneto	Verona			BIN, DAV
	SIS	0.2%	Veneto	Rovigo			OCC02,ROF09, ROF10
	Geofin	409800 l/y	Veneto	Verona	Ca' di David	12-45	DAV
	Geofin		Veneto	Verona	Binelunghe	12-45	BIN
	Geofin		Veneto	Isola della Scala	Borgodoltra	12-45	ISS
	Geofin	1781760 l/y	Veneto	Legnago	Paina	12-45	LEG01
	CALV	500 l/y	Veneto	Verona	Ca' di David	15	DAV
	CALV	500 l/y	Veneto	Verona	Binelunghe	15	BIN
	CALV	2000 l/y	Veneto	Isola della Scala	Borgodoltra	15	ISS
	CALV	2000 l/y	Veneto	Legnago	Paina	15	LEG01
	SIS	8.5%	Emilia Romagna	Ferrara			OCC02,ROF09, ROF10
	SIS	0.5%	Emilia Romagna	Forli Cesena	Forli		FRL66
	SIS	2.55%	Emilia Romagna	Forli Cesena	Cesena		CES06
	SIS	0.2%	Emilia Romagna	Rimini			RN07
	Ortotecnica	2000L/y	Emilia Romagna	Rimini	Bellaria	15	RN07
	CASA Mesola	30000l/y	Emilia Romagna	Ro Ferrarese		20	OCC02,ROF09, ROF10
	SIS	0.36%	Campania	Napoli			AC03
	Coppola Fertilizzanti	3000 l/year	Campania	Napoli	Accera	21	AC03
	Coppola Fertilizzanti	1000 l/year	Campania	Napoli	Lufrano	21	SN01
	SIS	13.86%	Campania	Salerno			FP,CIO,AV
	Coppola Fertilizzanti	4000 l/ year	Campania	Salerno	Battipaglia	12	FP,CIO,AV
	Coppola Fertilizzanti	2500/l year	Campania	Salerno	Eboli	12	FP,CIO,AV
	SIS	0.5%	Sicilia	Ragusa	Castellana		SCI
	Bioservice	2500 l/year	Sicilia	Ragusa	Castellana	10	SCI
	SIS	3.76%	Sicilia	Ragusa	Scicli		FER, CAS
	Bioservice	100000 L/y	Sicilia	Ragusa	Petraro	10	SCI
	SIS	3.16%	Sicilia	Caltanissetta	Gela		PAN02, PAN05
FRANCE	AGRIAL	5000l/y	Manche	Gatteville Le		10	MA-F13,MA-F14, MA-F16

Country	Distributor	Amount per year	Region	Locality	Application Proximity to Wells	Years Used	Relevant Well Monitored (code)
				Phare			
	AGRIAL	120000l/y	Manche	Breteville sur Ay		20	MA-F18,MA-F21
	AGRIAL		Manche	Creances		20	MA-F18,MA-F21
	Agriviti	250 l/year	Haut Rhin	Katzenthal		15	HR-F5, HR-F6
	Agralia	80000 l/y	Landes	Ychoux		7	YP-F4,YP-F5, YP-F8,YP-F9
	Agralia		Landes	Parentis-en-Born		7	YP-F10
	La Centrale	1600+700 = 2300 l/year	Pyrenee Orientales	Elne		4+	BY-F4, BY-F6, BY-F7
	La Centrale	800 + 500 = 1300 l/year	Pyrenee Orientales	Saint Cyprien		4+	BY-F2,BY-F8
	Coop Agricole Provence Languedoc	3000 + 4550 = 7550 l/year	Vaucluse	Athen-Chateauneuf/ Carpentras	Chateauneuf	4+	CA-F2,CA-F7
	Coop Agricole Provence Languedoc	1500 + 3500 = 5000 l/year	Vaucluse	Jonquieres/ Orange	Jonquieres	4+	CA-F5,CA-F8
	Coop Agricole Provence Languedoc	1500 + 2265 = 3765 /l year	Vaucluse	Courthezon/ Orange	Courthezon	4+	CA-F8
SPAIN	Agroquimicos Cespedes	1800 MT	Almeria	Almeria		>35	AL-1,AL-2,AL-3, AL-4,AL-5,AL-6, AL-7,AL-8
	Torrandell Ca'S Siulet	200 MT	Mallorca	Mallorca		>35	PM-1,PM-2,PM-3, PM-4,PM-5
	Enrique Ortuno	250MT	La Rioja	La Rioja		>35	R-1,R-2,R-3,R-4, R-5
	Fitesa	180 MT	Cadiz	Cadiz		>35	C-1,C-2
	Cahersa	1000 MT	Caceres	Caceres		>35	CC-1,CC-2,CC-3, CC-4,CC-5
UK	Boston Crop Sprayers	3600 l/y	Lincolnshire	SW Lincoln	Dunston	5	L D
	Boston Crop Sprayers	13500 l/y	Lincolnshire	N Scunthorpe	Winterton Holmes	5	L WH
	Frontier Ag	2000 L/y	Lincolnshire	N Scunthorpe	Winterton Holmes	11	L WH
	Boston Crop Sprayers	1800 l/y	Lincolnshire	W Grimsby	Ulceby	3	L U
	Boston Crop Sprayers	13000 l/y	Lincolnshire	NE Barrow Upon Humber	Goxhill No.2	5	L GT
	Boston Crop Sprayers	4500 l/y	Lincolnshire	SW Market Rasen	Sprindlington	2	L S
	Frontier Ag		Lincolnshire	SW Market Rasen	Sprindlington	12	L S
	Frontier Ag	20000 l/year	Lincolnshire	Dunston		10	LD
	Frontier Ag	45000 l/year	Lincolnshire	Sprindlington		15	LS
	Frontier Ag	15000 l/year	Norfolk	NE Norwich	Ludham	10	N L
	Boston Crop Sprayers	9000 l/year	Norfolk	N Fackenham	Wighton	10	N W

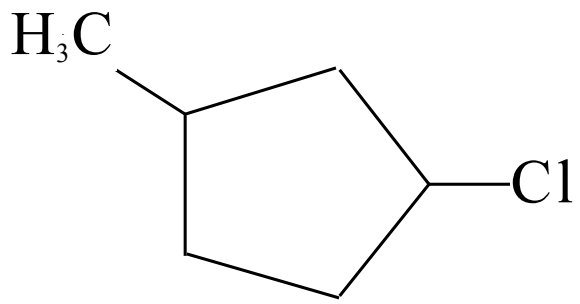
Country	Distributor	Amount per year	Region	Locality	Application Proximity to Wells	Years Used	Relevant Well Monitored (code)
	Boston Crop Sprayers	3000 l/year	Norfolk	N Norwich	Aylsham	10	N A
	Frontier Ag	15000 l/year	Norfolk	N Norwich	Aylsham	10	N A
	Boston Crop Sprayers	8000 l/year	Norfolk	SE Hunstanton	Sedgeford	10	N S
GREECE	N.Erasmio Xanthis	3MT	Thrace	Xanthi		15	KAV002,KAV003 KAV005,KAV015 KAV016
	Kouts Xanthi	4 MT	Thrace	Xanthi		10	KAV002,KAV003 KAV005,KAV015 KAV016
	Agroland Mavajirous	1 MT	Peloponisos	Filiatra		10	MES009,MES010,MES012, MES014, MES015
	Agro Titoe	8 MT	Crete	Mires	Tymbaki	15	HER007,HER009,HER012, HER013,HER015
	Tkeabephe	4 MT	Crete	Mires	Tymbaki	15	HER007,HER009,HER012, HER013,HER015
	IΩannhΣ	3 MT	Crete	Ierapetra	Ierapetra	15	LAS002,LAS005, LAS006, LAS015
	AgroService Zammetauhe	2 MT	Crete	Ierapetra	Ierapetra	15	LAS002,LAS005, LAS006, LAS015
	Geoplan Galanakis	8 MT	Crete	Ierapetra	Ierapetra	14	LAS002,LAS005, LAS006, LAS015

B.8.11 Environmental fate and behaviour of process impurities

B.8.11.2 Phys-chem properties of process impurities

Data Gap 4.6: A groundwater exposure assessment for process impurity 13 that could be considered by the peer review is not available. This information was provided by the RMS in the revised Vol 3-B8 (June 2009) but in line with Commission Regulation (EC) No 33/2008 neither additional information, nor the submission of new studies can be accepted in relation to stage 2 active substances.

Spain as RMS does not agree with this data GAP. Nothing is mentioned throughout the regulation regarding additional statements to clarify concerns during the Peer Review. Notifer states that impurity 13 is likely to behave similary in the environment than the rest of the impurites monitored based on QSAR calcualtions. RMS confirms the statement of notifier by calculating the phys-chem properties of impurity 13 with EPIwin 3.1 software, included below.



MolWt: 118.61 C6 H11 CL1

SMILES : C1(CL)CCC(C)C1
CHEM :
MOL FOR: C6 H11 CL1
MOL WT : 118.61
---------- EPI SUMMARY (v3.11) ----------
Physical Property Inputs:
Water Solubility (mg/L): ------
Vapor Pressure (mm Hg) : ------
Henry LC (atm-m3/mole) : ------
Log Kow (octanol-water): ------
Boiling Point (deg C) : ------
Melting Point (deg C) : ------

Log Octanol-Water Partition Coef (SRC):
Log Kow (KOWWIN v1.67 estimate) = 3.28

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.41):
Boiling Pt (deg C): 124.42 (Adapted Stein & Brown method)
Melting Pt (deg C): -60.11 (Mean or Weighted MP)
VP(mm Hg,25 deg C): 12.9 (Mean VP of Antoine & Grain methods)

Water Solubility Estimate from Log Kow (WSKOW v1.41):
Water Solubility at 25 deg C (mg/L): 159.7
log Kow used: 3.28 (estimated)
no-melting pt equation used

Water Sol Estimate from Fragments:
Wat Sol (v1.01 est) = 462.71 mg/L

ECOSAR Class Program (ECOSAR v0.99g):
Class(es) found:
Neutral Organics

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:
Bond Method : 1.49E-002 atm-m3/mole
Group Method: 5.73E-003 atm-m3/mole
Henrys LC [VP/WSol estimate using EPI values]: 1.261E-002 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.01):

Linear Model : 0.5797
Non-Linear Model : 0.3709
Expert Survey Biodegradation Results:
Ultimate Survey Model: 2.7639 (weeks)
Primary Survey Model : 3.5760 (days-weeks)
Readily Biodegradable Probability (MITI Model):
Linear Model : 0.4449
Non-Linear Model : 0.2559

Atmospheric Oxidation (25 deg C) [AopWin v1.91]:
Hydroxyl Radicals Reaction:
OVERALL OH Rate Constant = 4.1932 E-12 cm3/molecule-sec
Half-Life = 2.551 Days (12-hr day; 1.5E6 OH/cm3)
Half-Life = 30.609 Hrs
Ozone Reaction:
No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):
Koc : 235.3
Log Koc: 2.372

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:
Total Kb for pH > 8 at 25 deg C : 1.642E-015 L/mol-sec
Kb Half-Life at pH 8: 1.338E+013 years
Kb Half-Life at pH 7: 1.338E+014 years

BCF Estimate from Log Kow (BCFWIN v2.15):
Log BCF = 1.828 (BCF = 67.24)
log Kow used: 3.28 (estimated)

Volatilization from Water:
Henry LC: 0.0149 atm-m3/mole (estimated by Bond SAR Method)
Half-Life from Model River: 1.154 hours
Half-Life from Model Lake : 103.9 hours (4.33 days)

Removal In Wastewater Treatment (recommended maximum 99%):
Total removal: 85.85 percent
Total biodegradation: 0.05 percent
Total sludge adsorption: 5.09 percent
Total to Air: 80.71 percent

Level III Fugacity Model:

	Mass Amount (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	20.2	61.2	1000
Water	38.6	360	1000
Soil	40.6	360	1000
Sediment	0.647	1.44e+003	0

Persistence Time: 161 hr

B.8.12 References relied on.

Data Gap 4.2: The reference 'Computers and Electronics in Agriculture archive Volume 56 , Issue 2 (April 2007) Pages 111-119 ISSN:0168-1699 should be added to the dossier.

Data gap: 4.3: The references 'Simunek, J. and M. Th. van Genuchten. 1994. The CHAIN_2D Code for Simulating Two-Dimensional Movement of Water, Heat, and Multiple Solutes in Variably-Saturated Porous Media, Version 1.1. Research Report No. 136' and 'U. S. Salinity Laboratory, USDA, ARS, Riverside, California . Available from the following website:
http://www.ars.usda.gov/Services/docs.htm?docid=8914'
should be added to the dossier.

Data Gap 4.4: The reference 'Aller, L et al 1997 EPA/600/2-87/035' should be added to the dossier.

These references were taken by RMS from the public literature to support the evaluation of 1,3.-Dichlorpropene. These references are mentioned in reports already submitted by the notifier. RMS has included in the reference list and considers these data gaps closed.

Annex point/ reference no.	Author(s)	Year	Title Source (where different from company) Company, report no. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
IIA 7.4/01 IIIA 9.2.1/01	Knowles, S. Panagopoulos, S.A	2008	Residues of 1,3-Dichloropropene and Related Compounds in Groundwater in Greece - 2005 Report number: GHE-P-11707 (Masterfiel number: MK59) GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIA 7.4/02 IIIA 9.2.1/02	Kennedy	2008	Residues of 1,3-Dichloropropene and related compounds in Groundwater in Greece - 2006 to 2007 (final report) Report number: GHE-P-11693 (Masterfiel number: MK58) GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIA 7.4/03 IIIA 9.2.1/03	Dawson, J.	2006	Letter on Evidence of use of 1,3-D in EU countries - support to groundwater monitoring studies submitted in Europe (plus attachments) Dow AgroSciences DAS Report No:N/A (Masterfile Number K86): GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
IIA 7.4/05 IIIA 9.2.1/04	Antonio Pulido Bosch, Sara Jorreto Zajuirre	2005	Hydrological report on the possible explanations to the origin of the 1,3-D Metabolite (acid) in two wells of the sampling net of Caceres, Spain University of Almeria (Spain) DAS Report No.: GHE-P-11256 (Masterfile Number : MK55): GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
IIA 7.4/06 IIIA 9.2.1/05	Knowles,S. Hughes G Humphrey,R. Price,O.	2006	Borehole Vulnerability assessment in relation to 1,3-Dichloropropene groundwater monitoring programme in Europe ADAS UK Ltd DAS Report No GHE-P-11388 (Masterfile Number): MK56 GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
IIA 7.4/07 IIIA 9.2.1/06	Hughes G., Price O., Knowles, S.	2008	Pesticides in groundwater: Borehole vulnerability assessments to support a European groundwater quality monitoring programme Publication DAS Report No.: Not applicable (Masterfile Number): PK33 GLP/GEP (Y/N): N Published (Y/N): Y	N	P

Annex point/ reference no.	Author(s)	Year	Title Source (where different from company) Company, report no. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
IIA 7.4/08 IIIA 9.2.1/07	Terry D.Carter Humphrey et al	2008	A monitoring programme for 1,3-Dichloropropene and metabolites in 5 EU countries Publication DAS Report No.: Not applicable (Masterfile Number): PK32 GLP/GEP (Y/N): N Published (Y/N): Y (Pest Manag Sci 64(9):923-32)	N	P
IIIA 9.2.1/08	Aller,L Bennet, T Lehr, J. H. Petty, R.J.	1987	DRASTIC: A standardized system for evaluating Ground water pollution potential using hydrogeological settings US Environmental Protection Agency US EPA Report 600/2-85/018 GLP/GEP: N Published: Y	N	P
IIIA 9.2.3/01	Knowles, S	2005b	Surface water exposure assessment, PECsw-open use Dow Agroscience report Nº: N/A (Masterfile: K88) GLP/GEP: N Published: N	Y	DAS
IIIA 9.2.3/02	Knuteson, J.A Wang, D.	2001	DripFume: a Visual Basic Interface Program for simulating soil Fumigatoin by Drip irrigation Dow Agroscience report Nº: GH-C 5358 (Masterfile:MK 42) GLP/GEP: N Published: N	Y	DAS
IIIA 9.2.3/03	Wang, D., Knowles, S., Knuteson, J	2005	Two-Dimensional Soil Transport Modelling of 1,3-D For Exposure Assessment Dow Agroscience report Nº: GHE-P-11175 (Masterfile: K83) GLP/GEP: N Published: N	Y	DAS
IIIA 9.2.3/04	Knutenson and Dolder	2000	Field Volatility of 1,3-Dichloropropene and Chloropicrin from Shallow Drip Irrigation Application of Telone C-35 to Strawberry Beds Covered with VIF Tarp Dow AgroSciences, Report Nº GH-C 5075 (Masterfile MK33) GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
IIIA 9.2.3/05	Knuteson, J.A Wang, D.	2007	DripFume: a Visual Basic Interface Program for simulating soil Fumigatoin by Drip irrigation *Computers and electronics in Agriculture* 56 (2): 111-119 GLP/GEP (Y/N): N Published (Y/N): Y	N	P

Annex point/ reference no.	Author(s)	Year	Title Source (where different from company) Company, report no. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
IIIA 9.2.3/06	Simunek, J. and M. Th. van Genuchten.	1994	The CHAIN_2D Code for Simulating Two-Dimensional Movement of Water, Heat, and Multiple Solutes in Variably-Saturated Porous Media, Version 1.1. Research Report No. 136' and „U. S. Salinity Laboratory, USDA, ARS, Riverside, California GLP/GEP (Y/N): N Published (Y/N): Y	N	P
IIA 7.4/09 IIIA 9.3/01	Knowles, S	2005a	Correlation of pedo-climatic conditions for field locations used in 1,3-D air monitoring studies- letter in response to EFSA evaluation meetinf Dow Agroscience report Nº: N/A (Masterfile: K82) GLP/GEP: N Published: N	Y	DAS
-	Eversfield, S.G Knowles, S.	2007	Method development for Telone analytes Dow Agroscience report Nº: GHE-P-11384 (Masterfile: O49) GLP/GEP: Y Published: N	Y	DAS
-	Lamastra, L., Ferrari, F., Trevisan, E., Capri, E., Knowles, S.	2008	Hydrolytic Stability of the Telone Process Impurities Dow AgroSciences, report No. GHE-P-11780 (Masterfile A78) GLP/GEP: N Published: N	Y	DAS
-	Knowles, S	2007	. Modelling The Environmental Characteristics of 1,3-Dichloropropene And Its Process Impurities Using The US EPA Estimation Programs Interface (EPI Suite) Version 3.20 Dow AgroSciences Report GHE-P-11692 (Ref. Masterfile K85) GLP/GEP: N Published: N	Y	DAS
-	Mackay, D., Webster, E., Knowles, S.	2006	Fugacity Modelling of 1,3-D And Its Process Impurities For Exposure Assessment Dow AgroSciences report No. GHE-P-11335 (Masterfile K84) GLP/GEP: N Published: N	Y	DAS

ANNEX B

1,3-DICHLOROPROPENE

ADDENDUM VI

B - 9: ECOTOXICOLOGY

THIS ADDENDUM WAS PREPARED UNDER THE RESPONSIBILITY OF:

Mr. García - Baudín, J. Mª. Ph. D. (Co-ordinator).

Mr. Alonso - Prados, J. L. Ph D. (Scientific Co-ordinator).

Unidad de Productos Fitosanitarios I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FROM THE DOSSIERS SUBMITTED BY:

Task Force: Dow AgroScience & Kanesho Soil Treatment SPRL/BVBA

WITH THE ASSISTANCE OF THE FOLLOWING EXPERTS:

Ecotoxicology

Ms. Novillo Villajos, Apolonia Ph. D.

Unidad de Productos Fitosanitarios I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FOREWORD

This addendum has been prepared during commenting period of 1,3-Dichloropropene for the inclusion for 1,3-Dichloropropene[15] soil fumigant in Annex I of 91/414/EEC and taking into account the information provided by the notifier to address the critical areas of concern as specified in the evaluation table of 1,3-D (Agust-2009).

Critical areas of concern

- **Open point: 5.2. Evaluation table: August 2009.**

  Member State experts should discuss the relevant long-term endpoint for mammals.

- **Open point 5.3. Evaluation table: August 2009.**

Use of the field study submitted Blanckenhagen, F. (2006) should be discussed by Member State experts. E.g:

- Can the study be considered valid?
- How representative is the study?
- Is the preference for 1,3-D treated fields so low that no risk is expected?

- **Open point: 5.4. Evaluation table August 2009.**

The validity or the residue study in insects and earthworms should be discussed by Member State experts

- Is there a bias in the estimated concentration, based on a potential higher residue concentration in dead insects, which may compose a higher proportion of bird diet than expected from the residue study?
- Is reasonable to consider that birds/mammal have a bias for live arthropods/earthworms?

- **Open point: 5.6. Evaluation table August 2009**

Both growth rate and biomass are normally reported for algae and higher plants and the lower endpoint should be used in the aquatic risk assessment according to the Aquatic Risk Assessment Guidance Document. In the current risk assessment TER values for the parent do indicate a large margin of safety. However, for 3-chloroacrylic acid a TER of 84 does not provide an extensive margin of safety. Changes in GAP uses at national level and providing the endpoint based on both growth rate and biomass may change the conclusion of the risk assessment.

For consistency with other active substances endpoints should be provided based on both growth rate and biomass for the active substance and the two metabolites. The aquatic risk assessment should be updated accordingly (in the LoE).

- Open point: 5.7. Evaluation table: August 2009.

Member State experts should discuss the use of the field study by Small (2006) in the risk assessment for NTA.

[15] Commission Decision 2007/619/EC
[2] EFSA Scientific Report (2006) 72, 1-99

B.9. Ecotoxicology

Background: The active substance 1,3-dichloropropene (1,3-D) has been evaluated based on representative uses for control of soil nematodes prior to the planting of fruiting vegetable crops (e.g. tomatoes and peppers). For the evaluation of Annex I inclusion the representative uses of 1,3-D were for indoor applications (defined as permanent structures) to bare soil via drip irrigation as Telone EC Drip (EF-1478), and outdoor applications to open fields by soil injection as Telone Injected (XRM-5048, also known as Telone II) and sealing by compaction.

The supported application rates are up to 283 kg 1,3-D/ha for indoor uses and up to 224 kg 1,3-D/ha for outdoor uses, with a maximum of one application per year. Typically the soil is treated with 1,3-D and then left for a minimum of 14 – 21 days before a fruiting vegetable crop (seedlings) is transplanted into the soil. For the indoor uses via drip irrigation, the EFSA concluded that there are no critical areas of concern for non-target species for the purposes of Annex I evaluation.

This document is primarily concerned with evaluating the risks to non-target organisms associated with soil injection of 1,3-D (XRM-5048) to open fields through the provision of comments to address questions raised from EFSA and different Member States.

The use of 1,3-D as a soil fumigant in all crops is limited to small areas of agricultural land within the EU (estimated to be less than 70,000 ha/year), while fruiting vegetables represent approximately one third of these uses and are concentrated in the south (Mediterranean countries). Approximately 60% of all uses in EU Member States are by injection to open fields, and the remainder by drip irrigation for indoor crops. The single application per year to a relatively small land area across the EU, of which a significant proportion is under cover, is important when considering the potential magnitude, duration and scale of any risks to non-target organisms from the high label use rates and intentional temporary soil sterilisation effects.

Open point: 5.2. Evaluation table: August 2009.

Member State experts should discuss the relevant long-term endpoint for mammals.

Background information: The long-term oral toxicity endpoint (NOAEL: 2.5 mg a.s./kg bw/d) listed in the EFSA Scientific Report (2006) was taken from the 2 year dietary study in rats, based on body weight. Because 1,3-D does not persist in food items the notifier has been re-evaluated the chronic toxicity endpoint for mammals.

Notifier argumentation

It is unclear to the Notifier why the RMS proposed a NOEL of 5 mg/kg/day based on the results in a rat 90 day study (Haut et al, 1993; MD05). In this study, statistically significant effects of 1,3-D on body weight were only detected after 49 days exposure to 15 mg/kg_{bw}/day, and only for males. When body weights were measured following 7, 14, 21, 28, 35 and 42 days exposure no significant effect on male body weight was detected for the 15 mg/kg/d treatment group (for females, no significant effects on body weight were detected after 7, 14, 21, 28, 42, 49, 56, 63, 70 or 77 days of feeding on the equivalent of 15 mg/kg/d).

It is important to note that, as pointed out previously by the RMS, following a 4-week recovery period, rats fed 100 mg/kg/day showed definitive signs of recovery in most of the parameters examined including body weight.

Finally, as discussed previously by the RMS, the possibility of long-term effects from short-term exposure (as well as the ability to recover at high doses, as mentioned above), can be explained by the pharmacokinetic data for 1,3-D which illustrates that in mammals the active substance is rapidly eliminated from the bloodstream (half-life of 2.8 – 6.1 min). The principle route of excretion, via the urine, had an elimination half-life of less than 6 hours for both rat and mouse.

Therefore, taking all of these points together, the Notifier believes that within the relevant exposure time-window of 2 weeks, the available data indicate that (reversible) effects on body weight may occur if small mammals consume the equivalent of 50 mg/kg_{bw}/day or more. However, the available data also indicate that no effects on body weight are expected if small mammals consume the equivalent of 15 mg/kg/d for periods up to 42 days (6 weeks).

The following Tables are taken from the Notifier submission (Point B.9.3.1 Toxicological data for mammals), with the shading added to indicate at which treatment levels short-term effects (within 2 weeks) on body weight were observed.

Effect of 1,3-D on body weight of rats during first 2 weeks exposure to 1,3-D in long-term studies. Where effects were observed during first 2 weeks, the first day when an effect was detected is provided in brackets.

Concentration Tested ($mg/kg_{bw}/day$)	14-day study: Effects on body weight detected (Yes/No)	90-day study: Effects on body weight detected during first 2 weeks exposure (Yes/No)	2-year study: Effects on body weight detected during first 2 weeks exposure (Yes/No)
2.5	-	-	No
5		No	
10	No	-	-
12.5	-	-	No
15	-	No	-
25	No	-	Yes (after 8 days)
50	Yes (after 8 days)	Yes (after 7 days)	-
100	Yes (after 8 days)	Yes (after 7 days)	-

Effect of 1,3-D on body weight of mice during first 2 weeks exposure to 1,3-D in long-term studies. Where effects were observed during first 2 weeks, the first day when an effect was detected is provided in brackets

Concentration Tested ($mg/kg_{bw}/day$)	14-day study: Effects on body weight detected (Yes/No)	90-day study: Effects on body weight detected during first 2 weeks exposure (Yes/No)	2-year study: Effects on body weight detected during first 2 weeks exposure (Yes/No)
2.5	-	-	No
15	-	No	-
25	No	-	Yes (after 9 days)
50	No	Yes (after 13 days)	Yes (after 9 days)
100	Yes (after 15 days)	Yes (after 6 days)	-
175	Yes (after 8 days)	Yes (after 6 days)	-

Based on the combined results presented above the highest concentration tested in long-term dietary studies with rats and mice which did not result in a significant difference in body weight during the first 6 weeks of exposure is 15 $mg/kg_{bw}/day$.

RMS proposal:

RMS does not agree with notifier proposal. Effects in body weight at 15 mg/kg bw/d can be detected late (after two weeks) besides recovery can be expected at this dose. Thus, in the rat 90-day oral study (Haut et al., 1993, summarized in the DAR) effects on body weight were detected after 49 days exposure to 5 and 15 $mg/kg_{bw}/day$ in males. Effects at 50 and 100 $mg/kg_{bw}/day$ were detected in males within 7 days of exposure. Females were

less affected, with no effects even after 90 days at 5 mg/kg_{bw}/day, and effects at 15 mg/kg_{bw}/day only detected after 84 days. Following the 4-week recovery period, rats fed 100 mg/kg/day showed definitive signs of recovery in most of the parameters examined including body weight.

RMS proposal is to use for refinement the relevant NOAEL 5 mg/kg bw/d. This endpoint was based on the results from 90d-oral exposure study (Haul et al, 1993) in rat. In this study, the no-observed-adverse-effect level (NOAEL) for male rats and the no-observed effect level (NOEL) for female rats based on body weight was determined to be 5 mg Telone II/kg body weight/day.

This endpoint was based on body weight change as ecological relevant endpoint and, it may have some relevance to breeding success of wild mammals e.g. establishing breeding site, pairing and mating. This proposal is in line with EFSA opinion (EFSA Journal (2006) 344, 1-22). Specifically, for endpoints such as changes in body weight, the PPR Panel recommended to evaluate the endpoint for the exposure period relevant to the ecotoxicological assessment. Furthermore, it is stated in EFSA opinion that a way to refine the risk is by considering an endpoint from a study with a short period of exposure such as the 28-d or 90-day exposure study. Having in mind intended uses of 1,3-D in field long-term exposure it is not expected, and therefore endpoints from a study with shorter period of exposure should be suitable option for refinement.

Based on 90-days rat study, the no-observed-adverse-effect level (NOAEL) for male rats and the no-observed effect level (NOEL) for female rats based on body weight was determined to be 5 mg Telone II/kg body weight/day. This endpoint is suitable for long-term refinement risk assessment on mammals.

Open point 5.3. Evaluation table: August 2009.

Use of the field study submitted Blanckenhagen, F. (2006) should be discussed by Member State experts. E.g:

- **Can the study be considered valid?**
- **How representative is the study?**
- **Is the preference for 1,3-D treated fields so low that no risk is expected?**

Notifier argumentation:

The scenario evaluated is fully representative of the Annex I GAP for fruiting vegetables. The study clearly illustrates that small mammal activity on Telone treated fields is reduced due to the pre- and post- injection agricultural operations, and that potential for in-field exposure is therefore negligible. The study illustrates that, in reality, small mammals will not feed exclusively on treated fields (i.e. PT $\neq$ 1) for periods sufficient to affect growth (i.e. 6 weeks or more; See comment to Open Point 5.2), are not appropriate.

August 2009-RMS:

Addressing the questions rose in the open point 5.3:

Can the study be considered valid?

A summary of the study is depicted in

Addendum 5_B9_ECOTOX_ADDITIONAL REPORT_1-3D_MARCH 2009_24_06_09, pages 49-54.

Rapporteur member state has been re-evaluated the study in terms of usefulness. All this information has been summarized in addendum VI_ECOTOX_ADDITIONAL REPORT_1-3D_AGUST 2009.

In summary,

Usefulness, the study give information about wildlife mammals species exposed in the area treated with Telone II and surrounding fields, and indirectly assess in some extent the food available within the treated area. This is an important question that was a reason of concern in the first-tier assessment.

The endpoint of study was to determine species and abundance of small mammals on Telone treated fields compared to adjacent habitats before and after, and subsequent to tomatoes planting.

The study shows that, as not crop plants are grown at the time of Telone II treatment, the species potentially feeding on the treated field are omnivores (e.g. Apodemus) and insectivores (e.g. shrews) as was expected for tomato crops. Furthermore, the study shows that small mammals will not feed exclusively form the treated area during long-term periods, due to depletion in food availability (e.g. not plants) and agronomic operations (e.g. injection, soil sealed, and crop planting after 14 days).

Under RMS opinion the study contain useful information in identifying wildlife mammals species that can be exposed to 1,3-D residues. Relevant species are insectivorous and omnivores mammals.

How representative is the study?

The type of ecosystem is relevant for the local situation, thus the study focused on fields which were due to be planted with a fruiting vegetable crop and with representative surrounding habitats of South Europe. The study is performed in the intended crop (tomatoes).

Four field trial areas were selected for the study. The adjacent trapping areas are diverse, representing different ecosystems (woodland, grassland strip, tree plantation, narrow row of trees).

The product of concern is applied at the maximum doses rate (190L/ha), and the method of application is by injection (relevant for actual situation, GAP).

RMS agrees with notifier, and would like to point out that the scenario evaluated is fully representative of the Annex I GAP for fruiting vegetables in South European conditions for 1,3-D.

Is the preference for 1,3-D treated fields is low that not risk is expected?

RMS would like to point out that for outdoor uses, the application of 1,3-D is injected into the soil profile, typically at a depth of 15 - 20 cm, followed by capping to help seal the soil to maximise efficacy and minimise volatile losses. Typically, the soil is then harrowed to "open" the soil before the crop is planted, with a minimum interval between soil treatment and crop planting of 14 days. This interval between treatment and crop planting is necessary because 1,3-D is phytotoxic at the high initial soil concentrations achieved immediately following injection.

In this scenario, after telone application is expected that the presence of wildlife in Telone treated bare soil is reduced due to the pre- and post- injection agricultural operations, and the low levels of food available in bare soil.

Therefore, the potential for in-field exposure for mammals is low (PT lower than 1).This assumption is confirmed in the field study submitted Blanckenhagen, F. (2006).

Under RMS opinion the preference of mammals for 1,3-D treated field is expected to be low, and therefore the potential risk associated for wildlife mammals with the use of 1,3-D should be acceptable.

Open point: 5.4. Evaluation table August 2009.

The validity or the residue study in insects and earthworms should be discussed by Member State experts

- **Is there a bias in the estimated concentration, based on a potential higher residue concentration in dead insects, which may compose a higher proportion of bird diet than expected from the residue study?**
- **Is reasonable to consider that birds/mammal have a bias for live arthropods/earthworms?**

August 2009-RMS:

Field residue study Small (2007)

A summary and evaluation of study is depicted in Addendum 5_B9_ECOTOX_ADDITIONAL REPORT_1-3D_MARCH 2009_24_06_09, pages 16-22.

EPCO expert's meeting considered that a new study representative for the supported GAP (spring/summer applications under Mediterranean conditions) was needed. Therefore, a further field study (Small, 2007) has been conducted, in which residue levels of 1,3-D in arthropods and earthworms were determined following use of 1,3-D at 224 kg a.s./ha under Mediterranean conditions.

Under RMS opinion the study (Small, 2007) should be considered acceptable for risk assessment. The study is considered as a realistic study representative of agriculture sites of the South of Europe where Telone is intented to be applied.

Addressing the questions raised in the open point 5.4:

- Is there a bias in the estimated concentration, based on a potential higher residue concentration in dead insects, which may compose a higher proportion of bird diet than expected from the residue study?

In the study pitfall traps were used to collect arthropods. This technique is the most practical method to collect ground dwelling arthropods. They have of course the disadvantage of collecting only active and moving individuals, but, on the other hand, pitfall traps are the only method to selectively collect only arthropods.
To improve the sampling protocol, if dead arthropods were seen the personnel collected them. According to Appendix 5, the number of death arthropods was low, and therefore residue levels in most of the sites sampled accounted mostly for alive arthropods. Maximum residue levels for arthropods were 1.52 mg/kg. This value was used for risk assessment, and not unaceptable risk is expected.

To address if death arthropods has high level of residues, and address if bias on the low side due to the use of pitfall traps as collection method, RMS would like to refer to Fischer and Bower (1997) data set on arthropod residues and Brewer et al (1997) (Appendix II in Sanco 4145/2000). In Brewer's study residues for both adult insects (3.3 mg/kg) and larvae (2.1 mg/kg) were below the average of the Fischer and Bowers data set (5.1 mg/kg).This finding is inconsistent with the potential concern that Fischer and Bowers data are biased on the low side due to the use of pitfall traps as collection method.

RMS would like to point out that limited information is available to conclude how much residue levels is expected in death arthropods compare to live arthropods, and if pitfall traps protocol is really bias in the low side for the type of application of 1,3-D.

Is reasonable to consider that birds/mammal have a bias for live arthropods/earthworms?

It is an important question from an academic point of view, and that may have a potential impact in risk assessment of birds and mammals. But, in the current guidance document on risk assessment for birds and mammals, SANCO/4145/2000 this question is not addressed specifically.

Reference to this question is made in appendix 28 of EFSA opinion (birds and mammals risk assessment, 2008). Unfortunately, information available specifically addresses the impact of insecticides (e.g. spray applications), therefore extrapolation to other pesticides and application types increases the uncertainties. RMS would like to point out that the type of application of 1,3-D is not comparable to conventional spray applications.

For transparency, a copy of appendix 28 is inserted below:

Knock down samples during application

It can be assumed for insecticides (and other pesticides with insecticidal side effects like some fungicides) the highest initial residue loading occurs on those arthropods which are killed during or immediately after application of the product. These individuals are normally missed during the sample events for foliage dwelling arthropods (because they are already dead and have fallen on the ground) and will not be found in pitfall traps (because they can no longer move). ***It is unclear to what extent those arthropods are used as food items by birds and mammals****. At least some reports can be found in the scientific literature describing the uptake of dead and/or moribund arthropods by birds. Thus, in principle this scenario should not be overlooked and a respective sample of those arthropods affected directly from the product application should be obtained* ***whenever possible****.*

RMS would like to point out:

- It is unclear to what extent death arthropods are used as food ítems by birds and mammals.
- The use of 1,3-D as a soil fumigant in all crops is limited to small areas of agricultural land within the EU (estimated to be less than 70,000 ha/year), while fruiting vegetables represent approximately one third of these uses and are concentrated in the south (Mediterranean countries). Approximately 60% of all uses in EU Member States are by injection to open fields, and the remainder by drip irrigation for indoor crops. The single application per year to a relatively small land area across the EU, of which a significant proportion is under cover, is important when considering the potential magnitude, duration and scale of any risks to non-target organisms from the high label use rates and intentional temporary soil sterilisation effects.
- The applicants stated that only the use as nematicide will be supported in the EU review programme. This use in not an insecticide per se.
- Outdoor applications to open fields by soil injection as Telone Injected and sealing by compaction (not spraying), and therefore low levels of residue should be expected.
- In the field study submitted (Small, 2007), residue levels used for risk assessment of 1,3-D account for dead/alive arthropods/earthworms residues. Death arthropods/earthworms were collected when seen it. At this level of information it is not possible to know if dead arthropods/earthworms have more 1,3-D residues because for analytical purposes samples were combined in order to get enough sampling to conduct the analysis. Due to low number of animals and its level of residues (1,3-D) analysed it is unlikely that birds and mammals have a higher proportion of residues coming from dead insects in the diet.

<u>Impact on risk assessment</u>

To address uncertainties on risk assessment calculations, and to account for higher levels of residues on death arthropods it is assumed 5 times more of residue levels (estimated residue levels 7.50 mg/kg). Using this theoretical residue levels acceptable acute and short-term risk to birds is expected. Also, acute risk to mammals is acceptable.

Residue levels expected in earthworms are lower, therefore risk calculations for birds/mammals eating insects covers potential risk in birds/mammals eating earthworms.

Open point 5.6.

Both growth rate and biomass are normally reported for algae and higher plants and the lower endpoint should be used in the aquatic risk assessment according to the Aquatic Risk Assessment Guidance Document. In the current risk assessment TER values for the parent do indicate a large margin of safety. However, for 3-chloroacrylic acid a TER of 84 does not provide an extensive margin of safety. Changes in GAP uses at national level and providing the endpoint based on both growth rate and biomass may change the conclusion of the risk assessment.

For consistency with other active substances endpoints should be provided based on both growth rate and biomass for the active substance and the two metabolites. The aquatic risk assessment should be updated accordingly (in the LoE).

Notifier argumentation

1. Introduction

Upon the request of the RMS and EFSA, the toxicity end-points for 1,3-D and the metabolites 3-chloroallyl alcohol (3-CAA) and 3-chloroacrylic acid (3-CACA) *Lemna* have been re-calculated in terms of biomass (E_bC_{50}) and growth rate (E_rC_{50}) using frond counts reported in the original studies (DAR Section 9.2.8).

2. Methods

The source data used for the calculations of E_bC_{50} and E_rC_{50} are provided in Appendix I. *Lemna* growth rate (day^{-1}) and biomass (area under the growth curve) were determined based on mean measured or initial test concentrations in accordance with the recommendations of the RMS in the DAR (Section B.9.2.8); therefore, growth rate and biomass area were determined based on the initial measured concentrations for 1,3-D and 3-CAA and mean measured concentrations for 3-CACA. The E_rC_{50} values (the concentration that inhibited the growth rate to 50% relative to the control) and the E_bC_{50} values (the concentration that inhibited biomass area to 50% relative to the control) were calculated for the 0- to 14-day observation periods.

For the calculation of the EC_{50} values, the model used to describe the response to increasing concentrations was the four parameter logistic model with two parameters fixed, the minimum percent inhibition (A) at 0% and the maximum percent inhibition (D) at 100%. The logistic model used was:

Percent inhibition = D + ((A - D) / (1 + (CONC**(B)) * (EC50**(B)))),

Where:

Percent inhibition = 100*((Control Mean - Treatment Mean)/Control Mean).

CONC = test concentration,

B = slope,

EC50 = concentration corresponding to a 50% response,

The SAS nonlinear modeling procedure (PROC NLIN) was used to estimate B and EC50. Since the variability among replicates is not expected to be constant across concentrations, a weighted analysis was used so that more weight is placed on the observations having less variability (those at higher concentrations). Thus, the weights used are the predicted percent inhibitions.

The formula for the logistic model can be solved for ECx = EC50 * (((A x)/(x D)) ** (1/B)). The "distribution of x hat method" (Schwenke and Milliken, Biometrics 47: June 1991, pgs. 563-574) was used to estimate the 95% confidence intervals.

Growth Rate

The E_rC_{50} values were calculated for the 0 – 14 days using the following formula to calculate growth rate:

$$\mu_{i-j} = \frac{\ln N_j - \ln N_i}{t_j - t_i}$$

Where: μ = mean specific growth rate from moment i to j ($days^{-1}$)
Ln = natural logarithm
Ni = initial frond density
Nj = frond density at time j
ti = the moment time for the start of the period
tj = the moment time for the end of the period

For consistency with the methods used in the original studies the control and solvent control growth rates were pooled for the purposes of comparison to the growth rates for each treatment level.

Biomass (Area Under the Curve)

The E_bC_{50} values were determined for 0 – 14 days using the following formula to calculate Area Under the growth Curve:

$$A = \frac{N_1 - N_0}{2} \times t_1 + \frac{N_1 + N_2 - 2N_0}{2} \times (t_2 - t_1) + \frac{N_{n-1} + N_n - 2N_0}{2} \times (t_n - t_{n-1})$$

Where: A = area under the growth curve
N_0 = number of fronds at t_0
N_1 = number of fronds at t_1
N_n = number of fronds at t_n
t_1 = Time of first measurement after beginning of test
t_n = time of n^{th} measurement after beginning of test

For consistency with the methods used in the original studies the control and solvent control biomass values were pooled for the purposes of comparison to the biomass for each treatment level.

All calculations of E_bC_{50} and E_rC_{50} were carried out using SAS version 9.0.

3. Results

The calculated E_bC_{50} and E_rC_{50} values are summarized below. The EC_{50} values based on final frond counts, which are reported in the DAR and EFSA Scientific Report, 2006[16], are included below for information, since the EC_{50} values are equivalent to the E_yC_{50} (the concentration that inhibits the yield to 50% relative to the control)[17].

1,3-D

The reported 14-day EC_{50} (equivalent to E_yC_{50}) for 1,3-D is **14.56** mg/L (DAR IIA 9.2.8/01; EFSA Scientific Report, 2006[1])

Species	14-day E_bC_{50} (95% C.I.) (mg/L)	14-day E_rC_{50} (95% C.I.) (mg/L)	Study Reference
Lemna	**13.6** (11.9 – 15.4)	**41.5** (37.4 – 45.6)	Kirk *et al* (1999). IIA 9.2.8/01, MJ14.

3-chloroallyl alcohol (3-CAA)

The reported 14-day EC_{50} (equivalent to E_yC_{50}) for 3-CAA is **0.454** mg/L (DAR IIA 9.2.8/02; EFSA Scientific Report, 2006[1])

Species	14-day E_bC_{50} (95% C.I.) (mg/L)	14-day E_rC_{50} (95% C.I.) (mg/L)	Study Reference
Lemna	**0.484** (0.386 – 0.581)	**2.767** (2.185 – 3.348)	Kirk *et al* (1999). IIA 9.2.8/02, J22.

3-chloroacrylic acid (3-CACA)

The reported 14-day EC_{50} (equivalent to E_yC_{50}) for 3-CACA is **0.26** mg/L (DAR IIA 9.2.8/01; EFSA Scientific Report, 2006[1])

Species	14-day E_bC_{50} (95% C.I.) (mg/L)	14-day E_rC_{50} (95% C.I.) (mg/L)	Study Reference
Lemna	**0.28** (0.18 – 0.38)	**3.45** (2.90 – 4.00)	Kirk *et al* (1999). IA 9.2.8/03, J20.

4. Conclusion

Based on the calculated E_rC_{50} (growth rate), E_bC_{50} (area under the growth curve) and E_yC_{50} (yield; also equivalent to the EC_{50} for final frond density) for *Lemna* exposed to 1,3-D, or the metabolites 3-CAA or 3-

[16] EFSA Scientific Report (2006) 72, 1 – 99, Conclusion on the peer review of 1,3-dichloropropene. Finalised 12 May 2006.

[17] The EC_{50} is calculated using the final frond density values for each treatment. The E_yC_{50} is calculated using the difference between the final frond count and the initial frond count. Since, the initial frond count is the same in all treatments at test initiation, the calculated EC_{50} and E_yC_{50} are equivalent.

CACA, the lowest end-points are 13.6 mg/L (E_bC_{50}) for 1,3-D; 0.454 mg/L (EC_{50}) for 3-CAA; and 0.26 mg/L (EC_{50}) for 3-CACA.

Appendix I: Source data for 1,3-D, 3-CAA and 3-CACA

Kirk *et al* (1999). IIA 9.2.8/01, MJ14: 1,3-D and *Lemna gibba*

Initial measured Concentration (mg/L)	Mean No fronds				
	Day 0	Day 2	Day 5	Day 7	Day 14
0	16	33.3	65.3	114.7	471.7
solvent control	16	35.3	72.3	128.0	457.0
Pooled controls	16	34.3	68.8	121.3	464.3
3.59	16	33.7	68.0	115.0	431.3
7.17	16	34.0	65.3	93.3	318.0
14.3	16	33.0	44.0	62.0	213.3
28.4	16	30.3	44.7	50.7	105.3
55.2	16	30.7	42.0	41.0	75.3
101	16	25.0	30.7	29.7	39.3

Kirk *et al* (1999). IIA 9.2.8/02, J22: 3-CAA and *Lemna gibba*

Initial measured Concentration (mg/L)	Mean No fronds					
	Day 0	Day 2	Day 5	Day 7	Day 10	Day 14
0	12	30.7	69.0	96.7	172.0	275.7
solvent control	12	28.3	58.0	73.7	137.0	239.3
Pooled controls	12	29.5	63.5	85.2	154.5	257.5
0.042	12	30.7	55.3	76.0	133.3	182.0
0.133	12	28.3	46.0	62.0	116.0	204.0
0.395	12	27.0	35.7	48.0	80.3	148.7
1.175	12	26.0	31.3	42.7	64.0	76.0
3.490	12	23.3	26.7	29.3	40.7	53.7
11.170	12	20.3	21.7	22.7	25.7	27.7

Kirk *et al* (1999). IIA 9.2.8/03, J20: 3-CACA and *Lemna gibba*

Mean measured Concentration (mg/L)	Mean No fronds				
	Day 0	Day 2	Day 5	Day 7	Day 14
0	12	26.7	53.3	87.3	376.7
solvent control	12	26.0	53.7	82.3	384.7
Pooled controls	12	26.3	53.5	84.8	380.7
0.016	12	25.7	53.3	81.3	340.3
0.112	12	25.3	43.0	60.0	238.3
0.399	12	25.7	39.3	50.3	133.3
1.17	12	24.0	36.0	43.0	103.3
3.95	12	23.7	35.0	41.0	67.0

12.3	12	21.7	26.7	31.7	40.7

RMS assessment:

Calculations provided by notifier are considered acceptable. Based on the calculated E_rC_{50} (growth rate), E_bC_{50} (area under the growth curve) and E_yC_{50} (yield; also equivalent to the EC_{50} for final frond density) for *Lemna* exposed to 1,3-D, or the metabolites 3-CAA or 3-CACA, the lowest end-points are 13.6 mg/L (E_bC_{50}) for 1,3-D; 0.454 mg/L (EC_{50}) for 3-CAA; and 0.26 mg/L (EC_{50}) for 3-CACA.

TER calculations for *Lemna* using lowest endpoint for 1,3-D, 3-CAA and 3-CACA metabolites are depicted in the table below showing acceptable aquatic risk for intended uses of 1,3-D. Not further information is required.

TER values based on the calculated E_rC_{50} (growth rate), E_bC_{50} (area under the growth curve) and E_yC_{50} (yield; also equivalent to the EC_{50} for final frond density) for *Lemna* exposed to 1,3-D, or the metabolites 3-CAA or 3-CACA.

Substance	**Endpoint**	**Toxicity (µg/L)**	**PECsw (µg/L)**	**TER**
Outdoor applications- 224 kg as/ha				
1,3-D	14d-EbC50	13600	3.2	4250
	14d-ErC50	41500		12968
	14d-EyC50	1456		455
3-CAA	14d-EbC50	484	2.67	181
	14d-ErC50	2767		1036
	14d-EyC50	450		168
3-CACA	14d-EbC50	280	3.077	91
	14d-ErC50	345		112
	14d-EyC50	260		84
Indoor applications-drip irrigation 283 kg as/ha				
1,3-D	14d-EbC50	13600	1.4	9714
	14d-ErC50	41500		29642
	14d-EyC50	1456		1040
3-CAA	14d-EbC50	484	1.16	417
	14d-ErC50	2767		2385
	14d-EyC50	450		388
3-CACA	14d-EbC50	280	1.34	209
	14d-ErC50	345		257
	14d-EyC50	260		194

Open point: 5.7. Evaluation table: August 2009.

Member State experts should discuss the use of the field study by Small (2006) in the risk assessment for NTA.

Notifier argumentation:

The scenario evaluated was fully representative of the Annex I GAP for fruiting vegetables and represented a typical injection application scenario for Telone.

The report documents that the injection of Telone took place under GLP inspection (page 6), the injection equipment was calibrated prior to use (page 22), and the measured application rate was 199.34 L/ha (page 13).

All other aspects of the study were conducted in GLP compliant facilities and were subject to all the normal procedures of record keeping, calibrations and SOP compliance required by GLP. Key phases were audited by an independent GLP auditor as was the final report. It is the notifier opinion that the study is suitable for risk assessment, that has been conducted under realistic conditions for an exception product and if of the same high quality as all other fully compliant GLP studies.

The experimental constraints associated with this type of application method should not be underestimated (i.e. specialist application equipment, in furrow injection at 25-30 cm depth, soil closing with a roller immediately after application, operator safety considerations (during application and for post-injection sampling). This type of application is not comparable to conventional spray applications and the same expectations regarding analytical confirmation of soil concentrations or use of toxic standards cannot be applied.

RMS-August-2009:

A summary and evaluation of study is depicted in Addendum 5_B9_ECOTOX_ADDITIONAL REPORT_1-3D_MARCH 2009_24_06_09, pages 59-71.

RMS opinion is that results coming from this study can be used for risk assessment besides some shortcomings of the study can be highlighted. A shortcoming of the study was that concentrations of the compound in the soil are not measured, so it is not clear the actual exposure in the study. Also not positive control was used. As indicated by notifier, these shortcomings can be explained by the experimental constraints associated with type of application that is not comparable to conventional spray applications.

RMS agrees with notifier that scenario evaluated was fully representative of the Annex I GAP for fruiting vegetables and represented a typical injection application scenario for Telone.

In the field study, not statistical significant effects were observed for macroarthoprods and microarthopods investigated in Telone II treated and untreated plots at any of the post-treatment sampling intervals for an application rate of 224 kg as/ha.

However, effects on earthworms were observed. These effects on earthworms were transient, lasting less than 6 months, with no difference in earthworm abundance between treated and untreated plots detected at 6, 9 or 12 months post-treatment.

Results from the field study on arthropods are in line with results from risk assessment based on lab studies. The extended laboratory studies indicated that soils treated with single application of Telone II at 329 kg a.s./ha

may pose a high risk to some soil dwelling arthropods, as indicated by the study with *Folsomia candida*. The application rate evaluated in this study was 1.5-fold higher than that proposed for Telone II, and so is expected to be an overestimate of the likely risk to soil organisms.

Nevertheless, the studies with all species of arthropods tested indicated that 1,3-D has low residual toxicity. 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. Therefore, it is expected that for those species affected during soil treatment, recolonization will be possible within a short period following treatment.

Furthermore, according to intended uses of telone only 1 application per year is proposed. Full recovery of soil non target arthropods and earthworms is expected before next application. If uncertainties remaining may be this should be flagged at Member State Level.

ANNEX B

1,3-DICHLOROPROPENE

ADDENDUM 5
B - 6: TOXICOLOGY AND METABOLISM

Background

This addendum corresponding to Mammalian Toxicology (Section 6) has been prepared after the Teleconference in which all participants agreed to set a new AOEL (in this case, a new AOEC). Consequently, a new risk assessment for the operator, bystander and re-entry worker is needed.

THIS ADENDUM WAS PREPARED UNDER THE RESPONSIBILITY OF:

Mr. García - Baudín, J. Mª. Ph. D. (Co-ordinator).
Mr. Alonso - Prados, J. L. Ph D. (Scientific Co-ordinator).
Unidad de Productos Fitosanitarios I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FROM THE DOSSIERS SUBMITTED BY:

Task Force: Dow AgroScience & Kanesho Soil Treatment SPRL/BVBA

WITH THE ASSISTANCE OF THE FOLLOWING EXPERTS:
Toxicology and metabolism

Grupo de Evaluación de Productos Fitosanitarios.
Centro Nacional de Sanidad Ambiental. Instituto de Salud Carlos III.
Ctra. Majadahonda-Pozuelo, Km 2. E-28220-Majadahonda (Madrid). Spain.
Ms. Díaz López, G
Ms. González Caballero, M. C.
Ms. Alba González, M.
Mr. García Cambero, J.P. Ph D
Ms. Castaño Calvo, A Ph D.

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B.6.10.2.1 ADI estimation

EPCO 23 agreed an ADI=0.0125 mg/kg bw/day, based on NOAEL of 2-year study in rats (2.5 mg/kg/day) and a safety factor of 200 to ensure an appropriate margin of safety (1000) between ADI and irreversible effects, in this case, the apparition of benign tumors (biologically relevant) at 12.5 mg/kgbw/day.
During the Teleconference (PRAPeR TC17), it was highlighted that ECB did not classify 1,3-D as carcinogenic to humans (Cat 3, R40), and therefore the relevance of tumors were not considered for humans. This fact does not support the use of additional factors, in this case "2". Although 1,3-D arises some concerns about the potential carcionogenesis/genotoxicity, and some of the Members were worried about this aspect, it was agreed to select a safety factor of 100.
Thus, the ADI = 2.5/100 ;

ADI= 0.025 mg/kg bw/day

B.6.10.2.2 ARfD estimation

The ARfD selected at the EPCO meeting was confirmed in the Teleconference (PRAPeR TC17). Thus, the NOAEL of 20 mg/kg bw/day from the 2-week dog study, and a safety factor of 100 were chosen.
ARfD = NOAEL / SF
ARfD = 20/100

ARfD= 0.2 mg/kg bw

B.6.10.2.3 AOEL estimation

In the EPCO Round 5, it was decided to set a systemic AOEL of 0.1 mg/kg bw/day, based on the NOAEC (Non Observed Adverse Effect Concentration) of 10 ppm from the 13-week inhalation rat study, and considering rat breathing rate. However, the operator/worker and bystander evaluation exposure was assessed by specific field studies providing with data on atmospheric concentration and therefore, a comparison between a systemic AOEL and atmospheric concentrations was dismissed. In this point, the Experts agreed to derive an AOEC for humans from the systemic rat AOEL (0.1 mg/kg bw/day), but taking into account the inter-specific influence of the breathing rate between humans and rat. Thus, the AOEC for humans was estimated according to the following approach:

ppm (humans) = ppm (rat) * (rep rate (rat)/rep rate (humans)) * (time exposure (rat) * time exposure (human).

According to this approach, a new addendum (addendum III-sep 2005) was prepared, and the operator/worker and bystander exposure was recalculated with new values of the AOEC.
However, there was controversy regarding the respiratory rate selected for humans (it was relatively low according to some Member States), times of exposure and the acceptance of the final approach. These aspects were intensively discussed at the Teleconference (PRAPeR TC17).
Finally, it was agreed to follow the following approach:
AOEC in human = AOEC rat/SF, what implies not considering the difference between rat-human respiratory rates.
Therefore, the AOEC in human = 10 ppm / 100

AOEC = 0.1 ppm or 0.45 mg/m^3

B.6.14 Exposure Data

According to Experts decisions, new calculations for the operator, worker and bystander are needed taking into account the new AOEC.
In addition, some concern aroused at the Teleconferece regarding small data points provided by the Notifier to assess 1,3-D exposure. In this sense, some studies provided only 5 measurements. Therefore, it was agreed to not consider average values of exposure, but a more conservative value, such as percentile 75-95.
Operator, worker and bystander exposure was evaluated for both 1,3-D applied via irrigation system in greenhouses and injected into the soil.
In greenhouses, 1,3-D is handled only during loading into the irrigation system. The operator has to open the drums of 1,3-D, insert a venture tube and by means of the pump system, 1,3-D is mixed with water and via irrigation, 1,3-D is applied to the soil. Therefore, the Notifier has presented evaluation of the 1,3-D only for mixers/loaders. Although several studies were presented, the study MG48 (1 data) showed the highest value, therefore, we selected this value to express the worst case for operator exposure. This operator was exposed to 0.99 mg/m^3 (TWA 8h), which represented 220% of the AOEC (0.45 mg/m^3). In this situation, the use of a

respiratory mask would reduce levels of 1,3-D to 0.05 mg/m^3, which represented 11% of the AOEC. Worker activities are not expected until 21 days after treatment (planting). The studies MG48, MG33 and MG49) presented data for atmospheric concentration inside the greenhouse at different times. Levels of 1,3-D reported were less than 0.05 mg/m^3 (11% AOEC) or non detectable, therefore, work activities did not suppose any risk associated. However, there are re-entry tasks that can be performed during 1,3-D application. One study (MG33) showed that in this situation, levels of 1,3-D can be much higher than the AOEC (149% AOEC), however, the use of Respiratory masks can reduce the levels to values under the AOEC (7%). Therefore, re-entry tasks during greenhouse application of 1,3-D do PPE, specially Respiratory protection. In the case of bystander exposure, the studies MG48 and MG49 evaluated the atmospheric concentration of 1,3-D 1m outside the greenhouse and at certain distances from the greenhouses, respectively. At a realistic situation (> 7mts), bystanders would be exposed to levels under AOEC (37.5% AOEC; study MG49), however, it must be taken into account that bystanders can walk near a greenhouse in which 1,3-D is being applied. In this situation, the study MG48 showed that at a distance of 1m and during the first 6 h of 1,3-D application, bystanders can be exposed to levels above the AOEC (>100%).
In the case of telone injected, operators can be exposed during mixing/loading 1,3-D and during application. The study MG21 evaluated the operator exposure in 37 operators engaged in mixing/loading and application of 1,3-D. In this study, the 75th percentile of 1,3-D values (TWA 8h) was 4.83 mg/m^3, which represented 1073% AOEC. The use of respiratory protection reduced the exposure to levels under the proposed AOEC (54%). Another study (MG 08) provides data on operator exposure in different tasks (mixing/loading, application and worker activities) separately. In addition, several mitigation measures were proposed for the loading process and for application. This study showed that during the mixing and loading phase, the use of dry disconnects + vapor recovery reduced considerably the levels of atmospheric 1,3-D (15 mg/m^3 to 3.84 mg/m^3). In the application phase, the use of spill control and moreover, carbon filtered cabs during application reduced considerably atmospheric concentration of 1,3-D (from 6.63 mg/m^3 to 0.94 mg/m^3). Therefore, the use of mitigation measures both in the loading phase and the application phase are recommended, as long as the use of respiratory mask to avoid excessive 1.3-D. Worker exposure was evaluated in the study MG 8 and MG47. Normal re-entry tasks are carried out at day 26 for planting activities. In this situation, the levels of exposure were under AOEC (<5%). However, there are some other re-entry activities, such as bed shapping, install sheeting, sprinkler maintenance and rock removal that are usually carried out before the normal re-entry period. Install shetting represented the worst case of re-entry worker exposure (1266% of the AOEC), therefore, for install shetting and shapping, workers must use respiratory protection (64% AOEC in install shetting). The studies MK03 and MK13 reported data on atmospheric concentration of 1,3-D in/near the fields treated with 1,3-D. The worst case (edge of the field) showed average values of 0.094 mg/m^3, which represented 21% AOEC.

B.6.14.1 Operator Exposure to Drip 1,3-Dichloropropene

When 1,3-D is applied via drip irrigation, the operator has to open the drum and insert the venture tube of the irrigation system. Due to the relatively high vapor pressure of Telone Drip, operators can be exposed to 1,3-D by inhalation during mixing and loading, and when the instructions are followed, dermal exposure is not probably to occur.
Different field studies measured the operators exposure to 1,3-D (through personal air sampling) and the findings were summarized in the tables 6.14.1-1, 6.14.1-2 and 6.14.1-3.

Table 6.14.1-1: Summary Table of Mean 1,3-D Air Concentrations Experienced by Operators during mixing/loading (IIIA 7.2.1.2/01, MG33)

Operator	Exposure duration (min)	Mean air conc.1,3-D (mg/m^3)	TWA 8 h (mg/m^3)	% AOEC
1	16	11.65	0.39	
2	8	6.09	0.1	
3	9	2.18	0.04	
4	9	3.31	0.06	
5	7	16.69	0.24	
6	11	5.23	0.12	
Geometric mean		5.96	0.12	27
Percentile 95th			0.35	78
Maximum value			0.39	87

Table 6.14.1-2: Operator exposure associated with the mixing/loading and application of Dorlone EC (IIIA 7.2.1.2/04, MG48)

Task duration (min)	1,3-D residue (mg)	Average atmospheric concentration of 1,3-D over duration of task (mg/m^3)	TWA 8hr (mg/m3)	% AOEC	% AOEC using RPE+
47	0.101 / 0.091*	10.21	**0.99**	220	11

* Values by duplicate

\+ *Respiratory mask equipped with cartridges for organic vapours. Generic value of protection 95%.*

Table 6.14.1-3: Operator exposure associated with the mixing/loading and application of Dorlone EC (IIIA 7.2.1.2/05, MG49)

Task duration (min)	Average atmospheric concentration of 1,3-D over duration of task (mg/m^3)	TWA 8hr (mg/m3)	% AOEC
30	0.7	0.044	14.6

During mixing and loading 1,3-D via drip irrigation, operators are generally not expected to be exposed to levels higher than the estimated AOEL of 0.45 mg/m^3. However, in one case (table 6.14.1-2), operator was exposed to levels of 1,3-D higher than the AOEL, therefore, the use of respiratory protection is always recommended. With the use of respiratory mask, the levels of exposure can be reduced to levels up to 5% of the atmospheric values; therefore, the worst case of exposure, values of 0.99 mg/m^3 can be reduced to 0.05 mg/m^3 that are below the safe level of AOEC (table 6.14.1-2).

Generally, the operator can perform the application of Telone Drip staying in the pump-house, however, any accident in the irrigation system involve that the operator has to entry the greenhouse to amend the irrigation system, and therefore the risk of exposure can increase considerably (table 6.14.1-4).

Table 6.14.1-4: Mean 1,3-D Air Concentrations Experienced by Operator 1during the re-entry task of repairing the irrigation system (IIIA 7.2.1.2/01, MG33)

Operator	Exposure duration (min)	Mean air conc.1,3-D (mg/m^3)	TWA (8h) (mg/m3)	% AOEC	%AOEC using RPE*
1	7	45.92	0.67	149	7.5

** Respiratory mask equipped with cartridges for organic vapours. Generic value of protection 95%.*

Although the exposure can be rather low during incidental tasks, it should noted that operators will be exposed to additional 1,3-D by inhalation route. Thus, inhalation exposure during incidental tasks must be added to inhalation exposure during mixing and loading. In addition, dermal exposure can occur during incidental tasks, and this aspect was not sufficiently addressed by the Notifier, who concluded that the irrigation system must be checked before 1,3-D application, and therefore accidents are not expected to occur.

In addition to operator exposure to 1,3-D by means of personal air sampling devices, the atmospheric concentration of 1,3-D was also measured inside and outside the greenhouses. Data are showed in tables 6.14.1-5, 6.14.1-6 and 6.14.1-7. Data showed that risk for operators was evident for the first two days (table 6.14.1-5 and 6.14.1-6), or even until day 6 (table 6.14.1-7) when operators do not use respiratory protection.

However, the use of respiratory mask equipped with charcoal filters for organic substances would provide effective protection, when we take into account the results found by Spence (1988, 1st addendum). In this study, atmospheric levels of 1,3-D up to 4500 mg/m^3 were retained for 78 min or 225 mg/m^3 for 350 min by the filters. Thus, the worst case in which levels of 1,3-D inside the green-house were 242 mg/m^3 should not represent a true risk for that operator using protective equipment with respiratory mask fitted with cartridges for organic vapors.

Table 6.14.1-5: Air concentration of 1,3-Dichloropropene in the greenhouse during and after application (IIIA 7.2.1.2/01, MG33)

Time (hours)	Concentration of 1,3-Dichloropropene (mg/m^3)
-27 to –19	Not detected
0 to 4	11.69
21 to 29	0.36
40 to 48	0.37
66 to 74	0.15
89 to 97	0.12
115 to 123	0.07
140 to 148	0.01
163 to 171	0.01
At day 26	Not detected

Table 6.14.1-6: Atmospheric concentration of 1,3-D inside and immediately (1m) outside the Green house (IIIA 7.2.1.2/04, MG48).

Sample event	Sampling interval (h)	Mean atmospheric concentration (mg/m3)	location
1	-12 (day –1)	0.027 0.089	In out
2	0-6	4.762 0.614	In out
3	6-13	1.572 0.285	In out
4	13-21	5.524 0.263	In out
5	21-26 (day 1)	1.338 0.102	In out
6	26-32	0.868 0.044	In out
7	32-37	0.712 0.069	In out
8	37-47	0.772 0.052	In out
9	47-59 (day 2)	0.41 0.085	In out
10	59-69	0.138 0.019	In out
11	69-79 (day 3)	0.22 0.03	In out
12	79-91	0.209 0.031	In out
13	91-102 (day 4)	0.152 0.011	In out
14	102-114	0.117 0.032	In out
15	114-126 (day 5)	0.084 0.006	In out
16	126-138	0.1 0.022	In out
17	138-150 (day 6)	0.05 0.005	In out
18	150-174	0.074 0.038	In out
Re-entry exposure			
Sample event	**Sampling interval (h)**	**Mean atmospheric concentration (mg/m3)**	**location**
19	240-264 (day 10/11)	0.011 0.007	In out
20	336-360 (day 14/15)	0.005 0.003	In out

Table 6.14.1-7: Atmospheric concentration of 1,3-D inside and immediately (1m) outside the Green house (IIIA 7.2.1.2/05, MG49)

Mid point of sampling interval (days)	Mean atmospheric concentration (mg/m3)	location
0.1	242 1.4	In out
0.3	35 0.16	In out
0.6	24 0.45	In out
1	26 0.15	In out
1.2	17 0.09	In out
1.6	17 0.26	In out
2	40 0.053	In out
2.2	34 0.03	In out
2.6	3.66 0.09	In out
3.1	3.82 0.018	In out
3.6	5.87 0.088	In out
4.1	4.31 0.019	In out
4.6	3.23 0.021	In out
5.1	2.17 0.006	In out
5.6	0.9 0.002	In out
6.1	0.99 0.003	In out
6.8	0.38 0.04	In out
14.5	0.016 ND	In out
21.5	0.004 ND	In out
29.4	0.002 ND	In out

B.6.14.2 Worker Exposure to Drip 1,3-Dichloropropene

After 21 days of 1,3-D application (when planting is undertaken), no residues of 1,3-D were detected in the static air samples or in the personal samplers attached to the workers (tables 6.14.1-5; 6.14.1-6 and 6.14.1-7). As workers exposure is under proposed AOEC of 0.45 mg/m^3 when the tasks are performed at the appropriate interval, it can be concluded that re-entry workers activities will not represent risk for them when the activities are carried out following good agricultural practices.

Nevertheless, it should be recommended a minimum re-entry time for southern MSs in the GAP table of 14 days.

B.6.14.3 Bystander Exposure to Drip 1,3-Dichloropropene

Data from tables 6.14.1-6 and 6.14.1-7 showed that at the distance of 1 m from the greenhouse, bystanders can be exposed to average levels ranging from 0.6 to 1.4 mg/m^3, which were higher than proposed AOEC of 0.45 mg/m^3. Note, however, that the values of 0.6 and 1.4 mg/m^3 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 AOEL, even in the case of recent application of Drip 1,3-D (table 6.14.3-1 and 6.14.3-2).

Table 6.14.3-1: Atmospheric concentration of 1,3-D in Ambient samples at specific distances outside from the Green house walls (IIIA 7.2.1.2/05, MG49).

Mid point of sampling interval (days)	**Distance (m)**	**1**	**3**	**5**	**10**	**20**
	Directions averaged	**NESW**	**NESW**	**W**	**NSE**	**NSE**
0.19		0.78	0.72	0.059	0.29	0.15
0.26		0.45	0.37	0.083	0.15	0.074
0.96		0.15	0.17	0.042	0.053	0.022
1.19		0.097	0.10	0.013	0.044	0.023
1.58		0.26	0.18	0.075	0.063	0.037
3.25		0.018	0.018	0.001	0.008	0.004
6.58		0.037	0.019	ND	0.006	0.004
29.42		ND	ND	0.001	ND	ND

ND =not detected.

Table 6.14.3-2: Atmospheric concentration of 1,3-D in Ambient samples at 7/14 m outside from the Green house walls (IIIA 7.2.1.2/04, MG48).

Time (days)	**Direction from Green house**	**1,3-D (mg/m^3)**	
		7 m	**14 m**
-1	West	<0.001	0.004

Time (days)	Direction from Green house	1,3-D (mg/m^3)	
		7 m	14 m
0.15	West	0.003	0.003
0.15	East	0.169	0.012
1.17	West	0.011	0.015
1.17	East	0.018	<0.001
3.13	West	<0.001	0.004
3.13	East	0.004	0.004
6.88	West	0.002	0.003
6.88	East	0.002	0.153
14.38	West	0.002	0.002
14.38	East	<0.001	0.002

Therefore, a risk of exposure to 1,3-D was detected for those bystanders walking at distances less than 5 m from the greenhouses in which Drip-1,3-D is being applied or has just been applied, lowering down to acceptable levels of exposure when bystanders are situated at > 5 m from the greenhouse in which 1,3-D is being applied or when bystanders walk at less than 5 meters after at least 14 hr from the last 1,3-D Drip application.

Taking into account the whole data for bystanders, risk mitigating measures could be proposed to minimize the risk for bystanders, such as limiting the access of bystanders near the treated areas.

B.6.14.4 Operator Exposure to 1,3-Dichloropropene soil injected

The study MG21 measured the air exposure to 1,3-D in 37 workers by means of personal air sampling, and during mixing/loading and application of Telone injected. The geometric and the 75th percentile are expressed in the following table 6.14.4-1:

Table 6.14.4-1: Statistical values of 1,3-Dichloropropene concentrations (MG 21; IIIA 7.2.1.2/01) after Telone injected application (n= 37 samplings)

Statistic	Time (hr)	1,3-D (mg/m^3)	TWA (8hr) (mg/m^3)	% AOEC	% AOC with RPE*
Geometric Mean	6.70	2.33	1.93	429	22
75th percentile	10.21	4.84	4.83	1073	54

** Respiratory mask equipped with cartridges for organic vapours. Generic value of protection 95%.*

We consider appropriate to select both the geometric mean/75th percentile to express data on operator exposure. However, using the 75th percentile could overestimate the operator exposure, since the time of exposure exceeded the normal working period (8h).
Data from this study clearly evidenced a risk for those operators in mixing/loading and application of Telone injected.
Considering that the respiratory protection can reduce by 95% of the measured dose, operator exposure would be reduced to levels under the proposed AOEC of 0.45 mg/m^3.
In an independent study (ID study ECL92095-MG 08), 1,3-D was evaluated in operators by means of personal air sampling. In this study, the exposure was evaluated in several scenarios (different activities). In addition, Notifer proposes to use mitigation measures to reduce 1,3-D exposure during the two main processes of loading and application. For loading/application, 15 exposure values were provided for each scenario (no mitigation and two other mitigation measures), while only 5 exposure values were provided in each of the re-entry scenarios. Values of exposure are showed in table 6.14.4-2, in which it is observed that all of the evaluated tasks represented a true risk for operators, except for re-entry tasks such as rock removal and sprinkler maintenance. With the use of respiratory protection, operators can reduce exposure levels to values under the proposed AOEC of 0.45mg/m^3.

Table 6.14.4-2: Air concentration for 1,3-D (MG 08; IIIA 7.2.1.2/04)

Work Task	1,3-D concentration (mg/m^3)		Regarding 95th perc.	
	Mean (SD)	95th percentile	% AOEC	% AOEC Use of RPE
Loader				
No mitigation	5.94 (4.46)	15.0	3333,3	166,7
Dry disconnects	2.14 (2.13)	6.23	1384,4	69,2
Dry disc. + Vapor recovery	1.23 (1.5)*	3.84	853,3	42,7
Applicator				
No mitigation	2.87 (2.26)	6.63	1473,3	73,7
Spill control	1.27 (1.56)	3.70	822,2	41,1
Spill control + Carbon filtered cab++	0.46 (0.27)	0.94	208,9	10,4
Re-entry (Operators)				
Bed shaping (15-24 h post application)	0.61	0.93	206,7	10,3

Rock removal (64-68 h post application)	0.06	0.07	15,6	0,8
Sprinkler maintenance (85 h post application)	0.10	0.11	24,4	1,2

* Site 2 (Arizona) values were not considered

++ Exposure was measured when the operator exit the tractor cabin to perform equipment repair/replacement. Concern arises from the idea that Notifier has evaluated operator exposure considering that one operator carries out different tasks; one operator for loading process, another one for application and others for re-entry activities. However, 1.3-D loading and application are simultaneous activities that one operator can afford within the same day. This means exposure addition.

The study MG 47 calculated the TWA 8 hr for different tasks associated to the application of Telone injected (table 6.14.4-3) in a close atmosphere of a greenhouse. The study showed operator exposure levels higher than AOEL for tasks such as application and installation of sheets (table 6.14.4-3), as long as high air concentrations in the greenhouse (table 6.14.4-4).

Table 6.14.4-3: Summary of operator and worker exposure for specific tasks associated with the application of Telone injected (MG 47; IIIA 7.2.2/01)

Days after Application	**Task description**	**Task duration (min)**	**Aver. Atmos. Conc. Over duration of task (mg/m^3)**	**TWA 8 hr (mg/m^3)**	**% AOEL**	**% AOEC when RPE is used***
0	Mixing/loading	2	3.30	0.014	3.1	0.16
0	Application	27	12.04	0.68	151.1	7.56
0	Install Sheeting	69	5.66	0.81	181	9.0
14	Remove sheeting and application of manure (1)	48	Nd			
14	Remove Sheeting (2)	9	Nd			
14	Harrowing (1)	40	Nd			
26	Sheet and pipe laying (1)	120	Nd			
26	Sheet and pipe	119	Nd			

	laying (2)					
27	Planting (1)	59	Nd			
27	Planting (2)	58	Nd			

* 95% protection assumed.

The use of respiratory protection can reduce the operator exposure during 1,3-D application or other activities to levels under the proposed AOEC (see table 6.14.4-3).

Table 6.14.4-4: Summary of atmospheric concentration of 1,3-D **in the greenhouse** for key events associated with the application of Telone (MG 47)

Key Events	**Post application days (hr)**	**Concentration (mg/m^3)**
Pre application	-1	Nd
Post application	0.02 (0.5 hr)	1.89
Conc. prior to lowering greenhouse walls	0.17 (4.1 hr)	6.24
Greenhouse walls lowered	0.33 (7.95 hr)	75.61
Greenhouse ventilated after walls raised	1.06	9.32
Maximum conc after walls raised	1.21	15.12
Conc at end of sampling phase 1	3	1.77
Conc prior to plastic sheet removal	13	0.01
Plastic sheet removed	14	0.02
Plastic sheet removed	14	Nd
Soil harrowed	14	0.02
Soil harrowed	15	0.02
Conc reaches pre-study level	16	Nd

As in the case of Telone drip, operators can be exposed to levels higher than the AOEC estimated when the operators do not wear any protection. The use of PPE and specially, respiratory protection (fitted with cartridges for organic vapours), would reduce considerably the operator exposure to levels lower than the estimated AOEC of 0.45 mg/m^3.

B.6.14.5 Re-entry workers exposure to 1,3-Dichloropropene soil injected

After injection, 1,3-D is rapidly evaporated into the atmosphere and no activities are required until planting, at least 14 days after last application. The tables 6.14.5-1 and 6.14.5-2 show data on average 1.3-D atmospheric concentration during re-entry activities. It was observed that during normal re-entry activities, 1,3-D is not present in the atmosphere.

Table 6.14.5-1: Summary of worker exposure for specific tasks associated with the application of Telone injected (MG 47; IIIA 7.2.2/01)

Days after Application	**Task description**	**Task duration (min)**	**1.3-D atmos. Concentration (mg/m^3)**
14	Remove sheeting and application of manure (1)	48	Nd
14	Remove Sheeting (2)	9	Nd
14	Harrowing (1)	40	Nd
26	Sheet and pipe laying (1)	120	Nd
26	Sheet and pipe laying (2)	119	Nd
27	Planting (1)	59	Nd
27	Planting (2)	58	Nd

When plastic need to be removed or the soil harrowed, levels of 1,3-D achieved mean values of 0.02 mg/m3, which represents 4% of the AOEC.

Table 6.14.5-2: Summary of atmospheric concentration of 1,3-D **in the greenhouse** for key events associated with re-entry (MG 47).

Key Events	Post application days (hr)	Concentration (mg/m^3)
Plastic sheet removed	14	0.02
Plastic sheet removed	14	Nd
Soil harrowed	14	0.02
Soil harrowed	15	0.02
Conc reaches pre-study level	16	Nd

However, there are activities carried out just after 1,3-D application or in the following days (see table 6.14.5-3. These activities can be considered either operator activities or re-entry activities.
For the activity of installing the sheeting or bed shaping immediately after 1,3-D injection, operators/workers can be exposed to levels higher than AOEC, and only the use of RPE can decrease levels of 1.3-D to values under AOEC. Therefore, for these re-entry activities (bed shapping/install shetting), the use of appropriate respiratory protection is needed.

Table 6.14.5-3: 1,3-D average air concentration associated to re-entry tasks

Work Task	ID study	1,3-D concentration (mg/m^3)		% AOC	% AOEC using RPE
		Average	95th percentile		
Bed shaping	MG 8	0.61	0.93	207	10.3
Install Sheeting*	MG 47	5.7		1266	63.3
Sprinkler maintenance	MG 8	0.10	0.11	24.4	
Rock removal	MG 8	0.06	0.07	16	

*only 2 samples, therefore the average value was considered.

B.6.14.6 Bystander exposure to 1,3-Dichloropropene soil injected

Application of 1,3-D by injection to the soil did not suppose any risk for bystanders walking near the fields recently applied. As shown in the tables 6.14.6-1 and 6.14.6-2, the levels of 1,3-D measured in the air near application were within the value of estimated AOEC of 0.45 mg/m^3. Note however, that the values expressed in tables are the average from several days.

Table 6.14.6 -1: Levels of 1,3-dichloropropene in sampled air (MK 03; IIIA 7.2.2/03)

1,3-dichloropropene concentrations (mg/m^3)				
Location	**Nº samples**	**Minimum**	**Maximum**	**average**
Above treated field	52	0.022	2.27	0.47
Edge of field	45	0.00028	0.78	0.094
¼ m. from field	114	< 0.0002	0.5	0.039
400 m. from field	39	< 0.0002	0.047	0.005
800 m. from field	32	< 0.0002	0.033	0.004

** Air sampling was conducted continually for a period of 7 days at 3-12 h intervals

Table 6.14.6 -2: Multidirectional 14-day average 1,3-D air concentration (MK 13; IIIA 7.2.2/04)

Distance from edge of field	Multidirectional 14 day average site 1 (mg/m^3)	Multidirectional 14 day average site 2 (mg/m^3)	Multidirectional 14 day average site 3 (mg/m^3)
0	0.11	0.037	0.16
5	0.075	0.018	0.10

Distance from edge of field	Multidirectional 14 day average site 1 (mg/m^3)	Multidirectional 14 day average site 2 (mg/m^3)	Multidirectional 14 day average site 3 (mg/m^3)
25	0.064	0.013	0.11
125	0.041	0.005	0.054
500	0.016	0.001	0.012
800	0.014	0.001	0.007
1200	0.009	0.0007	0.003
1600	0.007	0.0005	0.002

** Values expressed in the table represented the average from a 14-days period.

ANNEX B

1,3-DICHLOROPROPENE

ADDENDEUM 5

B - 8 : ENVIRONMENTAL FATE AND BEHAVIOUR

THIS ADDENDUM WAS PREPARED UNDER THE RESPONSIBILITY OF:

Mr. García - Baudín, J. Mª. Ph. D. (Co-ordinator).

Mr. Alonso - Prados, J. L. Ph D. (Scientific Co-ordinator).

Unidad de Productos Fitosanitarios I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FROM THE DOSSIERS SUBMITTED BY:

Task Force: Dow AgroScience & Kanesho Soil Treatment SPRL/BVBA

WITH THE ASSISTANCE OF THE FOLLOWING EXPERTS:

Environmental fate and behaviour

Ms. Alonso-Prados, Elena

Unidad de Productos Fitosanitarios I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

FOREWORD

The following addendum has been done in order to address the new open point 4.9 arisen during the PRAPeR EXPERT MEETING TC 15 and collected in the evaluation table rev. 1-1 (03.09.2009) for the active substance 1,3-dichloropropene.

This new open point comes from the comment of one MS (comment 4(3) in the reporting table rev. 1-1 (17.07.2009). Despite the RMS explanations during the PRAPeR EXPERT MEETING TC 15, the delegate of the MS expressed that concerns were still on the description of the lateral movement of the water in the model.

As these concerns are on the hydrological balance simulated in the model rather than on the specific 1,3-D assessment it was agreed that clarifications on how the hydrological processes are taken into account in the model should be provided by the RMS.

Provided that clarifications that will be given by the RMS are found satisfactory by EFSA while drafting the conclusions, experts in the meeting agreed that the SW assessment can be used to finalise the risk assessment.

B.8 Environmental fate and Behaviour.

B.8.6.2 Estimation of concentrations in surface water.

B.8.6.2.1 Drainage /lateral flow

New open point: 4.9: RMS to provide in an addendum a detailed water balance description (daily water balance; proportion of precipitation moving vertically out of the soil column and lateral movement and evapotranspiration) used in the DripFume / CHAIN 2D model used in the SW assessment for 1,3-D.

CHAIN 2D code was one of the models evaluated by FOCUS SW working group in the report SURFACE WATER MODELS AND EU REGISTRATION OF PPP (6476/VI/96) and they concluded that CHAIN 2_D code has the potential to be one of the most useful models in the context of modelling drainage system inputs to surface water since it is fully 2-dimensional. The main limitation found of the available version evaluated was the difficult to use but these difficulties would covered with the new version of the model.

As stated in FOCUS SW work group document, the algorithms of CHAIN 2D_code defines finite elements for spatial distribution and implicit finite differences for temporal discretization of Richards' equation for water flow. The code is based on finite elements according to the Galerkin method, and the time derivatives in the solute transport equation were approximated by a Crank-Nicholson finite differences scheme

Hydrological model is based on Richards' equation for unsaturated water flow and the drain flow is a simplified representation of nodal drains using results of electrical analogue experiments. Runoff is not considered by the model and the Potential evapotranspiration is input by user. Actual evapotranspiration is calculated as a function of root distribution and soil water pressure head.

According to the report GHW-P-1175, already evaluated in addendum 3, lateral transport of 1,3-D was defined for the purposes of this study as the gradient driven horizontal movement through vertical planes located in the untreated portion of the simulation domain. The cumulative flux over the lifetime of the simulation was an estimate of the total mass of 1,3-D (in both liquid and vapour phases) that possessed through the vertical flux plane selected at several sections of the fumigated field. Each vertical section required a new grid file with different nodal code at the vertical plane. A separate simulation run was required for each scenario. The model calculated the movement of 1,3-D due to diffusion in the vapour phase and convection in the liquid phase in the unsaturated soil. Transport was mediated by soil solid phase sorption processes.

To determine total 1,3-D mass discharging to the ditch, six flux planes were selected at 0.3, 1, 1.5, 3, 5, and 10 m from the field edge (Figure 8.6.2.1-2 in addendum 3). Note the edge of field was defined at 3 m point of the x-axis of the domain, so the x-coordinate for the flux planes was 3.3, 4, 4.5, 6, 8, and 13 m, respectively. For numerical stability and providing sufficient detail in 1,3-D concentration determination, very small (5-cm) grid sizes were used for both the vertical and horizontal directions throughout the simulation domain. A total of 11,525 nodal points and 1 1,040 elements were used in
each scenario and model run.

Surface environmental boundary conditions were created based on long-term weather information from Etain, France (representing northern EU zones) and Almeria, Spain (representing southem EU) (www.weatherbase.com). The variables included surface mean temperature (15 ºC for northern EU and 30ºC for southern EU) and its amplitude, mean and peak precipitation and its frequency, and evapotranspiration (ET) between and during precipitation events. These weather-related boundary parameter values can be found in Table 8.6.2.1-1 of addendum 3. The surface was also considered as a bare soil, and 1,3-D volatilization loss was allowed. A constant diffusion layer thickness of 0.5 cm above the soil surface was used throughout the simulation .

Additionally, in order to clarify any other concerns that MS might still may have on this issue the RMS reproduces in this addendum the chapters 2, 4 and 5 of the manual of CHAIN_2D code[18], hoping that these explanations may help to answer them:

Chapter 2 of CHAIN 2D code manual: Variably saturated water flow

a) Governing Flow equation

Consider two-dimensional isothermal Darcian flow of water in a variably saturated rigid porous medium and assume that the air phase plays an insignificant role in the liquid flow process. The governing flow equation for these conditions is given by the following modified form of the Richards' equation:

$$\frac{\partial \theta}{\partial t} = \frac{\partial}{\partial x_i}\left[K\left(K_{ij}^{A}\frac{\partial h}{\partial x_j} + K_{iz}^{A}\right)\right] - S \qquad (2.1)$$

Where θ is the volumetric water content [L^3L^{-3}], h, is the pressure head [L], S is a sink term [T^{-1}], x_i, (i=1,2) are the spatial coordinates [L] , t is time [T], K_{ij}^{A} t are components of a dimensionless anisotropy tensor K^A, and K is the unsaturated hydraulic conductivity function [LT^{-1}] given by

$$K(h,x,z) = K_s(x,z)\,K_r(h,x,z) \qquad (2.2)$$

Where, K_r. is the relative hydraulic conductivity and K_s, the saturated hydraulic conductivity [LT^{-1}]. The anisotropy tensor K_{ij}^{A}; in (2.1) is used to account for an anisotropic medium. The diagonal entries of K_{ij}^{A} equal one and the off-diagonal entries zero for an isotropic medium. If (2.1) is applied to planar flow in a vertical cross-section, x_1 =x is the horizontal coordinate and x_2=z is the vertical coordinate, the latter taken to be positive upward. Einstein's summation convention is used in (2.1) and throughout the manual. Hence, when an index appears twice in an algebraic term, this particular term must be summed over all possible values of the index […]

b) The Unsaturated soil hydraulic properties

The unsaturated soil hydraulic properties in the CHAIN - 2D code are described by a set of closed-form equations resembling those of van Genuchten [1980] who used the statistical pore-size distribution model of Mualem [1976] to obtain a predictive equation for the unsaturated hydraulic conductivity function. The original van Genuchten equations were modified to add extra flexibility in the description of the hydraulic properties near saturation [Šír et aL, 1985; Vogel and Císlerová, 1988]. The soil water retention, θ(h), and hydraulic conductivity, K(h), functions in CHAIN - 2D are given by

[18] Šimůnek, J., and M.Th. van Genuchten. 1994. The CHAIN2-D code for simulating the two-dimensional movement of water, heat, and multiple solutes in variably-saturated porous media. Res. rep. no. 136. U.S. Salinity Laboratory, USDA-ARS Riverside, CA.

$$\theta(h) = \begin{cases} \theta_a + \dfrac{\theta_m - \theta_a}{(1 + |\alpha h|^n)^m} & h < h_s \\ \theta_s & h \geq h_s \end{cases}$$

(2.11)

and

$$K(h) = \begin{cases} K_s K_r(h) & h \leq h_k \\ K_k + \dfrac{(h - h_k)(K_s - K_k)}{h_s - h_k} & h_k < h < h_s \\ K_s & h \geq h_s \end{cases}$$

(2.12)

Respectively, where

$$K_r = \frac{K_k}{K_s} \left[\frac{S_e}{S_{ek}} \right]^{1/2} \left[\frac{F(\theta_r) - F(\theta)}{F(\theta_r) - F(\theta_k)} \right]^2$$

(2.13)

$$F(\theta) = \left[1 - \left[\frac{\theta - \theta_a}{\theta_m - \theta_a} \right]^{1/m} \right]^m$$

(2.14)

$$m = 1 - 1/n \quad , \quad n > 1$$

(2.15

$$S_e = \frac{\theta - \theta_r}{\theta_s - \theta_r}$$

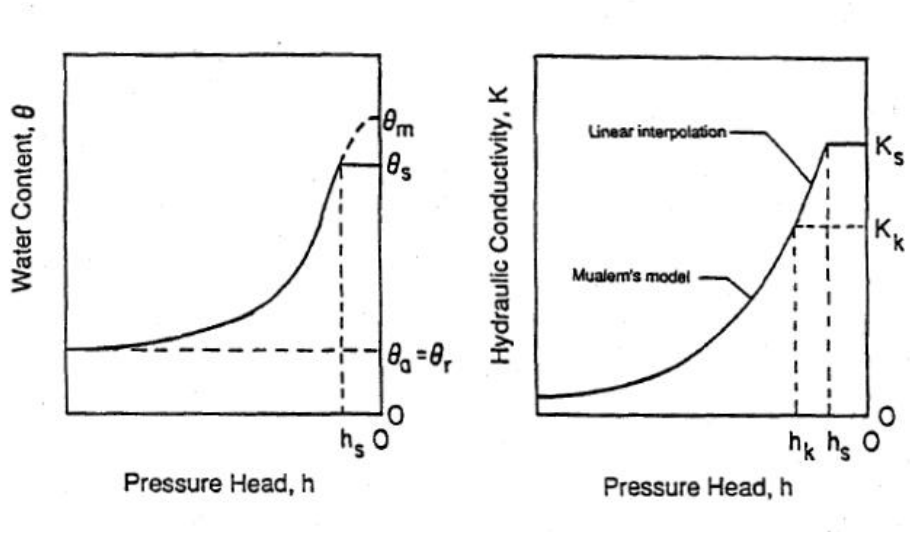
(2.16)

$$S_{ek} = \frac{\theta_k - \theta_r}{\theta_s - \theta_r}$$

(2.17)

in which θ_r, and θ_s, denote the residual and saturated water contents, respectively, and Ks is the saturated hydraulic conductivity. To increase the flexibility of the analytical expressions, and to allow for a non-zero air-entry value, hs, the parameters θ_r, and θs, in the retention function were replaced by the fictitious (extrapolated) parameters $\theta a \leq \theta$, and $\theta m \geq \theta s$ as shown in Figure 8.6.2.1-1. The approach maintains the physical meaning of θr, and θs as measurable quantities. Equation (2.13) assumes that the predicted hydraulic conductivity function is matched to a measured value of the hydraulic conductivity, Kk=K(θk), at some water content, θk , less that or equal to the saturated water content, i.e., $\theta k \leq \theta s$, and $Kk \leq Ks$, [Vogel and Císlerová, 1988; Luckner et d, 1989].

Figure 8.6.2.1-1: Schematics of the soil water retention (a) and hydraulic conductivity (b) functions as given by equations (2.11) and (2.12), respectively.



Inspection of (2.11) through (2.17) shows that the hydraulic characteristics contain 9 unknown parameters: θr, θs, θa ,.θm , α, n,Ks, Kk, and θk,. When θa=θr; θm=θk=θs, and Kk=Ks, the soil hydraulic functions reduce to the original expressions of vm Genuchten [1980]:

$$K(h) = \begin{cases} K_s K_r(h) & h < 0 \\ K_s & h \geq 0 \end{cases} \qquad (2.18)$$

Where

$$K_r = S_e^{1/2}\left[1 - (1 - S_e^{1/m})^m\right]^2 \qquad (2.19)$$

c) Scaling of the Soil Hydraulic Functions

c.1 Spatial variability of the Soil Hydraulic Functions

CHAIN - 2D implements a scaling procedure designed to simplify the description of the spatial variability of the unsaturated soil hydraulic properties in the flow domain. The code assumes that the hydraulic variability in a given area can be approximated by means of a set of linear scaling transformations which relate the individual soil hydraulic characteristics θ(h) and K(h) to reference characteristics $\theta^*(h^*)$ and $K^*(h^*)$. The technique is based on the similar media concept introduced by Miller and Miller [1956] for porous media which differ only in the scale of their internal geometry. The concept was extended by Simmons et al. [1979] to materials which differ in morphological properties, but which exhibit 'scale-similar' soil hydraulic functions. Three independent scaling factors are embodied in CHAIN - 2D. These three scaling parameters may be used to define a linear model of the actual spatial variability in the soil hydraulic properties as follows [Vogel et al.,1991]

$$K(h) = \alpha_K K^*(h^*)$$

$$\theta(h) = \theta_r + \alpha_\theta [\theta^*(h^*) - \theta_r^*]$$

$$h = \alpha_h h^*$$

(2.21)

in which, for the most general case, α_θ, α_h and α_K are mutually independent scaling factors for the water content, the pressure head and the hydraulic conductivity, respectively. Less general scaling methods arise by invoking certain relationships between α_θ, α_h and/or α_K. For example, the original Miller-Miller scaling procedure is obtained by assuming $\alpha_\theta = 1$ (with $\theta_r^* = \theta_r$), and $\alpha_K = \alpha_h^{-2}$. A detailed discussion of the scaling relationships given by (2.21), and their application to the hydraulic description of heterogeneous soil profiles, is given by Vogel et al. [1991].

c.2 Temperature Dependence of the Soil Hydraulic Functions

A similar scaling technique as described above is used to express the temperature dependence of the soil hydraulic functions. Based on capillary theory that assumes that the influence of temperature on the soil water pressure head can be quantitatively predicted from the influence of temperature on surface tension, Philip and de Vries [1957] derived following equation

$$\frac{dh}{dT} = \frac{h}{\sigma}\frac{d\sigma}{dT}$$

(2.22)

where T is temperature [K] and a is the surface tension at the air-water interface [MT^{-2}].
From (2.22) it follows that

$$h_T = \frac{\sigma_T}{\sigma_{ref}} h_{ref} = \alpha_h^* h_{ref}$$

(2.23)

where h_T and h_{ref} (σ_t, and σ_{ref}) are pressure heads (surface tensions) at temperature T and reference temperature Tref , respectively; and $\alpha^*_h$is the temperature scaling factor for the pressure head.

Following Constantz [1982], the temperature dependence of the hydraulic conductivity can be expressed as

$$K_T(\theta) = \frac{\mu_{ref}}{\mu_T}\frac{\rho_T}{\rho_{ref}} K_{ref}(\theta) = \alpha_K^* K_{ref}(\theta)$$

(2.24)

where K_{ref} and K_T denote hydraulic conductivities at the reference temperature T_{ref} and soil temperature T, respectively; μ_{ref} and μ_T (ρ_{ref} and ρ_T) similarly represent the dynamic viscosity [$ML^{-1}T^{-1}$] (density of soil water [ML^{-3}]) at temperatures Tref and T, respectively; and α_K^* is the temperature scaling factor for the hydraulic conductivity […]

d) Initial and Boundary Conditions

The solution of Eq. (2.1) requires knowledge of the initial distribution of the pressure head within the flow domain, Ω:

$$h(x,z,t) = h_0(x,z) \qquad for\ t = 0$$

(2.25)

where ho is a prescribed function of x and z.

CHAIN - 2D implements three types of conditions to describe system-independent interactions along the boundaries of the flow region. These conditions are specified pressure head (Dirichlet type) boundary conditions of the form

$$h(x,z,t) = \psi\,(x,z,t) \qquad for\ (x,z) \epsilon\ \Gamma_D$$

(2.26)

specified flux (Neumann type) boundary conditions given by

$$-[K(K_{ij}^A \frac{\partial h}{\partial x_j} + K_{iz}^A)]n_i = \sigma_1(x,z,t) \qquad for\ (x,z) \epsilon\ \Gamma_N$$

(2.27)

and specified gradient boundary conditions

$$(K_{ij}^A \frac{\partial h}{\partial x_j} + K_{iz}^A)n_i = \sigma_2(x,z,t) \qquad for\ (x,z) \epsilon\ \Gamma_G$$

(2.28)

where Γ_D, Γ_N, and Γ_G indicate Dirichlet, Neumann, and gradient type boundary segments, respectively; ψ [L], σ_1 [LT^{-1}], and σ_2 [-] are prescribed functions of x, z and t; and n_i are the components o£ the outward unit vector normal to boundary ., Γ_N or Γ_G. As pointed out by McCord [1991], the use of the term "Neumann type boundary condition" for the flux boundary is not very appropriate since this term should hold for a gradient type condition . However, since the use of the Neumann condition is standard in the hydrologic literature [Neuman, 1972; Neuman et aL, 19741, we shall also use this term to indicate flux boundaries throughout this report. CHAIN - 2D implements the gradient boundary condition only in terms of a unit vertical hydraulic gradient simulating free drainage from a relatively deep soil profile. This situation is often observed in field studies of water flow and drainage in the vadose zone [Sisson, 1987; McCord, 19911. McCord [1991] states that the most pertinent application o£ (2.28) is its use as a bottom outflow boundary condition for situations where the water table lies far below the domain o£ interest.

In addition to the system-independent boundary conditions given by (2.26), (2.27) and (2.28), CHAIN - 2D considers two different types of system-dependent boundary conditions which cannot be defined a priori. One o£ these involves soil-air interfaces which are exposed to atmospheric conditions. The potential fluid flux across these interfaces is controlled exclusively by externa1 conditions. However, the actual flux depends also on the prevailing (transient) soil moisture conditions. Soil surface boundary conditions may change from prescribed flux to prescribed head type conditions (and vice-versa). In the absence of surface ponding, the numerical solution of (2.1) is obtained by limiting the absolute value

o£ the flux by the following two conditions [Neuman et al., 1974]:

$$|\,K(K_{ij}^A \frac{\partial h}{\partial x_j} + K_{iz}^A)n_i\,| \le E$$

(2.29)

and

$$h_A \le h \le h_S$$

(2.30)

where E is the maximum potential rate of infiltration or evaporation under the current atmospheric conditions, h is the pressure head at the soil surface, and h_A, and h_s, are, respectively, minirnum and maximum pressure heads allowed under the prevailing soil conditions. The value for h_A is determined from the equilibrium conditions between soil water and atmospheric water vapor, whereas h_s, is usually set equal to zero. CHAIN- 2 D assumes that any excess water on the soil surface is immediately removed. When one of the end points of (2.30) is reached, a prescribed head boundary condition will be used to calculate the actual surface flux. Methods of calculating E and h_A on the basis of atmospheric data have been discussed by Feddes et al. [1974]

A second type of system-dependent boundary conditions considered in CHAIN - 2D is a seepage face through which water leaves the'saturated part o£ the flow domain. In this case, the length of the seepage face is not known a priori. CHAIN- 2 D assumes that the pressure head is always uniformly equal to zero along a seepage face. Additionally, the code assumes that water leaving the saturated zone across a seepage face is immediately removed by overland flow or some other removal process.

Chapter 4 of the CHAIN 2D Code Manual: Heat transport
a) Governing heat equation

Neglecting the effects of water vapor diffusion, two-dimensional heat transport can be described as [Sophocleous, 1979]:

$$C(\theta)\frac{\partial T}{\partial t} = \frac{\partial}{\partial x_i}[\lambda_{ij}(\theta)\frac{\partial T}{\partial x_j}] - C_w q_i \frac{\partial T}{\partial x_i} \qquad (4.1)$$

where $\lambda_{ij}(\theta)$ is the apparent thermal conductivity of the soil [$MLT^{-3}K^{-1}$] (e.g. $Wm^{-1}K^{-1}$) and $C(\theta)$ and Cw are the volumetric heat capacities [$ML^{-1}T^{-2}K^{-1}$'] (e.g. $Jm^{-3}K^{-1}$) of the porous medium and the liquid phase, respectively. Volumetric heat capacity is defined as the product of the bulk density and gravimetric heat capacity. The first term on the right-hand side of (4.1) represents heat flow due to conduction and the second term accounts for heat being transported by flowing water. We do not consider the transfer of latent heat by vapour movement. According to de Vries [1963] the volumetric heat capacity can be expressed as

$$C(\theta) = C_n\theta_n + C_o\theta_o + C_w\theta + C_g a_v \approx (1.92\,\theta_n + 2.51\,\theta_o + 4.18\,\theta)\,10^6 \quad [\mathrm{J\,m^{-3}K^{-1}}] \qquad (4.2)$$

where θ refers to a volumetric fraction [L^3L^{-3}] and subscripts n, o, g, w represent solid phase, organic matter, gas phase and liquid phase, respectively.

b) Apparent Thermal Conductivity Coeficient

The apparent thermal conductivity, $\lambda_{ij}(\theta)$, combines the thermal conductivity $\lambda_o(\theta)$ of the porous medium (solid plus water) in the absence of flow, and the macrodispersivity which is assumed to be a linear function of the velocity [de Marsily, 1986]. In analogy with the dispersion coefficient for solute transport, the apparent thermal conductivity $\lambda_{ij}(\theta)$is given by [Šimůnek and Suarez , 1993b]

$$\lambda_{ij}(\theta) = \lambda_T C_w |q| \delta_{ij} + (\lambda_L - \lambda_T) C_w \frac{q_j q_i}{|q|} + \lambda_0(\theta)\delta_{ij} \qquad (4.3)$$

where 1q 1 is the absolute value of the Darcian fluid flux density [LT^{-1}],δ_{ij}, is the Kronecker delta function as before, and λ_L and λ_T are the longitudinal and transverse thermal dispersivities [L], respectively. The individual components of the thermal conductivity tensor for two-dimensional transport are as follows:

$$\lambda_{xx} = \lambda_L C_w \frac{q_x^2}{|q|} + \lambda_T C_w \frac{q_z^2}{|q|} + \lambda_0$$

$$\lambda_{zz} = \lambda_L C_w \frac{q_z^2}{|q|} + \lambda_T C_w \frac{q_x^2}{|q|} + \lambda_0$$

$$\lambda_{xz} = (\lambda_L - \lambda_T) C_w \frac{q_x q_z}{|q|} \qquad (4.4)$$

The volumetric heat capacity of the liquid phase is included here in the definition of the thermal conductivity in order to have the dirnensions of the thermal dispersivities in the length units [de Marsily, 1986]. The thermal conductivity, $\lambda_o(\theta)$, accounts for the tortuosity of the porous mediurn, and is described with the simple equation [Chung and Horton, 1987]

$$\lambda_0(\theta) = b_1 + b_2\theta_w + b_3\theta_w^{0.5} \tag{4.5}$$

where b_1,, b_2, and b_3 are empirical parameters [$MLT^{-3}K^{-1}$] (e.g. $Wm^{-1}K^{-1}$').

c) Initial boundary conditions

Equation (4.1) will be solved subject to the general initial condition

$$T(x,z,0) = T_i(x,z) \tag{4.6}$$

where Ti is a prescribed function o£ x and z. Two types of boundary conditions (Dirichlet and Cauchy type conditions) can again be specified along the boundary of Ω. First-type (or Dirichlet type) boundary conditions prescribe the temperature along a boundary segment Γ_D:

$$T(x,z,t) = T_0(x,z,t) \qquad for\ (x,z) \epsilon \Gamma_D \tag{4.7}$$

whereas third-type (Cauchy type) boundary conditions prescribe the heat flux along a boundary segment Γ_c as follows:

$$-\lambda_{ij}\frac{\partial T}{\partial x_j}n_i + TC_w q_i n_i = T_0 C_w q_i n_i \qquad for\ (x,z) \epsilon \Gamma_C \tag{4.8}$$

in which $q_i n_i$ represents the outward fluid flux, ni is the outward unit normal vector and To is the temperature of the incoming fluid. When Γ_c, is an impermeable boundary ($q_i n_i = 0$) or when water flow is directed out of the region, (4.8) reduces to a second-type (Neumanntype) boundary condition of the form:

$$\lambda_{ij}\frac{\partial T}{\partial x_j}n_i = 0 \qquad for\ (x,z) \epsilon \Gamma_N \tag{4.9}$$

The atmospheric boundary condition for soil temperature is assumed to be given by a sine function as follows [Kirkham and Powers, 1972]:

$$T_0 = \bar{T} + A\sin\left(\frac{2\pi t^*}{t_p} - \frac{7\pi}{12}\right) \tag{4.10}$$

where t_p is the period of time [T] necessary to complete one cycle of the sine wave (taken to be 1 day), Ťis the average temperature at the soil surface [K] during period t_p, A is the amplitude of the sine wave [K], and t* is the local time [T] within the period t_p. The second term within the argument of the sine function is included to allow the highest temperature to occur at 1 p.m.

Chapter 5 of the CHAIN 2D Code Manual: NUMERICAL SOLUTION OF THE WATER FLOW EQUATION

The Galerkin finite element method with linear basis functions is used to obtain a solution of the flow equation (2.1) subject to the imposed initial and boundary conditions.Since the Galerkin method is relatively standard and has been covered in detail elsewhere [Neuman, 1975; Zienkiewicz, 1977; Pinder and Gray, 1977], only the most pertinent steps in the solution process are given here.

Space Discretization

The flow region is divided into a network of triangular elements. The corners of these elements are taken to be the nodal points. The dependent variable, the pressure head function h(x,z, t), is approximated by a function h' (x,z, t) as follows

$$h'(x,z,t) = \sum_{n=1}^{N} \phi_n(x,z)\, h_n(t) \qquad (5.1)$$

where $\phi_{n,}$, are piecewise linear basis functions satisfying the condition $\phi_n(x_m,z_m)=\delta_{nm}$, h_n are unknown coefficients representing the solution of (2.1) at the nodal points, and N is the total number of nodal points.

The Galerkin method postulates that the differential operator associated with the Richards' equation (2.1) is orthogonal to each of the N basis functions, i.e

$$\int_{\Omega} \{\frac{\partial \theta}{\partial t} - \frac{\partial}{\partial x_i}[K(K_{ij}^{A}\frac{\partial h}{\partial x_j} + K_{iz}^{A})] + S\}\,\phi_n d\Omega = 0 \qquad (5.2)$$

Applying Green's first identity to (5.2), and replacing *h* by *h'*, leads to

$$\sum_{e} \int_{\Omega_e} (\frac{\partial \theta}{\partial t}\phi_n + KK_{ij}^{A}\frac{\partial h'}{\partial x_j}\frac{\partial \phi_n}{\partial x_i})d\Omega =$$

$$\sum_{e} \int_{\Gamma_e} K(K_{ij}^{A}\frac{\partial h'}{\partial x_j} + K_{iz}^{A})n_i\phi_n d\Gamma + \sum_{e} \int_{\Omega_e} (-KK_{iz}^{A}\frac{\partial \phi_n}{\partial x_i} - S\phi_n)d\Omega \qquad (5.3)$$

where Ω_e represents the domain occupied by element *e*, and T*e* is a boundary segment of element e. Natural flux-type (Neumann) and gradient type boundary conditions can be immediately incorporated into the numerical scheme by specifying the line integral in equation (5.3)

After imposing additional simplifying assumptions to be discussed later, and performing integration over the elements, the procedure leads to a system of time dependent ordinary differential equations with nonlinear coefficients. In matrix form, these equations are given by

$$[F]\frac{d\{\theta\}}{dt} + [A]\{h\} = \{Q\} - \{B\} - \{D\} \qquad (5.4)$$

Where,

$$A_{nm} = \sum_e K_l K_{ij}^A \int_{\Omega_e} \phi_l \frac{\partial \phi_n}{\partial x_i} \frac{\partial \phi_m}{\partial x_j} d\Omega$$

$$= \sum_e \frac{\kappa}{4A_e} \bar{K} \left[K_{xx}^A b_m b_n + K_{xz}^A (c_m b_n + b_m c_n) + K_{zz}^A c_n c_m \right]$$

(5.5)

$$B_n = \sum_e K_l K_{iz}^A \int_{\Omega_e} \phi_l \frac{\partial \phi_n}{\partial x_i} d\Omega = \sum_e \frac{\kappa}{2} \bar{K} (K_{xz}^A b_n + K_{zz}^A c_n)$$

(5.6)

$$F_{nm} = \delta_{nm} \sum_e \int_{\Omega_e} \phi_n d\Omega = \delta_{nm} \sum_e \frac{\kappa}{3} A_e$$

(5.7)

$$Q_n = -\sum_e \sigma_{1_l} \int_{\Gamma_e} \phi_l \phi_n d\Gamma = -\sum_e \sigma_{1_n} \lambda_n$$

(5.8)

$$D_n = \sum_e S_l \int_{\Omega_e} \phi_l \phi_n d\Omega = \sum_e \frac{\kappa}{12} A_e (3\bar{S} + S_n)$$

(5.9)

where the overlined variables represent average values over an element e, the subscripts i and j are space direction indices (i,j = 1,2), and

$$l = 1,2,...,N \quad m = 1,2,...,N \quad n = 1,2,...,N$$

$$\begin{aligned} b_i &= z_j - z_k & c_i &= x_k - x_j \\ b_j &= z_k - z_i & c_j &= x_i - x_k \\ b_k &= z_i - z_j & c_k &= x_j - x_i \end{aligned}$$

$$A_e = \frac{c_k b_j - c_j b_k}{2} \qquad \bar{K} = \frac{K_i + K_j + K_k}{3} \qquad \bar{S} = \frac{S_i + S_j + S_k}{3}$$

(5.10)

Equation (5.8) is valid for a flux-type boundary condition. For a gradient-type boundary condition the variable σ_1, in (5.8) must be replaced by the product of the hydraulic conductivity K and the prescribed gradient σ_2, (= 1). Equations (5.5) through (5.9) hold for flow in a two-dimensional Cartesian (x,z) domain, as well as for flow in an axisymmetric (x,z) system in which x is used as the radial coordinate. For plane flow we have

$$\kappa = 1 \qquad \lambda_n = \frac{L_n}{2}$$

(5.11)

while for axisymmetric flow

$$\kappa = 2\pi \frac{x_i + x_j + x_k}{3} \qquad \lambda_n = L_n \pi \frac{x'_n + 2x_n}{3}$$

(5.12)

The subscripts i, j and k in equations (5.10) and (5.12) represent the three corners of a triangular element e. A_e. is the area of element e, $\bar{K}$ and $\bar{S}$ are the average hydraulic conductivity and root water extraction values over element e, L_n, is the length of the boundary segment connected to node n, and x'_n, is the x-coordinate of a boundary node adjacent to node n. The symbol σ_n, in equation (5.8) stands for the flux [LT^{-1}] across the boundary in the vicinity o£ boundary node n (positive when directed outward o£ the system). The boundary flux is assumed to be uniform over each boundary segment. The entries of the vector Q_n, are zero at all internal nodes which do not act as sources or sinks for water.

The numerical procedure leading to (5.4) incorporates two important assumptions in addition to those related to the Galerkin finite element approach. One assumption concerns the time derivatives of the nodal values of the water content in (5.4). These time derivatives were weighted according to

$$\frac{d\theta_n}{dt} = \frac{\sum_e \int_{\Omega_e} \frac{\partial \theta}{\partial t} \phi_n d\Omega}{\sum_e \int_{\Omega_e} \phi_n d\Omega}$$

(5.13)

This assumption implements mass-lumping which has been shown to improve the rate of convergence o£ the iterative solution process.

A second assumption in the numerical scheme is related to the anisotropy tensor K^A which is taken to be constant over each element. By contrast, the water content θ, thehydraulic conductivity K, the soil water capacity C, and the root water extraction rate S, at a given point in time are assumed to vary linearly over each element, e. For example, the water content is expanded over each element as follows:

$$\theta(x,z) = \sum_{n=1}^{3} \theta(x_n, z_n) \phi_n(x,z) \qquad for\ (x,z) \in \Omega_e$$

(5.14)

where n stands for the corners of element e. The advantage of linear interpolation is that no numerical integration is needed to evaluate the coefficients in (5.4).

Time Discretization

Integration of (6) in time is achieved by discretizing the time domain into a sequence of finite intervals and replacing the time derivatives by finite differences. An implicit (backward) finite difference scheme is used for both saturated and unsaturated conditions:

$$[F] \frac{\{\theta\}_{j+1} - \{\theta\}_j}{\Delta t_j} + [A]_{j+1} \{h\}_{j+1} = \{Q\}_j - \{B\}_{j+1} - \{D\}_j$$

(5.15)

where j+ 1 denotes the current time level at which the solution is being considered, j refers to the previous time level, and Atj=íj,,-$. Equation (17) represents the final set of algebraic equations to be solved. Since the coefficients θ, A, B, D, and Q (Q for only gradient-type boundary conditions) are functions of h, the set of equations is generally highly nonlinear. Note that the vectors D and Q are evaluated at the old time level.

Numerical Solution Strategy

a) Iterative process

Because of the nonlinear nature of (5.15), an iterative process must be used to obtain solutions of the global matrix equation at each new time step. For each iteration a system of linearized algebraic equations is first derived from (5.15) which, after incorporation of the boundary conditions, is solved using either Gaussian elimination or the conjugate gradient method. The Gaussian elimination process takes advantage of the banded and syrnmetric features of the coefficient matrices in (5.15). After inversion, the coefficients in (5.15) are re-evaluated using the first solution, and the new equations are again solved. The iterative process continues until a satisfactory degree of convergence is obtained, i.e., until at all nodes in the saturated (or unsaturated) region the absolute change in pressure head (or water content) between two successive iterations becomes less than some small value determined by the imposed absolute pressure head (or water content) tolerance. The first estimate (at zero iteration) of the unknown pressure heads at each time step is obtained by extrapolation from the pressure head values at the previous two time levels.

b) Treatment of the Water Capacity Term

The iteration process is extremely sensitive to the method used for evaluating the water content term $(\Delta\theta/\Delta t)$ in equation (5.15). The present version of CHAIN - 2D code uses the "mass-conservative" method proposed by Celia et al. [1990]. Their method has been shown to provide excellent results in terms of minimizing the mass balance error. The mass conservative method proceeds by separating the water content term into two parts:

$$[F]\frac{\{\theta\}_{j+1}-\{\theta\}_j}{\Delta t_j}=[F]\frac{\{\theta\}_{j+1}^{k+1}-\{\theta\}_{j+1}^{k}}{\Delta t_j}+[F]\frac{\{\theta\}_{j+1}^{k}-\{\theta\}_j}{\Delta t_j} \qquad (5.16)$$

where k+ 1 and k denote the current and previous iteration levels, respectively; and j+ 1 and j the current and previous time levels, respectively. Notice that the second term on the right hand side of (5.16) is known prior to the current iteration. The first term on the right hand side can be expressed in terms of the pressure head, so that (18) becomes

$$[F]\frac{\{\theta\}_{j+1}-\{\theta\}_j}{\Delta t_j}=[F][C]_{j+1}\frac{\{h\}_{j+1}^{k+1}-\{h\}_{j+1}^{k}}{\Delta t_j}+[F]\frac{\{\theta\}_{j+1}^{k}-\{\theta\}_j}{\Delta t_j} \qquad (5.17)$$

where $C_{nm}=\delta_{nm}C_{n}$ in which Cn represents the nodal value o£ the soil water capacity. The first term on the right hand side of (5.17) should vanish at the end of the iteration process if the numerical solution converges. This particular feature guarantees relatively small mass balance errors in the solution.

c) Time Control

Three different time discretizations are introduced in CHAIN 2D: (1) time discretizations associated with the numerical solution, (2) time discretizations associated with the implementation of boundary conditions, and (3) time discretizations which provide printed output of the simulation results (e.g., nodal values of dependent variables, water and solute mass balance components, and other information about the flow regime). Discretizations 2 and 3 are mutually independent; they generally involve variable time steps as described in the input data file. Discretization 1 starts with a prescribed initial time increment,Δt. This time increment is automatically adjusted at each time level according to the following rules [Mls, 1982; Vogel, 1987]:

a. Discretization 1 must coincide with time values resulting from discretizations 2 and 3.
b. Time increments cannot become less than a preselected minimum time step Δt_{min} nor exceed a maximum time step, Δtmax (i.e.,$\Delta t_{min} \leq \Delta t \leq \Delta t_{max}$).
c. If, during a particular time step, the number of iterations necessary to reach convergence is $\leq$ 3, the time increment for the next time step is increased by multiplying Δt by a predetermined constant > 1 (usually between 1.1 and 1.5). If the number of iterations is $\geq$ 7, Δt for the next time level is multiplied by a constant < 1 (usually between 0.3 and 0.9).

d. If, during a particular time step, the number of iterations at any time level becomes greater than a prescribed maximum (usually between 10 and 50), the iterative process for that time level is terminated. The time step is subsequently reset to $\Delta t/3$, and the iterative process restarted.

The selection of optimal time steps, Δt, is also influenced by the solution scheme for solute transport

d) Treatment of Pressure Head Boundary Conditions

Finite element equations corresponding to Dirichlet nodes where the pressure head is prescribed can, at least in principie, be eliminated from the global matrix equation. An alternative and numerically simpler approach is to replace the Dirichlet finite element equations by dummy expressions of the form [Neuman, 1974]

$$\delta_{nm} h_m = \psi_n \tag{5.18}$$

where δ_{nm} is the Kronecker delta and ψ_n, is the prescribed value of the pressure head at node n. The values of h_n, in all other equations are set equal to ψ_n, and the appropriate entries containing ψ_n, in the left hand side matrix are incorporated into the known vector on the right-hand side of the global matrix equation. When done properly, this rearrangement will preserve symmetry in the matrix equation. This procedure is applied only when Gaussian elimination is used to solve the matrix equations. When the conjugate gradient solver is used, then the finite element equation representing the Dirichlet node is modified as follows. The right hand side of this equation is set equal to the prescribed pressure head multiplied by a large number (10^{30}'), and entry on the left hand side representing the Dirichlet node is set equal to this large number. After solving for al1 pressure heads, the value of the flux Q, can be calculated explicitly and accurately from the original finite element equation associated with node n [e.g., Lynch, 1984].

e) Flux and Gradient Boundary Conditions

The values of the fluxes Q, at nodal points along prescribed flux and gradient boundaries are computed according to equation (10). Interna1 nodes which act as Neumann type sources or sinks have values of Q_n, equal to the imposed fluid injection or extraction rate.

f) Atmospheric Boundary Conditions and Seepage Faces

Atmospheric boundaries are simulated by applying either prescribed head or prescribed flux boundary conditions depending upon whether equation (2.29) or (2.30) is satisfied [Neuman, 1974]. If (2.30) is not satisfied, node *n* becomes a prescribed head boundary. If, at any point in time during the computations, the calculated flux exceeds the specified potential flux in (2.29), the node will be assigned a flux equal to the potential value and treated again as a prescribed flux boundary.

All nodes expected to be part of a seepage face during code execution must be identified a priori. During each iteration, the saturated part of a potential seepage face is treated as a prescribed pressure head boundary with h =O, while the unsaturated part is treated as a prescribed flux boundary with Q=0. The lengths of the two surface segments are continually adjusted [Neuman, 19741 during the iterative process until the calculated values of Q (equation (5.8)) along the saturated part, and the calculated values of h along the unsaturated part, are all negative, thus indicating that water is leaving the flow region through the saturated part of the surface boundary only.

g) Tile Drains as Boundary Conditions

The representation of tile drains as boundary conditions is based on studies by Vimoke et al. [1963] and Fipps et al. [1986]. The approach uses results o£ electric analog experiments conducted by Vimoke and Taylor [1962] who reasoned that drains can be represented by nodal points in a regular finite element mesh, provided adjustments are made in the hydraulic conductivity, K, of neighboring elements. The adjustments should correspond to changes in the electric resistance o£ conducting paper as follows

$$K_{drain} = K C_d \tag{5.19}$$

where K_{drain} is the adjusted conductivity [LT^{-1}], and C_d is the correction factor [-]. C_d is determined from the ratio of the effective radius, d_e [L], of the drain to the side length, D [L], of the square formed by finite elements surrounding the drain node [Vimoke et al,1962]:

$$C_d = \frac{Z_0'}{Z_0} \approx \frac{\sqrt{\mu_0/\epsilon_0}}{138\log_{10}\rho_d + 6.48 - 2.34A - 0.48B - 0.12C} \tag{5.20}$$

where Z_0,' is the characteristic impedance of free space (~376.7 ohms), μ_0, is the permeability of free space, E, is the permittivity of free space, and Zo is the characteristic impedance of a transmission line analog of the drain. The coefficients in (5.20) are given by

$$\rho_d = \frac{D}{d_e} \qquad A = \frac{1 + 0.405\rho_d^{-4}}{1 - 0.405\rho_d^{-4}}$$

$$B = \frac{1 + 0.163\rho_d^{-8}}{1 - 0.163\rho_d^{-8}} \qquad C = \frac{1 + 0.067\rho_d^{-12}}{1 - 0.067\rho_d^{-12}} \tag{5.21}$$

where d_e is the effective drain diameter to be calculated from the number and size of smallopenings in the drain tube [Mohammad and Skaggs, 1984], and D is the size of the square in the finite element mesh surrounding the drain having adjusted hydraulic conductivities. The approach above assumes that the node representing a drain must be surrounded by finite elements (either triangular or quadrilateral) which form a square whose hydraulic conductivities are adjusted according to (5.19). This method of implementing drains by means of a boundary condition gives an efficient, yet relatively accurate, prediction of the hydraulic head in the immediate vicinity of the drain, as well as of the drain flow rate [Fipps et al, 1986]. More recent studies have shown that the correction factor, C, could be further reduced by a factor of 2 [Rogers and Fouss, 1989] or 4 [Tseng, 1994, personal comunication]. These two studies compared numerical simulations of the flow of ponded water into a tile drain system with an analytical solution given by Kirkham [1949]. Pressure head contours calculated numerically with the original correction factor Cd (24), as well as with the additionally reduced correction factor $C_d/4$, were compared with the analytical results in Šimůneke t al. [1994].

The CHAIN - 2D code performs water balance computations at prescribed times for several preselected subregions of the flow domain. The water balance information for each subregion consists of the actual volume of water, in that subregion, and the rate, 0, of inflow or outflow to or from the subregion. V and O are given by:

$$V = \sum_e \kappa A_e \frac{\theta_i + \theta_j + \theta_k}{3} \tag{5.22}$$

and

$$O = \frac{V_{new} - V_{old}}{\Delta t} \tag{5.23}$$

respectively, where θ_i, θ_j and θ_k are water contents evaluated at the corner nodes of element *e*, and where V_{new}, and V_{old}, are volumes of water in the subregion computed at the current and previous time levels, respectively. The summation in (5.22) is taken over all elements within the subregion.

The absolute error in the mass balance is calculated as

$$\epsilon_a^w = V_t - V_0 + L_t \int_0^t T_a dt - \int_0^t \sum_{n_r} Q_n dt \qquad (5.24)$$

where V_t and V_o, are the volumes of water in the flow domain at time t and zero, respectively, as calculated with (5.22). The third term on the right-hand side represents the cumulative root water uptake amount, while the fourth term gives the cumulative flow through nodes, n_r located along the boundary of the flow domain or at interna1 source and sink nodes.

The accuracy of the numerical solution is evaluated in terms of the relative error, $\in_r^w$ [%], in the water mass balance as follows:

$$\epsilon_r^w = \frac{|\epsilon_a^w|}{\max\left[\sum_e |V_t^e - V_0^e|, L_t \int_0^t T_a dt + \int_0^t \sum_{n_r} |Q_n| dt\right]} 100 \qquad (5.25)$$

where V^e_t and V^e_0 are the volumes of water in element e at times t and zero, respectively. Note that CHAIN - 2D does not relate the absolute error to the volume of water in the flowdomain, but instead to the maximum value of two quantities. The first quantity represents the sum of the absolute changes in water content over all elements, whereas the second quantity is the sum of the absolute values of all fluxes in and out of the flow domain. This criterion is much more strict than the usual criterion involving the total volume of water in the flow domain. This is because cumulative boundary fluxes are often much smaller than the volume in the domain, especially at the beginning of the simulation.

h) Computation of Nodal Fluxes

Components of the Darcian flux are computed at each time level during the simulation only when the water flow and solute transport equations are solved simultaneously. When the flow equation is being solved alone, the flux components are calculated only at selected print times. The x- and z-components of the nodal fluxes are computed for each node n according to:

$$q_x = -\frac{K_n}{N_e}\sum_{e_n}\left[\frac{\gamma_i^x h_i + \gamma_j^x h_j + \gamma_k^x h_k}{2A_e} + K_{xz}^A\right]$$

$$q_z = -\frac{K_n}{N_e}\sum_{e_n}\left[\frac{\gamma_i^z h_i + \gamma_j^z h_j + \gamma_k^z h_k}{2A_e} + K_{zz}^A\right]$$

$$\gamma_n^x = K_{xx}^A b_n + K_{xz}^A c_n$$

$$\gamma_n^z = K_{xz}^A b_n + K_{zz}^A c_n$$

(5.26)

where N, is the number of sub-elements e_n adjacent to node n. Einstein's summation convention is not used in (5.26) […]

[…] j) Evaluation of the Soil Hydraulic Properties

At the beginning of a numerical simulation, CHAIN - 2D generates for each soil type in the flow domain a table of water contents, hydraulic conductivities, and specific water capacities from the specified set of hydraulic parameters. The values of θ_i, K_i and C_i in the table are evaluated at prescribed pressure heads hi within a specified interna1 (h_a, h_b). The entries in the table are generated such that

$$\frac{h_{i+1}}{h_i} = constant$$

(5.28)

which means that the spacing between two consecutive pressure head values increases in a logarithmic fashion. Values for the hydraulic properties, θ(h), K(h) and C(h), are computed during the iterative solution process using linear interpolation between the entries in the table. If an argument h falls outside the prescribed interval (h_a, h_b), the hydraulic characteristics are evaluated directly from the hydraulic functions, i.e., without interpolation. The above interpolation technique was found to be much faster computationally than direct evaluation of the hydraulic functions over the entire range of pressure heads, except when very simple hydraulic models were used.

k) Implementation of Hydraulic Conductivity Anisotropy

Since the hydraulic conductivity anisotropy tensor, KA, is assumed to be syrnmetric, it is possible to define at any point in the flow domain a local coordinate system for which the tensor K^A is diagonal (i.e., having zeroes everywhere except on the diagonal). The diagonal entries K: and K_1^A of K^A are referred to as the principal components of K^A.

The CHAIN - 2D code permits one to vary the orientation of the local principal directions from element to element. For this purpose, the local coordinate axes are subjected to a rotation such that they coincide with the principal directions of the tensor K^A. The principal components K_1^A and K_2^A, together with the angle ω_a between the principal direction of K_1^A and the x-axis of the global coordinate system, are specified for each element. Each locally deterrnined tensor K^A is transformed to the global (x,z) coordinate system at the beginning o£ the simulation using the following rules:

$$K_{xx}^{A} = K_1^{A} \cos^2\omega_a + K_2^{A} \sin^2\omega_a$$

$$K_{zz}^{A} = K_1^{A} \sin^2\omega_a + K_2^{A} \cos^2\omega_a$$

$$K_{xz}^{A} = (K_2^{A} - K_1^{A}) \sin\omega_a \cos\omega_a$$

(5.29)

I) Steady-State Analysis

All transient flow problems are solved by time marching until a prescribed time is reached. The steady-state problem can be solved in the same way, Le., by time rnarching until two successive solutions differ less than some prescribed pressure head tolerance. CHAIN - 2D irnplements a faster way of obtaining the steady-state solution without having to go through a large number of time steps. The steady-state solution for a set of imposed boundary conditions is obtained directly during one set of iterations at the first time step by equating the time derivative term in the Richards' equation (2.1) to zero.