PEER REVIEW REPORT ON **1,3 DICHLOROPROPENE** 01 10 2009

TABLE OF CONTENTS

Comments on the Additional Report on 1,3 dichloropropene (EAS - Resubmission)

RMS ES

End of commenting period: 20 May 2009 (MS, APPLICANT)

Date	Supplier	File
2009 05 19	APPLICANT	01 1,3-dichloropropene comments APPL 2009-05-19.doc
2009 05 19	FR	02 1,3-dichloropropene comments FR 2009-05-19.doc
2009 05 20	NL	03 1,3-dichloropropene comments NL 2009-05-20.doc
2009 05 20	DE	04 1,3-dichloropropene comments DE 2009-05-20.doc
2009 05 20	UK	05 1,3-dichloropropene comments UK 2009-05-20.doc
2009 05 25	EFSA	06 1,3-dichlorpropene comments EFSA 2009-05-25.doc

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

Identity (B.1, Annex C)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 4, page 11, impurities exceeding 1g /kg	**Notifier** [redacted] Max content should be 2 g/kg and not 12 g/kg.	See 5 batch analysis summary on page 25
(2)	Vol. 4, page 17, summary of Dow AgroSciences and Kanesho specifications	**Notifier** **Table C.1.2.2-1.** [redacted] should be max of 3 g/kg and not 4 g/kg for DAS specification. [redacted] should be max of 3 g/kg and not 4 g/kg for DAS specification	See 5 batch analysis summary on page 25

Physical and chemical properties of the active substance (B.2.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Physical, chemical and technical properties of the formulation (B.2.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, page 7, 1.2.1 Name and address of applicant(s)	**Notifier** Dow AgroSciences contact is Mr John Dawson Kanesho contact is Mr Toshiyuki Kubota	
(2)	Vol. 1, page 8, 1.2.7, Manufacturer or manufacturers of the active substance	**Notifier** For Solvay the details are:- Solvay Chemicals International S.A. Rue du Prince Albert, 44 B-1050, Brussels Belgium See Kanesho Soil Treatment contact in section 1.2.1	
(3)	Vol. 1, page 10, 1.4.1.a, Current, former and proposed trade names and development code numbers	**Notifier** The Tradenames for Solvay products include:- D-D 92, D-D Top 90 EC, DD Emulsionnable	
(4)	Vol. 1, page 10, 1.4.2.a, Manufacturer or manufacturers of the plant protection product	**Notifier** The Solvay product is made at 2 locations, Solvay Electrolyse France s.a. FR-39501 Tavaux Cedex France And Solvay Chemicals Gmbh Xantener Strasse 237 47495 Rheinberg	

<table>
<tr><th colspan="4">Physical, chemical and technical properties of the formulation (B.2.2)</th></tr>
<tr><th>No.</th><th>Column 1
Reference to draft assessment report</th><th>Column 2
Comment (restricted to 500 characters, ca.10 lines)</th><th>Column 3
Further explanations</th></tr>
<tr><td></td><td></td><td>Germany</td><td></td></tr>
<tr><td>(5)</td><td>Vol. 1, page 12, 1.5.4.a,
Information on authorisations in EU Member States</td><td><u>Notifier</u>
Please amend table to reflect all DAS and Kanesho authorisations
See table in column 4</td><td>
<table>
<tr><th>Product</th><th>Member State</th><th>Existing or proposed</th></tr>
<tr><td>EF-1478 XX (Condor)</td><td>Cyprus</td><td>Existing</td></tr>
<tr><td>EF-1478 XX(Condor)</td><td>Greece</td><td>Existing</td></tr>
<tr><td>EF-1478 XX(Telone EC)</td><td>Italy</td><td>Existing</td></tr>
<tr><td>EF-1478 XX(Telone EC)</td><td>Malta</td><td>Existing</td></tr>
<tr><td>EF-1478 XX (Dorlone EC)</td><td>Spain</td><td>Existing</td></tr>
<tr><td>EF-1478 XX (Telone II EC)</td><td>Spain</td><td>Existing</td></tr>
<tr><td>D-D 92</td><td>France</td><td>Existing</td></tr>
<tr><td>D-D Top 90 EC</td><td>Greece</td><td>Existing</td></tr>
<tr><td>DD Emulsionnable</td><td>Spain</td><td>Existing</td></tr>
</table>
Registered as: Telone EC; Condor; Dorlone EC; Telone II EC; D-D 92, DD Top 90 EC, DD Emulsionnable
</td></tr>
<tr><td>(6)</td><td>Vol. 1, page 14, 1.5.4.b
Information on authorisations in EU Member States</td><td><u>Notifier</u>
Please amend table to reflect all DAS and Kanesho authorisations
See table in column 4</td><td>
<table>
<tr><th>Product</th><th>Member State</th><th>Existing or proposed</th></tr>
<tr><td>XRM-5048 AL (Telone II)</td><td>Belgium</td><td>Existing</td></tr>
<tr><td>D-D 95</td><td>Belgium</td><td>Existing</td></tr>
<tr><td>XRM-5048 AL (Dorlone 2000)</td><td>France</td><td>Existing</td></tr>
<tr><td>XRM-5048 AL (Telone II)</td><td>Greece</td><td>Existing</td></tr>
</table>
</td></tr>
</table>

Physical, chemical and technical properties of the formulation (B.2.2)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
			XRM-5048 AL (Telone-97) – Italy – Existing D-D Soil Fumigant – Italy – Existing XRM-5048 AL (Telone II) – Portugal – Existing XRM-5048 AL (Telone II) – Spain – Existing XRM-5048 AL (Dorlone) – Spain – Existing DD Inyectable – Spain – Existing XRM-5048 AL (Telone II) – UK – Existing Registered as: Dow AgroSciences, Telone II; Telone-97; Dorlone II; Dorlone 2000, Kanesho, D-D 95, DD Soil fumigant, DD- Inyectable
(7)	Vol. 1, page 15, 1.5.4.b LIST OF USES SUPPORTED BY AVAILABLE DATA	**Notifier** Footnotes 1 and 2 need to be amended to read:- (1) KST Tradenames for 1,3-D Injection product are D-D 95, DD Inyectable, D-D Soil Fumigant (2) KST Tradename for 1,3-D Drip Irrigation EC are D-D 92, DD Emulsionnable, D-D Top 90 EC	

Further information (B.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from the notifier.	

Methods of analysis (B.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from the notifier.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from the notifier.	

2. Mammalian toxicology (B.6)

Toxicokinetics (B.6.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, page 20, 2.3 Impact on human and animal health	**Notifier** No comments from notifier.	

Acute toxicity (B.6.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Short-term toxicity (B.6.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Genotoxicity (B.6.4)

Section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Long-term toxicity and carcinogenicity (B.6.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Reproductive toxicity (B.6.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Neurotoxicity (B.6.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Other toxicological studies & Medical data (B.6.8-B.6.9)

Section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Summary of mammalian toxicology and setting ADI, AOEL, ARfD (B.6.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.1, page 20, 2.3 Impact on human and animal health Page 229, Appendix 1.3, summary endpoints	**Notifier** The notifier is still of the opinion that the calculations and/or assumptions made in the DAR for the calculation of the AOEL are incorrect. Therefore the AOEL calculation and explanation previously provided by the notifier following the September 2005 EFSA review is provided again as an Appendix to this document.	See appendix to this document. The key point of the notifier is that there needs to be an adjustment in the calculation to reflect the actual hours and days of exposure to 1,3-Dichloropropene. When this adjustment is made then the AOEL changes from DAR proposal of 0.066 ppm(equivalent to 0.30 mg/m^3) to 0.277 ppm(equivalent to 1.25 mg/m^3)

Toxicity of the product(s) (B.6.11)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Dermal absorption (B.6.12)

Section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Toxicity of non-active substances (B.6.13)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>,	**Notifier**	

Section 2 - Mammalian toxicology (B.6)

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	<<description>>	No comments from notifier.	

3. Residues (B.7)

Storage Stability (B.7.0)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Metabolism in plants (B.7.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Metabolism in livestock (B.7.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Residue definition (B.7.3)

Section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 3, appendix 1.4 residues, page 234, summary of critical residues data	**Notifier** It should perhaps be noted that, as part of the confirmation of ND residues on impurities, a series of trials on peppers and tomatoes (injection and drip irrigation trials) were conducted in EU S Zone. These were assessed as part of DAR additional report and also confirmed that parent molecules of 1,3-D showed no detectable residues (<0.01 mg/kg).	

Processing (B.7.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Livestock feeding (B.7.8)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	
Succeeding/Rotational crops (B.7.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

4. Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Adsorption, desorption and mobility in soil (B.8.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

PEC in soil (B.8.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Fate and behaviour in water and impact on water treatment procedures (B.8.4 – B.8.5)

Section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Fate and behaviour in air and PEC in air (B.8.7 – B.8.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Definition of the residues (B.8.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Other comments

Section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

5. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Section B.9.3.1, page 44 and Appendix I.6, page 39 RMS proposal: Based on the results of 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 value is suitable for risk assessment refinement.	**Notifier** The notifier believes this choice of NOEL for body weight change is over-conservative as it does not take into account the potential duration for exposure to 1,3-D for wild mammals (less than 2 weeks), or the ability of mammals to recover any body weight loss quickly even after feeding at significantly higher exposures (100 mg/kg_{bw}/day). The notifier would like to reiterate that a precautionary, and ecologically relevant, NOEC is 15 mg/kg_{bw}/day as supported by the available information provided in Section B.9.3.1.	**Addendum 5, Volume 3, Section B9**: Page 44-45: The NOEL from the rat 90-day oral study (Haut et al., 1993, summarized in the DAR) indicates that effects on body weight were only detected after 49 days exposure to 5 and 15 mg/kg_{bw}/day in males. 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 after 84 days. 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. On the other hand, 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. Page 53: 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 (Blanckenhagen, 2006). Based on these findings, the ecologically relevant NOAEL, considering a realistic duration of exposure of 2 weeks or less, would be 15 mg/kg_{bw}/day, which is still conservative since it does not take into consideration the ability to recover at significantly higher exposure levels than this. It is therefore acceptable to use this NOAEL for risk assessment for the proposed use of 1,3-D.

Aquatic organisms (B.9.2)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 3 Appendix I.6, page 259	**Notifier** Typographical error; for Anabaena flos aquae, the endpoints should read 120 h or 5 d (not 120 d).	

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)

Section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 3, Appendix I.6, page 267	**Notifier** The source of the NOEC of 11.25 mg a.s./kg soil for seedling emergence (tomato) and vegetative vigour (onion) is unclear; the NOEC should not be higher than the corresponding EC_{50} values (7.4 and 3.8 mg a.s./kg soil respectively). Furthermore, the NOEC for non-target terrestrial plants is not relevant for risk assessment or labelling purposes and should not be reported in the list of endpoints.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	**Notifier** No comments from notifier.	

Appendix: Calculation Error for AOEL

1,3-D AOEL's in the EU Review

The inhalation AOEL is incorrectly calculated from the systemic AOEL, as is shown below:-

Two provisional AOEL's are proposed for 1,3-D:

1) Systemic AOEL = 0.1 mg/kg bw/day, based on the NOAEL from the 90 day inhalation rat study - 10 ppm = 9,72 mg/kg bw/day and supported by the 2 year mouse study with a SF 100. The margin of safety is 1000 to the LOAEL for lung tumours in the mouse study.
2) Inhalation AOEL = 0.066 ppm, equivalent to 0.30 mg/m^3, based the systemic AOEL.

The systemic AOEL was converted to an inhalation AOEL in the original DAR Addendum 3 (B6, dated September 2005) as follows:

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

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

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

Therefore, we can establish a human AOEL of 0.066 ppm, equivalent to 0.30 mg/m^3, which will be used for risk assessment."

The respiration rates are reasonable but not the adjustments for hours or days exposed because:

1. It assumes that humans work for 24 hours a day - the standard international default value is 8 hours
2. It assumes that humans work for 7 days a week - the standard international default value is 5 days

Therefore, using 8-hours/day, 5-days/week the calculation is:

$$\text{ppm (human)} = \text{ppm (animal)} \times \frac{\text{animal respiration rate}}{\text{human respiration rate}} \times \frac{\text{hours animals exposed}}{8\ \text{hr}}$$

ppm in human* = 0.1 x 0.96/0.26 x 6/8 = 0.277 ppm, equivalent to 1.25 mg/m^3

*see Note 1 overleaf

Note 1 – MoE to lung tumours in male mice:

Operator exposure to 1,3-D from use of its products is both intermittent and seasonal – a few days per year for some individuals, always less than 3 months, even for professional contractors. Therefore, proposed AOEL's should NOT be influenced by data from a 2-year mouse study.

However, to confirm the statement made by the DAR/Addenda that the MoE is 1000 to the LOAEL for the benign lung tumours in male mice (that the ECB concluded were not relevant to humans, 31st ATP) using the effect level of 60 ppm, a 1000 SF and a respiration rate for male mice of 2.0 m^3/kg/day:

$$\text{ppm (human)} = \text{ppm (animal)} \times \frac{\text{animal respiration rate}}{\text{human respiration rate}} \times \frac{\text{hours animals exposed}}{8\ \text{hr}}$$

ppm in human = 0.06 x 2.0/0.26 x 6/8 = 0.346 ppm, equivalent to 1.56 mg/m^3

6. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

Identity (B.1, Annex C)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 4 Method of manufacture	FR : The purity of the starting material must be provided.	
(2)	Vol. 4 Identity of impurities	FR : Notifier Dow AgroSciences : Maximum content given for the impurity 5b p10-11 of the additional report Volume 4 is different than this given in the Table C.1.2.3.4. Please RMS correct.	
(3)	Vol. 4 Identity of impurities	FR: Notifier Kanesho Soil Treatment : The impurity 5b is not listed in the list of significant impurities.	
(4)	Vol. 4 Batch analysis	FR : The specifications proposed for impurities 5a and 6 are not in accordance to the batch analysis form USA (pilot scale).	

Physical, chemical and technical properties of the formulation (B.2.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	B.2.2.17a Shelf life Formulation EF-1478	FR : The variation of the pH (1%) during the storage is important (3.75 before storage and 5.33 after storage).An explanation is required.	

7. Mammalian toxicology (B.6)

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.8 identity of the impurities	<<FR>>: The mutagenic potential of several impurities specified above 0.1% has not been investigated, especially impurities 8a,8b,8c which were not present in batch TSN101035, the only batch used in genotoxicity studies whose analytical profile was provided.	QSAR Screening (DEREK analysis) for impurities 8a,8b,8c shows several structural alerts :Mutagenicity, carcinogenicity, hepatotoxicity, nephrotoxicity).

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1. , <<2.3 >>, << ADI>>	<< FR>>: << The margin of safety of 1000 is applied to the LOAEL (12.5 mg/kg bw/day) for liver tumours in the same study (2-year long term and carcinogenicty study) and not to the LOAEL for lung tumour in mice (inhalation study) . >>	In the review report the experts stated that the margin should be at least 1000 between the ADI and the dose level where tumours are observed. As the LOAEL for tumours is 12.5 mg/kg bw/day an additional safety factor of 2 was agreed. The margin of safety is based on the 2-year oral carcinogenicty study in rats and not on the 2-year inhalation study in mice (LOAEL=60 ppm/101 mg/kg bw/day) .

8. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. I level 2 LOEP general comment	FR : according to the LOEP Appendix 1.1: Identity (Annex IIA, point 1) - p. 205, 1.2-dichloropropene is a relevant impurity.	No mention was given on [redacted] whereas in the residue section it was.
(2)	Vol. III B.7.6 Residues resulting from supervised trials	FR: As [redacted] was considered toxicologically relevant, because of its oral toxicity (see B.7.15 Estimation of the potential and actual exposure though diet and other means, p. 55); shouldn't it have been assessed?.	
(3)	Vol. III B.7.6 Residues resulting from supervised trials	FR: It would be helpful to know exactly the concentration of each impurity in the batch(es) used in the field trials, and then to know the exact application rates of these impurities. Tables 7.6-1 to –4 (pp..49 – 52) only show the rate of **total product** applied in kg as/ha.	this information is needed to establish the validity of these studies and to make a link between residue levels and applied impurities.

9. Environmental fate and behaviour (B.8)

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.8.6.2.1, Estimation of concentration in surface water, Drainage/Lateral flow	FR: The whole description of the DripFume model is very clear, apart from the partition of 1,3-D between the 3 phases on page 63. The relationship used to describe the partition should be explicitly given. On page 64: please give the source of the weather data. On page 68: we cannot make much of figure 8.6.2.1-3 since it is not easily readable. On page 72: we agree with the proposition of the mitigation measure for the aquatic systems.	
(2)	Vol. 3, B.8.10.1.1, Monitoring data on Groundwater, Monitoring conducted in Greece	FR: When does the application occur on the Tymbaki and Irapetra basins? Considering the high mobility of the a.i, and the possibility of preferential pathways to the GW (see comment on page 87), this point might be of importance.	

10. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, LoEP, Table with TER values for birds and mammals	FR: Some values from tier 2 calculations are missing compared to Tables from vol.3, and there are some mistakes in the reported values: - tier 2 acute TER values for earthworm-eating and insectivorous birds are missing, - values reported as acute tier 2 for earthworm-eating and insectivorous birds are in fact short-term values. - Tier 2 acute TER values for herbivorous mammals are missing	
(2)	Vol. 3, B.9.3.1 Effects on terrestrial vertebrates other than birds, 90 days exposure	FR: We agree with RMS proposal for the NOEL value to be set at 5 mg/kg/bw/d	

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(3)	Vol. 3, B.9.2.5 Chronic toxicity to aquatic invertebrates, Table 9.2.5-1	FR: It could be useful to indicate in this table the statistical results expressed as difference statistically significant from the control.	
(4)	Vol. 1, LoEP, Toxicity data for aquatic species	FR: There are typo errors in the names of green algae: write ***Selenastrum capricornutum*** instead	

Section 5 - Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		of *capricornotum*, and ***Skeletonema costatum*** instead of *Skeletonenam constatum*	

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol. 3, B.9.4.7 Risk assessment to bees, Inhalation study	FR: It would be useful to add in the text that the amount of 190 L Telone II/ha corresponds to 224 kg/ha. This information is available in other paragraphs, but it would help the risk assessor to have this information in the paragraph related to risk assessment to bees.	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	Vol. 1, LoEP, Effects on non target plants	FR: The NOEC for seedling emergence for the technical 1,3-D is the one of soybean and not tomato	

11. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

NL did not consider this section.

12. Mammalian toxicology (B.6)

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, Vol. 3, B.6.8 Other toxicological studies – identy of the impurities	NL: A complicated evaluation has been performed with regard to the toxicological relevance of the impurities, based on literature data, the QSAR model TOPKAT and calculations on potential toxicity. It should be discussed whether this evaluation is acceptable and sufficient.	

Summary of mammalian toxicology and setting ADI, AOEL, ARfD (B.6.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report Vol. 3, B.6.4 and B.6.4.5 and Addendum III (Sept. 2005), B.6.10.2.3, AOEL estimation	NL: The RMS considers the reference values and risk assessment now as definitive. In EPCO 23 (May 2005), the ADI, ARfD and a systemic AOEL of 0.1 mg/kg bw/day (which would correspond to a dose of 0.1 ppm) were agreed. However, the RMS was asked to recalculate the inhalatory AOEL based on the systemic AOEL. The RMS presented this in addendum III (Sept. 2005), which has not been peer reviewed. For this calculcalation a mean respiration volume for humans was used (mean over 24 h) which is too low for the working population. A higer value for respiration during effort (working hours) should be used: 10 m^3/**8**	

Section 2 - Mammalian toxicology (B.6)

Summary of mammalian toxicology and setting ADI, AOEL, ARfD (B.6.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		hours, which is about 0.14 m^3/kg/**8** hours.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report Vol. 4, C.1.2.3-3 – information of batches used in toxicological studies and residue data	NL: There is no assessment on the equivalence of the batches used in the tox studies and the technical specification.	

Section 3 - Residues (B.7)

13. Residues (B.7)

NL did not consider this section.

14. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
1	B.8.6.2.1 Drainage /lateral flow a) Shank use. Field conditions a.1) Description of DripFume model	NL: The surplus water is not only available to the soil system, but also for horizontal and vertical transport. It does not become clear how this is accounted for in the model.	
2	B.8.6.2.2 Run off; Table 8.6.2.2-1	NL: The annual rainfall in the EU R-scenarios is compared to the rainfall + simulated rain event in the US study. How are the rain events situated towards the application events in the R-scenarios. In other words: is the US study indeed a realistic worst case?	
3	B.8.6.2.4 PEC sw	NL: Regardless of the fact that it has not been made clear that the US study represents a worst case situation for run off, no PECsw calculations were done for the R-scenarios. The contribution of run off to PECsw therefore has not been addressed.	
4	PECgw	NL: in the assessment of the GW monitoring false positive findings are discussed in more detail. The possibility of false negative measurements is not addressed. (e.g. origin of the groundwater from the treated aera).	
5	B.8.10.1.4 Borehole vulnerability assessment	NL: more detail on the method used for ranking vulnerability of the individual boreholes per country.	

Section 5 - Ecotoxicology (B.9)

15. Ecotoxicology (B.9)

NL did not consider this section.

16. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

Identity (B.1, Annex C)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 4, Table C.1.2.3-4	DE: It seems that the proposed specification is acceptable from an analytical point of view.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	List of end points	DE: The RMS should consider to use the current version (September, 2005) of the harmonised template.	

17. Mammalian toxicology (B.6)

Genotoxicity (B.6.4)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.4, Genotoxicity	DE: In the whole, data suggest that genotoxicity of 1,3-dichloropropene depends on a sufficient amount of glutathione to be present to detoxify the active substance. Because glutathion depletion is not so uncommon, this is a further reason for a very restricted use (professional users wearing RPE only, exposure of bystanders should be avoided).	

Long-term toxicity and carcinogenicity (B.6.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.5, Carcinogenicity	DE: 1,3-dichloropropene caused liver tumours in rats and bladder tumours in mice following long-term oral administration and lung tumours in mice following inhalation. The mechanism behind carcinogenicity has not been elucidated so far although there were clear NOAELs for tumour formation obtained. A genotoxic mode of action is not very likely but, because of the uncertainties with regards to mutagenicity and since there is no convincing alternative explanation of carcinogenicity, cannot be completely excluded. However, in spite of this evidence, the ECB did not classify 1,3-dichloropropene for carcinogenicity (see comments on Vol. 1, 2.1.4). The reasons behind this decision are not known to us.	

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3 (Addendum 4), B.6.8, Toxicological relevance of impurities	DE: The toxicological assessment of most impurities, their hazards and relevance is confined to either experimentally determined or theoretically predicted data on acute toxicity. Information on genotoxicity and carcinogenicity is scarce and limited to very few impurities although these are crucial points for evaluation	To our knowledge, the approach taken to calculate the (additional) hazard by impurities is rather new to the EU, at least in the field of pesticides. It should be discussed between EFSA and MS whether it is applicable.

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		of the technical active substance According to the new Vol. 4, there are still uncertainties about the specification. Thus, the potential health impact of the impurities should be considered a potential ”area of concern” to which special attention should be given by the MS when national authorisations are to be granted.	

Toxicity of the product(s) (B.6.11)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.1.4, Classification and labelling of the preparation	DE: Classification and labelling of the preparations under consideration of classification and labelling of the active substance should be discussed on the PRAPeR meeting.	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.3, Impact on human and animal health, Vol. 3, Appendix 1, List of end points and Addendum III (September, 2005)	DE: Using all available data, RMS considers that intended uses will be acceptable, if PPE and RPE (respiratory mask with filter for organic vapours) are used. However, risk assessment is only based on inhalation exposure. It is assumed that dermal exposure probably will not occur, if use instructions are followed. In the case that	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		dermal exposure during mixing/loading or application cannot be excluded definitively, risk assessment should be based on possible dermal and inhalation exposure (realistic worst case). Risk assessment is based on 8 h $_{TWA}$ concentrations. However, measured mean air concentrations during (shorter) mixing/loading tasks, re-entry (e.g. repairing the irrigation system) or other key tasks are far above the AOEL of 0.3 mg/m^3 (up to 75.61 mg/m^3 during intended uses). Therefore, an acute reference value for inhalation exposure has to be established. Intended uses will be only acceptable for operators if engineering controls are available to protect operators including the provision and use of personal protective equipment as well as air monitoring devices to ensure that concentrations never exceed occupational exposure levels. In addition, measured concentrations outside greenhouses (1 m) are also above the AOEL (particularly 0-6 hours after application). Therefore, prohibited areas for bystanders are necessary. Re-entry should be allowed only, if no active substance is detectable above reference values. Hence, application should be restricted to well-trained authorised personnel only.	
(2)	Vol. 3, Appendix 1, List of end points and Addendum III	DE: Representative uses include outdoor and greenhouse applications. However, risk assessment was performed for greenhouse	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	(September, 2005)	applications only!	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.1.4, Classification and labelling (active substance)	DE: 1,3-dichloropropene caused liver tumours in rats and bladder tumours in mice following long-term oral administration and lung tumours in mice following inhalation. Although it is acknowledged that the ECB did not classify and label the as for carcinogenicity or mutagenicity (see 31.ATP). However, with regard to carcinogenicity, a higher safety factor was agreed by the EPCO meeting for deriving the ADI. U.S. EPA had classified the substance in 1998 as a B_2 (probable human) carcinogen.	

18. Residues (B.7)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.6, Residues resulting from supervised trials	DE: It is assumed that all residue concentrations refer to matrix 'fruit'.	It is not unambiguously stated which matrix was investigated when it is referred to tomatoes and peppers.

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Appendix 1.4 (LoE)	DE: Higher consumer exposure from an amplified European data set (PRIMo).	Although almost exclusively driven by the current LOQs of the regulation (EC) no 396/2005, TMDI based on PRIMo nevertheless suggests almost 20 % ADI (UK toddler); in addition highest percentages of ARfD are found to be 1.5 % for BE children due to tomato consumption and 1.6 % for DE children for bell peppers.

19. Ecotoxicology (B.9)

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, Addendum V, point B.9.5.2, Field tests NTAs	DE: Evaluation of the field study by Small (2006) concerning potential effects on Collembolans is not possible since no detailed data are presented. Besides that, such field studies without analytical confirmation of exposure and without reference testing (at least this is not mentioned in the report) are usually not acceptable, despite the statement that the study was performed under GLP.	

20. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

Identity (B.1, Annex C)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 4, C.1.2, technical specification	UK: It should now be possible to reach agreement on a technical specification. The very high application rates potentially introduce new considerations beyond normal technical specification criteria (e.g. amount getting into water etc.) and might raise risk management issues. The WHO Environmental Health Criteria publication (#146, 1993) recommends that the potential for contamination from 1,3-D impurities is reduced by lowering the impurity levels. The impurities are likely to be volatile and probably unlikely to bioaccumulate. Overall the as low as reasonably practicable (ALARP) approach would seem appropriate for these impurities.	

Physical and chemical properties of the active substance (B.2.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.2.1.26, Hydrolysis of impurities	UK: we assume (since not stated otherwise) that the preceding hydrolysis study, GHE-P-11384 by Eversfield & Knowles was done in the dark, and the 7 more stable impurities were analysed for in GW monitoring studies. If they were analysed for and not detected (and these studies are accepted as valid) then we are content with the RMS	

Physical and chemical properties of the active substance (B.2.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		conclusion.	

Methods of analysis (B.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.5.1.1.2, analytical method for determination of significant/relevant impurities in formulation	UK: A confirmatory technique is still required for this method. The Notifier has stated that GC-MS can be used however there is no validation data or method details provided for this technique. According to current guidance this is required.	
(2)	Vol 3, B.5.2.2, analytical method for plant material and B.5.3.2, analytical method for water	UK: The residues methods presented for crops and water do not meet the guidelines with respect to specificity. GC-MS is only considered specific for pre-registration methods when 2 or more ions with m/z ratio > 100 are used and for post registration monitoring methods when 3 or more ions with m/z ratio > 100 are used – in most instances for these methods the ion fragments used are < 100. However we note the highly volatile nature of the compounds and that the RMS states this method is not required for monitoring purposes.	

21. Mammalian toxicology (B.6)

Genotoxicity (B.6.4)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.4 and 6.4.5, Genotoxicity and carcinogenicity	UK: Given the clear decision by the expert committee (who make what are in effect the legally binding decisions for C&L) we agree that we should follow the line that this material is not a genotoxin or a carcinogen. The reference values and risk assessments can therefore stand.	The carcinogenic effects may have been confounded by the use of a carcinogen as a stabiliser in older technical material? This might also apply to the mutagenicity effects (also possibly high dose) – the point is that the mutagenicity and carcinogenicity effects had some significant uncertainty.

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B .6.8, identity of the impurities	UK: The Notifier seems to have done a lot of work, including lowering the levels of impurities in technical material to as low as feasible (many below the normal cut-off values). Manufacturing 1,3-dichloropropene with lower amounts of 1,2-dichloropropane has been an ongoing process since the 1980's according to WHO documents. A lot of identification work seems to have been done (18? Impurities identified). It should now be possible to get a revised tech spec agreed, and we note the company are proposing to further refine	

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		their method of manufacture only if necessary	
(2)	Vol. 3, B .6.8, identity of the impurities	UK: From the data available for these impurities and they seem to be of lower toxicity than the active with mostly quite high NOAELs (lots of data for 1,2-dichloropropane). Some (older) studies in the Dossier may have contained significant (>1%) impurity levels. Combined with the low impurity level manufacturing process it would seem reasonable to consider these impurities acceptable in a conventional assessment. The very high application rates potentially introduce new considerations beyond normal technical specification criteria (e.g. amount getting into water etc.) and might raise risk management issues. The WHO Environmental Health Criteria publication (#146, 1993) recommends that the potential for contamination from 1,3-D impurities is reduced by lowering the impurity levels. The impurities are likely to be volatile and probably unlikely to bioaccumulate. Overall the as low as reasonably practicable (ALARP) approach would seem appropriate for these impurities.	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Section 2 - Mammalian toxicology (B.6)

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.14, exposure Protected use / Drip application	UK: The highest concentration immediately after application is 242 mg/m^3 (Table 6.14.1.7,). This would require RPE of the type self contained breathing apparatus (SCBA) to allow re-entry, i.e no exposure will occur. Reducing this exposure level by 95% as discussed by the evaluator would result in exposure to concentrations of 12 mg/m^3.	
(2)	Vol. 3, B.6.14, exposure Protected use / Drip application	UK: For drip application the data suggest concentrations close to the glasshouse (i.e. <5 metres) at the time of/soon after application have the potential to exceed the 0.3 mg/m3 AOEC (We agree that for this a.s. the AOEL should be expressed as an air concentration) - average levels ranging from 0.6 to 1.4 mg/m^3 . However it would be reasonable to suggest that bystanders should not be permitted to get this close to glasshouses where 1,3-D was being used. At a more realistic (minimum) distance (>5m) the highest air concentrations are below the 0.3 mg/m^3 AOEC value.	
(3)	Vol. 3, B.6.14, exposure Protected use / Drip application	UK: We note there appear to be data for only 2 sites (study MG 48 and MG 49) If so are we happy they have provided sufficient data to address the potential variability in air concentrations?	
(4)	Vol. 3, B.6.14, exposure Soil injection	UK: The study covers 37 operators. Where RPE were used with an assigned protection factor (APF) of 20, i.e. giving 95% protection, the exposures would be within the 0.3 mg/m^3 AOEC. The 8 hour TWA values are more useful for considering	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		operator exposure. Thus those involved in the application work tasks, including installing the sheeting/bed shaping immediately after the application, will need to use RPE.	
(5)	Vol. 3, B.6.14, exposure Soil injection	UK: For bystanders, the average air concentration values for bystanders at the edge of a field after treatment (Table 6.14.6-1, p280) were up to 0.78 mg/m^3 which is above the AOEC (data from 3 sites). This value was obtained from a monitoring period of 7 days after treatment. Concentrations averaged over a 14 monitoring period were all below the 0.3 mg/m3 AOEC value. Do we know how long the peak concentration lasted for and what is the tox significance to an exposure at around 0.8 mg/m3 for this duration? This is important to enable assessment Of risk to those living next to the treated area.	

Section 3 - Residues (B.7)

22. Residues (B.7)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.6, residues resulting from supervised trials	UK: It would be helpful to know what method was used to determine the impurities in the crops and if it was validated. However generally we agree that the information provided indicates that residues of the impurities will not be of concern in plants at harvest. This is based on the fact that the use is a soil treatment with a 2 week interval before planting.	

23. Environmental fate and behaviour (B.8)

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B. 8.6.2.1, drainage/lateral flow	UK: Use of the DripFume model is a new approach to addressing drainage to SW and as such it is difficult to comment on its validity in the time available without further evaluation.	
(2)	Vol 3, B. 8.6.2.1, drainage/lateral flow	UK: DripFume is reported to be a modification of CHAIN 2D model (Simunek and van Genuchten, 1994, also used by the USDA) which is provided here for 1,3-dichloropropene to simulate lateral transport for shank injection in the field. Again this is a novel approach and it is difficult in the time available to comment on the validity of the model, representativeness of assumptions about field configuration to EU practice, or input parameters in the time available. The potential for lateral transport following drip irrigation is addressed by experimental evidence.	
(3)	Vol 3, B.8.6.2.2, run off	UK: The applicant has compared to the rainfall, hydrologic soil group and % slope with FOCUS run-off scenarios and claims it appears to be worst case. This seems to be the case for these parameters and that maximum run-off /day was higher than for FOCUS scenarios. However, should there also be some comment about temperature in the justification for geo-climatic conditions being comparable, as temperature could influence extent of volatilisation and	

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		therefore residues remaining in soil available for run-off? PECsw concentrations were predicted for various run-off percentage loadings from 0.001-1%. The PECsw referenced is 2.24 ug/l based on 0.003% loading, we presume that this % loading was accepted previously as being appropriate.	
(4)	Vol 3, B.8.6.2.3, deposition from vapour phase	UK: The approach taken of assuming 100% of mass from 1 litre if air is deposited into 1 litre of water, based on typical peak air concentration of 500 µg/m^3 to give PECsw of 0.5 µg/ is conservative. For metabolites no formation fraction is taken into account, so again this is a conservative approach. Without raw data it is difficult to say how typical 500 µg/m^3 concentration is and whether a more worst case or maximum concentration should have be assumed, (in the past the maximum concentration measured from bystander monitoring trials has been assumed in calculating deposition). However, the approach taken is conservative, so probably acceptable on balance.	
(5)	Vol 3, B.8.6.2.4, PEC sw	UK: RMS has run FOCUSsw for comparison with the D (drainage) scenarios and these gave comparable results, (slightly higher for S. EU and less worst case for N EU). On balance we can accept the PECsw approaches as reasonable. The modelling approaches for lateral transport are novel, but RMS has obtained comparable results	

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		with FOCUS. Lateral transport contributed the most to overall PECsw. Justification for use of US field data for run-off and deposition concentrations have been made. (Though these appear to be minor contributions compared to lateral transport).	

Fate and behaviour in air and PEC in air (B.8.7 – B.8.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.8.7.2.1, volatilisation, correlation of geoclimatic characteristics of US field studies to EU conditions	UK: A justification is provided for the geoclimatic comparability for these US volatilisation studies based on soil temperature and moisture maps, demonstrating similar conditions for 4 of the US sites to some EU situations. Perhaps a comment should be added on how the air concentrations seen at these 4 sites relevant to EU, compare to the typical concentration that was used above.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.8.10.1, groundwater monitoring	UK: One of the reasons given for positive findings of 3-chloroacrylic acid at the Spanish site was the	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	study	proximity of agricultural activity to the well, but it is not clear from the report what the distance between treated site and well was and how this compared for other sites. (Though more detailed information may be in the applicant's report). Information on what was applied is not clear so it is difficult to what was actually applied at the sites near to the wells, and thus for example how this use might compare to UK use. We were previously concerned that lack of detection in UK monitoring might be due to low use rates. What was the depth of the well where positive findings were detected? The depth of water table may also influence concentrations detected i.e. higher concentration if shallow. Only the range of depth of wells per country is reported, (the lowest range for Spain was 3m compared to 16m for UK) not information for individual wells.	
(2)	Vol. 3, B.8.10.1, groundwater monitoring study	UK: Overall, the UK would want to evaluate more detailed data at MS level before relying on this monitoring for a national regulatory decision.	For example additional information might include, typical use, over what area and to what crops/ methods. Information on the depth and water level of individual wells and their distance from treated sites (and preferably details of treatment applied at that site). Information on sampling regime and frequency and storage stability of samples. (It may be that this level of detail is available in the original report). Some information on the potential for recharge of the aquifers that were monitored from untreated areas, and therefore potential dilution of concentrations might be useful. We would also wish to see a comment addressing what expected usage would be in UK and how an increase in use of this active ingredient (in terms of area of the catchment treated) would affect potential increase in

Section 4 - Environmental fate and behaviour (B.8)

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
			concentrations that could be present in groundwater.

24. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.1.3, bird subchronic tox and reproduction	UK: This study is considered acceptable for risk assessment purposes. It is noted that two exposure periods were used, namely a 7 and 20 weeks, it is noted that the NOEC from both studies is the same, i.e. 36 mg a.s./kg bw/day.	
(2)	Vol 3, B.9.1.4, risk assessment for birds	UK: In order to carry out the risk assessment the Notifier has carried out two residue studies to determine the likely residues in potential items of birds and mammal food. The study on residues in tomatoes is considered to be of limited value as birds and mammals are unlikely to graze tomato plants; however this study does indicate that the compound is not systemic and hence the risk to birds and mammals from the consumption of plants grown in treated soil is likely to be low. The study carried out to determine the residues in soil organisms is considered to be acceptable and hence can be used for risk assessment purposes. It is interesting to note the difference between the residues in earthworms in the study conducted in NMS with those in the study conducted in SMS. It would have been useful to have had a more detailed consideration of why there is such a difference. It would appear that environmental factors as well as availability of earthworms are likely to play a major role in the likely residue.	

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		On the basis of what is submitted it would appear that the risk to birds and mammals that consume earthworms is low, however as this is reliant on a SEU specific field study, it is felt that should use be extended to NEU then the previous study is likely to be more relevant.	
(3)	Vol 3, B.9.3.1, effects on terrestrial vertebrates other than birds	UK: It is noted that the RMS has proposed a change to the long-term mammalian endpoint, it is unclear from what is written why the change has focused on body weight change; does the endpoint cover reproductive endpoints as well? Was body weight the parameter driving the selection of the previous endpoint?	
(4)	Vol 3, B.9.3.1, effects on terrestrial vertebrates other than birds	UK: A field study on the effects of 1,3-D to small mammals has been presented. It is felt that this study can only really be used as supplemental evidence.	

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.2.9, aquatic risk assessment	UK: If fate confirm that the PEC values are appropriate then the risk to aquatic life is low.	

Bees and non-target arthropods (B.9.4 and B.9.5)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.4.7, risk assessment for bees	UK: A new honeybee toxicity study has been submitted. This is a novel study and consequently the risk assessment is somewhat novel as well; however the risk assessment indicates that there are large margins of safety between the likely exposure levels and the toxicity endpoints, therefore on the basis of the data submitted, the risk should be low.	
(2)	Vol 3, B.9.5, other non-target arthropods	UK: A new study has been conducted and evaluated; there is a lack of detail in the study summary to draw conclusive findings, for example there is a lack of details regarding the number of individuals found. The lack of soil analysis is considered to be a major deficiency and not addressed by the fact the study was carried out to GLP. It would be preferable if further details were provided. It is also proposed that this study is discussed at an expert meeting.	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.9, risk assessment sewage treatment	UK: Potential contamination may occur, therefore RMS has proposed a restriction that washing water from cleaning tools should not be disposed of in to surface water; this is should be flagged and dealt with at a MS level.	

There are a number of aspects to this assessment that are novel and we would suggest that expert discussion will be required. As a minimum I would suggest Chemistry - to reach a clear agreement on the appropriate tech spec taking account of the novel issues raised by the high dose rates; Tox to discuss the risk to bystanders and neighbours; pr environmental fate to confirm the PECs derived from novel modelling and experimental approaches; ecotox to examine the novel approaches adopted in generating the data.

25. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

Identity (B.1, Annex C)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Add 2 to Vol. 4,rev.1, Table 3, p. 12	EFSA: it seems that in the case of the a.s., based on the QC data from Dow and the batch data from KNS a higher specification can be set. The QC data do not support the specification for the a.s.	
(2)	Add 2 to Vol. 4,rev.1, Table 3, p. 13	EFSA agrees with RMS in setting a data gap for batch data for the impurities specified but not measured in the technical originating from the KNS source	
(3)	Add 2 to Vol. 4,rev.1, Table 4, p. 14	EFSA: is there any information about the sources of the boiling point and vapour pressure estimations?	
(4)	Add 2 to Vol. 4,rev.1, III. Summary of Impurities in Telone II, p. 16, Table 2, p.11, Table 3, p.12	EFSA: if only these 6 impurities are expected to be at above 0.1% level, it is not clear why specifications are given for the other impurities in Tables 2 and 3? EFSA agrees with the evaluation and conclusions of the RMS, specification should be based on data	

Identity (B.1, Annex C)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Additional report to Vol. 4, Foreword, p. 4-5	EFSA: clarification is needed what exactly RMS meant by the request to consider „Addendum 2 to Vol 4' and „Corrigendum to addendum 2 to Annex C' as background documents for the evaluation? Is the Additional report replacing the addenda or all of them should be considered together? In the addenda there is a joint specification, in the additional report both notifiers have individual specifications. There are QC data, batch data from different years, pilot batch data, which one should be taken into account when considering the specifications? It is stated that the new specification is that one in Table C.1.2.3-4, which are the data supporting this specification?	
(6)	Additional report to Vol. 4, Table C.1.2.3-4 Five batch data, p. 25	EFSA: the manufacturing dates of the batches are missing	
(7)	Additional report to Vol. 4, Table C.1.2.3-7 Pilot scale batch data, p. 32; Additional report Vol.1 1.2.7 manufacturer of the a.s. p. 8	EFSA: clarification is needed if the US source still has not to be considered for Annex I inclusion	
(8)	Additional report to Vol. 4, Table C.1.2.3-4 Five batch data, p. 25, Table C.1.2.3-5 Five batch data, p. 28, Table C.1.2.3-6 Five batch data, p. 29	EFSA proposes to discuss the specification on an expert meeting after the clarification on which data to use for setting the specification(s) and on the final decision on the tox/ecotox relevance of the impurities	

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

Identity (B.1, Annex C)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(9)	Additional report to Vol. 4, Table C.1.2.3-4 Five batch data, p. 25, Table C.1.2.3-5 Five batch data, p. 28, Table C.1.2.3-6 Five batch data, p. 29 and Additional report Vol.3 , B.6.8 Identity of impurities, p. 29	EFSA: it is not clear what is/are the specification(s) for the technical material(s)	
(10)	Additional report Vol.1 1.4.5.1a Identity and content of a.s., p. 10	EFSA: it is true that the FAO tolerance for formulations above 50 % is ±25 g/kg, however not for the technical material. In this special case the product contains 96% technical, in conclusion it would be more appropriate to have a minimum purity for the product of 965 x 0.96 = 926 g/kg and not 926-25. In any case 926 is not the nominal content.	
(11)	Additional report Vol.1 1.5.3.2a Proposed application rates., p. 11	EFSA: the absence of the mass unit (g) in 1132 as/L is probably a typo	
(12)	Additional report Vol.1 1.5.3.2b Proposed application rates., p. 14	EFSA: the absence of the mass unit (g) in 1180 as/L is probably a typo	
(13)	Additional report Vol.1 2.1.1 identity, p. 18 and 1.2.9 Specification of purity of a.s. p.8	EFSA: clarification is needed on the correct value of the minimum content of *cis* and *trans* isomer	

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

Physical and chemical properties of the active substance (B.2.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Physical, chemical and technical properties of the formulation (B.2.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Further information (B.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Methods of analysis (B.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

26. Mammalian toxicology (B.6)

Example (to be deleted):

(1)	Vol. 3, B.6.1.2 through B.6.1.4, Absorption, excretion and distribution studies	UK: Justification for the adequacy of the use of a single radiolabel in these studies may be necessary.	

Toxicokinetics (B.6.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Acute toxicity (B.6.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Short-term toxicity (B.6.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Genotoxicity (B.6.4)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3 B.6 Additional report	EFSA: it is acknowledged that 1, 3-dichloropropene was discussed at the meeting of the European Chemicals Bureau on Classification and Labelling in March 2006, and that the a.s. was not classified as mutagenic Cat. 3 R68. Can the RMS give further information on whether the database on which the ECB based its decision is the same as the one available in the peer review process?	

Long-term toxicity and carcinogenicity (B.6.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3 B.6 Additional report	EFSA: it is acknowledged that 1, 3-dichloropropene was discussed at the meeting of the European Chemicals Bureau on Classification and Labelling in March 2006, and that the a.s. was not classified as carcinogenic Cat. 3 R40. Can the RMS give further information on whether the database on which the ECB based its decision is the same as the one available in the peer review process?	

Reproductive toxicity (B.6.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Reproductive toxicity (B.6.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Neurotoxicity (B.6.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3 B.6 Additional report B.6.8	EFSA: after the first discussion of the a.s.(May 2005) , the applicant was asked to address the toxicological relevance of the already known polychlorinated and two unknown polychlorinated impurities, to be identified as well. Furthermore, the section on physical chemical properties asked whether taking into account the high amount applied, there was a concern for the polychlorinated impurities. This point was left open as a conclusion could not be drawn up, because of lack of information.	

Section 2 - Mammalian toxicology (B.6)

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		A new technical specification is now proposed, to be confirmed by the physical chemical properties section. It contains 18 impurities. For 4 of them only, toxicological information in a tabular form are reported in the additional report. The comparison with the former proposed specification and with the batches tested in the mammalian toxicology datapackage is missing.	

Summary of mammalian toxicology and setting ADI, AOEL, ARfD (B.6.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3 B.6 Additional report B.6.8	EFSA: the RMS confirms as definitive the reference vales proposed as “provisional” in the previous assessment. TO be confirmed by experts.	

Toxicity of the product(s) (B.6.11)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Section 2 - Mammalian toxicology (B.6)

Dermal absorption (B.6.12)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Toxicity of non-active substances (B.6.13)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

27. Residues (B.7)

Storage Stability (B.7.0)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Metabolism in plants (B.7.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Metabolism in livestock (B.7.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Residue definition (B.7.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Section 3 - Residues (B.7)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.6 Supervised trials	EFSA: In B.7 there is no information with regard to the identity of the batches used to conduct the individual set of residue trials, neither any reference where this information can be found.	
	Vol. 3, B.7.6 Supervised trials	EFSA: In tables 7.6-.1 to 7.6-4 the sum of 6 impurities is reported to be <LOD. Does the LOD of 0.003 mg/kg reported at the bottom of the table refer to the sum of impurities or to the individual impurities?	
	Vol. 3, B.7.6 Supervised trials	EFSA: The analytical method used in the residue trials (data generation method) should be reported in B.7, as well as validation data for this method /these methods.	
	Vol. 3, B.7.6 Supervised trials	EFSA: 6 of the process impurities (1, 2, 3, 5b, 5c and 8a) are analysed for in residue trials. However there are more process impurities than the ones selected. What was the rational for choosing them? For impurity 6 it was mentioned it is considered toxicologically relevant, but it was not analysed.	

Processing (B.7.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Livestock feeding (B.7.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Succeeding/Rotational crops (B.7.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.15 Exposure assessment	EFSA: It is understood that the main rational used to conclude on the acceptability of consumer exposure to impurities was their very similar volatility and physical chemical properties when compared to 1,3 D. It was therefore considered not necessary to investigate all impurities. It is noted that in particular 9a and 9b (oxiranes) are predicted to have lower vapour pressures than 1,3-D, and impurity 13 is structurally dissimilar. This should be addressed.	

Section 3 - Residues (B.7)

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	Vol. 3, B.7.15 Exposure assessment	EFSA: The assessment based on very similar volatility and physical chemical properties of the impurities to 1,3 D is moreover pending clarification of sources for vapour pressure and phys.-chem. property data in section 1.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

28. Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Adsorption, desorption and mobility in soil (B.8.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

PEC in soil (B.8.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Fate and behaviour in water and impact on water treatment procedures (B.8.4 – B.8.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Section 4 - Environmental fate and behaviour (B.8)

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, addendum 3 B.8.6.2-4, proposed predicted estimated concentrations in surface water for 1,3-D and its metabolites: page 73	EFSA: It is stated that ‚a buffer zone of 3-5 m was proposed by the notifier as a mitigation to aquatic sysyems', but then information is only presented for exposure at distances of 1m and 3m from the crop. No information is presented for 5m?	

Fate and behaviour in air and PEC in air (B.8.7 – B.8.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Definition of the residues (B.8.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Monitoring Data (B.8.10)

Section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(2)	Vol. 3, addendum 3 B.8.10.1, groundwater monitoring conducted in Greece: pages 77 to 88.	EFSA: The information reported in the additional report on well characteristics is not sufficient to draw any conclusion on the pertinence of this Greek monitoring exercise. However EFSA notes more detailed information appears to be contained in the original study report.	
(3)	Vol. 3, addendum 3 B.8.10.1, groundwater monitoring.	EFSA: In the original EFSA conclusion it was noted that for the monitoring program in France inadequate data on soils, cropping, hydrogeology and climate were reported. No additional information regarding this has been reported in the additional report. Without further information the usefulness of the French data is compromised.	
(4)	Vol. 3, addendum 3 B.8.10.1.2, Evidence of 1,3-D use in the areas of monitoring pages 88-90	EFSA: Whilst sales figures have been presented, no information on use rate recommendations over the monitoring duration or in the preceding years to the commencement of monitoring is reported. Clarification of this, to compare to the applied for intended use is essential. For the Sales figures for Italy France and the UK some of the units for the figures presented are omitted. It is essential the units associated with the numbers presented are clarified.	
(5)	Vol. 3, addendum 3 B.8.10.1, groundwater monitoring conducted in Greece: pages 86 to 88.	EFSA: No information has been presented on whether the soil fumigant / insecticide active substance 1,2-dichloropropane was authorised for use in Greece prior to its non inclusion in annex 1 (products should not have been used after January 2004 in line with the pertinent non inclusion	

Monitoring Data (B.8.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		decision). Was 1,2-dichloropropane authorised for use in Greece on the crops grown in the Tymbaki basin in the vicinity of Well B13HER007 in the past?	
(6)	Vol. 3, addendum 3 B.8.10.1, groundwater monitoring conducted in Greece, analysis of impurities: pages 84 to 85.	EFSA: 6 of the process impurities (1, 2, 3, 5b, 5c and 8a) are analysed for in well samples and an explanation for not analysing another 5 (impurities 4, 5a, 6, 7 and 8b) is provided. However there are another 6 process impurities (9a, 9b, 10, 11, 12 and 13) not analysed for in the monitoring exercise? What was the rational for this? In particular 9a and 9b ([redacted]) are predicted by QSAR to have significantly higher water solubilities and lower vapour pressures than 1,3-D so are least likely to be covered by the available monitoring results for the active substance and other impurities. Impurity 13 is also structurally dissimilar to 1,2-D and for this moiety there are not even any QSAR values reported? This impurity (13) would also have been a good candidate to have been monitored for?	

Environmental fate and behaviour of process impurities (B.8.11)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Section 4 - Environmental fate and behaviour (B.8)

Environmental fate and behaviour of process impurities (B.8.11)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(7)	Vol. 3, addendum 3 B.8.11.1, hydrolytic degradation. Stability of Telone impurities in water: pages 96 to 97.	EFSA: Experimental data is presented that demonstrates that 5 of the process impurities (4, 5a, 6, 7 and 8b) are rapidly hydrolysed in water such that they are very unlikely to be able to leach to groundwater. This is a reasonable argument. However no assessment has been made of the expected hydrolysis breakdown products of these impurities that would still have the potential to leach to groundwater. Such a consideration would appear appropriate.	
(8)	Vol. 3, addendum 3 B.8.11.2, Phys-chem properties of process impurities: pages 98 to 99.	EFSA: There is of course uncertainty in QSAR estimates and such estimates would not usually be accepted for assessing groundwater exposure of substances that will be applied at amounts in the range of 22 to 138 g/ha (estimated range for the 6 impurities 9a, 9b, 10, 11, 12 and 13 that are not currently covered at all by any monitoring exercise). Whilst it might possibly be accepted to use a QSAR approach for the more structurally related compounds to 1,3-D (short chain aliphatic chlorinated compounds) this is much more difficult to accept for impurities 9a, 9b ([redacted]) and 13. If the QSAR approach might be considered to have some value for 9a and 9b (oxiranes), then the estimated values indicate that these compounds might have a significantly higher leaching potential (much higher water solubility and lower vapour pressure indicated)	

Environmental fate and behaviour of process impurities (B.8.11)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		than measured for 1,3-D and estimated for the more closely structurally related impurities. Not even QSAR information was presented for compound 13?	
(9)	Vol. 3, addendum 3 B.8.11.2, Phys-chem properties of process impurities: pages 98 to 99.	EFSA: There is a potential concern for long range atmospheric transport of 9 of the impurities that are expected to be volatile (they have atmospheric half lives estimated by the Atkinson calculation of >2 days). The estimated application rate range of these 9 impurities can be up to 28 to 340 g/ha.	
(10)	Vol. 3, addendum 3 B.8.11.2, Phys-chem properties of process impurities: page to 99.	EFSA: Please check the name given to the oxirane metabolite in table 8.11.2-1. Ethyl is written, a compound with this name is not listed in volume IV annex C. The oxiranes listed in volume IV annex C are indicated as methyl?	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

29. Ecotoxicology (B.9)

General (B.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
5(1)	Vol. 3, Adenda V, B.9.	EFSA: In the LoEP the name „3-chloroprop-2-en-1-ol' needs to be replaced by „3-chloroallyl alcohol' to maintain consistency through the available documentation.	
5(2)	Vol. 1, Level 2, LoE	EFSA: Please use the agreed template for the LoE, last updated in January 2009. (http://circa.europa.eu/Members/irc/sanco/pest/library?l=/epcosmanuals/epcosmanualses4&vm=detailed&sb=Title)	

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
5(3)	Vol. 3, Adenda V, B.9.1.3, repro study by Temple et al., 2006	EFSA: Is there an explanation to why the growth of male bobwhite quail in the control gr. (both 20w and 7w exposure) is low compared to the growth of exposed males?	
5(4)	Vol. 3, Adenda V, B.9.1.4, Risk assessment birds, Small, 2007, Residues in insects and earthworms	EFSA: Pitfall fall traps were used to collect arthropods, but also to dead arthropods observed on the soil surface were collected. It's not clear from the study report how much effort there was put into colleting dead arthropods.	

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		It needs to be considered if there is a bias in the collection of arthropods. Could it be the case that dead arthropods would have a higher concentration of 1,3-D and could it be the case that birds and mammals would have a higher proportion of dead insects in the diet than was analysed in the collected samples? The same bias in sampling could be the case for earthworms. Possible implications on the risk assessment for birds and mammals should be considered	
5(5)	Vol. 3, Adenda V, B.9.3.1, Effects on terrestrial vertebrates	EFSA: It is argued that the NOAEL of 5 mg/kg bw/d (based on body weight in rat) from the 90 days oral exposure study is the ecologically relevant reproduction effect endpoint to be used in the refined mammalian risk assessment, given the expected field exposure of less that 2 weeks. Can we be sure that effects may not occur after 90 day from short term (less than 14 days) exposure?	

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
5(6)	Vol. 3, Adenda V, B.9.2.5, Chronic toxicity to invertebrates, Mirino et	EFSA: It's not clear from Table 9.2.5-1 if the effects on length are significant.	

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	al., 2007		
5(7)	Vol. 3, Adenda V, B.9.2.6, Effects on algae growt	EFSA: Please explain why there are differences between the ErC50 values for algae calculated for the a.s. and metabolites in the additional report and the values presented in the EFSA scientific report (2006) or the original DAR.	
5(8)	Vol. 3, Adenda V, B.9.2.8, Effects on aquatic plants	EFSA: Please provide the *Lemna gibba* endpoints based on both as growth rate and biomass	

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
5(9)	Vol. 3, Adenda V, B.9.4.7, Risk assessment to bees	EFSA: Given the very steep dose-response curve in the inhalation toxicity test and the fact that exposure (5.793 mg a.s./m^3) was estimated 25 m off-field, it may be considered if bees closer to the field and in-field are at risk	
5(10)	Vol. 3 Adenda V, B.9.5.3, Risk assessment to non-target arthropods	EFSA: It's questioned if the risk to Collembolan is addressed sufficiently, as there are indications of effects in the field study. The lack of significant effects may rather be linked to the dry conditions and inappropriate sampling method.	

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)

Section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
5(11)	Vol. 3, Adenda V, B.9.6.4, Risk assessment for earthworms	EFSA: In the EFSA Scientific report on 1,3-D it is mentioned that a field study in UK potato fields was announced to address concerns. This study is however not mentioned in the additional report. Why not?	
5(12)	Vol. 3, Adenda V, B.9.7, Risk assessment to micro-organisms	EFSA: Duration of the recovery period does extend 100 days in the field. The acceptable duration of recovery for micro-organisms in the field may be discussed.	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
5(13)	Vol. 3, Adenda V, B.9.8.2, Risk assessment to NTP	EFSA: The modelled off-crop PECsoil for 1,3-D should be confirmed by the fate section.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
5(14)	Vol. 3, Adenda V, B.9.10, Ecotoxicological profile of impurities	EFSA: the assessment of [redacted] seems to be limited, compared to the other metabolites.	