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

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section 0 – General comments

0. General

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0(1)	List of end points	DE: The RMS should consider to use the current version (September, 2005) of the harmonised template.	RMS: Due to the strict deadlines we have not changed the version of the LoEP, but we recognise that should be used.	Open point: RMS to use the agreed new template for the list of endpoints

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	Vol. 4 Method of manufacture	FR : The purity of the starting material must be provided.	Notifier: [redacted]	Addressed: The purity of the starting materials was already given in the original vol. 4

Identity (B.1, Annex C)				
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			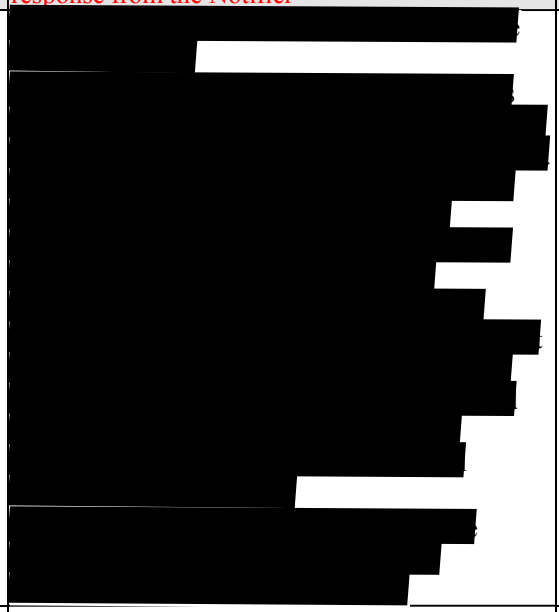	
1(2)	Vol. 4 Identity of impurities	FR : Notifier Dow AgroSciences : Maximum content given for the impurity 5b p10-11 of the additional report Volume 4 is different than this given in the Table C.1.2.3.4. Please RMS correct.	Notifier: The correct value is 2 g/kg. See comment 1(20) from notifier. **RMS:** Amended in Addendum 3 Annex C_rev (C.1.2.2)	Addressed: The value has been corrected in the revised vol. 4

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1(3)	Vol. 4 Identity of impurities	FR: Notifier Kanesho Soil Treatment : The impurity 5b is not listed in the list of significant impurities.	Notifier: The impurity 5b ([redacted] was quantified in Kanesho sources from both sites (Tavaux and Rheinberg). Based on the 5 batch analysis of both these sources the proposed maximum level of [redacted] from Kanesho sourced material is 1g/kg maximum.(See table C.1.2.3.5 and C.1.2.3.6). **RMS:** List of significant impurities amended in Addendum 3 Annex C_rev (C.1.2.2)	Addressed: RMS amended the list of significant impurities in the revised vol. 4
1(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).	Notifier: The USA (pilot scale) batch was provided to demonstrate that further progress on reducing impurities are feasible; but would require further time to invest in new manufacturing plant (3 years). From risk assessment viewpoint then DAS **wish to consider only the recent (2008) 5 batch from Stade Germany** i.e. current production material. The 5 batches and proposed specifications presented in Table C.1.2.3.4 (Report Masterfile A81) are the most recent typical production samples from Dow Stade plant and all impurities above 1 g/kg have been analysed using validated methods. Therefore Dow AgroSciences can	Addressed: The specification is not based on the pilot plant production

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			manufacture 1,3-Dichloropropene to the quality proposed in Table C1.2.3.4 . This proposed spec is for minimum of 965 g/kg 1,3-D and only 4 impurities above 1g/kg, namely:- [redacted] **(5b) 2g/kg max** **(5a) 3g/kg max** **(3) 2g/kg max** **(6) 3g/kg max** **RMS:** Agree with notifier	
1(5)	Vol. 4, Table C.1.2.3-4	DE: It seems that the proposed specification is acceptable from an analytical point of view.	**RMS:** The recent (2008) 5 batch analysis from Stade Germany has already been accepted and also the proposed specification of Dow. For more transparency, an assessment has been included in Addendum 3 Annex C_rev, C.1.2.2, page 18.	Addressed: The specification of Dow is acceptable
1(6)	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)	**RMS:** The recent (2008) 5 batch analysis from Stade Germany has been accepted and also the proposed specification of Dow. The proposed specification of Kanesho Soil Treatment should be considered only as provisional until a reliable analysis of batches is available. For more transparency, an assessment has been included in Addendum 3 Annex C_rev, C.1.2.2, page 18. The risk assessment for the technical material for	Addressed: The specification of Dow is acceptable

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		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.	Annex I inclusion (active substances + impurities) has been included all over the DAR (environmental fate, residues, toxicology and ecotoxicology).	
1(7)	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.	Notifier: See notifiers comments of 1(4) above The EFSA report concluded that further work on identity of impurities and provision of analytical methods was required. DAS have provided this in the most recent re-submission and wish to put forward a specification that is based on this study (Table C.1.2.3.4 (Report Masterfile A81) and not previous studies or QC data from 2006. **RMS:** Agree with notifier. In addition RMS points out that the proposed specification of Kanesho Soil Treatment should be considered only as provisional until a reliable analysis of batches is available.	Addressed: The specification is based on new five batch data evaluated in vol. 4
1(8)	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	Notifier: Kanesho are developing synthetic routes to those impurities above 1g/kg that are not yet quantified by analytical method. When these analytical standards are available then	Data gap: A reliable analysis of batches for the Kanesho Soil Treatment should be provided.

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		source	validated methods will be developed. Current view of the notifier is that the response factor of these impurities is unlikely to be significantly different to the other chlorinated impurities for which analytical standards are available and that the maximum levels currently proposed for Kanesho sources will not be significantly changed. **RMS:** The data gap for the impurities 2, 3, 4 and 5 generated in Add 2 to Vol. 4, rev.1, Table 3, p. 13 has been addressed in Add 3 to Vol. 4 (see Tables C.1.2.3-5 and C.1.2.3-6 and assessment) but new data gap were generated for other impurities for which an analytical method was not properly validated. **Therefore the proposed specification of Kanesho Soil Treatment should be considered only as provisional until a reliable analysis of batches is available.**	
1(9)	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?	Notifier: A separate table is provided to the RMS which contains boiling point and vapour pressure information for those impurities which are listed in the Dow AgroSciences source of 1,3-D. The table indicates both Boiling point , freezing point, and vapour pressure information (real or estimated values): **RMS**: The sources of these values are not reported only they are theoretical,	Addressed.

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			experimental or from literature, but RMS considers that is sufficient for the evaluation	
1(10)	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	Notifier: During the EFSA review concern was raised on the need to try and identify and quantify all impurities in the 1,3-D technical material. We agree that it is not normal to propose specifications of max 1 g/kg for impurities but notifier was unsure of whether EFSA needed something additional for soil fumigants, given that they are all used at high use rates. **RMS:** Agree with notifier. The specifications have already been updated in Add 3 to Vol. 4_rev (see Table C.1.2.2-1 and assessment) following new 5-batch analysis and improve in the analytical methods for the impurities. In the EFSA conclusion report, critical areas of concern and outstanding data requirements regarding the identity of the active substance and impurities were identified. Further clarification on the content, nature and potential hazard of the polychlorinated impurities in the material that will be applied was required due to the very high application rates of 1,3-D and the potential for significant amounts of impurities in the environment. Now impurities above 0.01% (10 fold below the trigger value of 0.1%)	Addressed: The updated specification evaluated in revised Vol. 4 was acceptable

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			were identified and quantified and it was considerer sufficient.	
1(11)	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	Notifier: See comments from 1(4) above. For Dow AgroSciences the proposed specification is based on Report A81 (Table C.1.2.3.4) and other information given in Volume 4 is historical (before final identification and impurity method validation studies were finalised) For Kanesho the proposed specification is based on the combined results of both Tavaux and Rheinberg sources (Report A70R, Tables C1.2.3.5 and Tables C1.2.3.6) **RMS:** Agree with the notifier. The information given in previous Volume 4 is historical (before final identification and impurity method validation studies were finalised) and they should be taken into account for transparency of the procedure. The last	Addressed: For Dow AgroSciences the proposed specification is based on Report A81 evaluated in Volume 4 and for Kanesho the proposed specification is based on the combined results of both Tavaux and Rheinberg sources

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		one in Table C.1.2.3-4, which are the data supporting this specification?	technical specifications for the Dow technical material (Stade, German plant) and for the Kanesho technical material (Tavaux and Rheinberg sources) are summarised in Table C.1.2.2-1, Addendum 3_Vol. IV_Additional report and supported by the analysis of batches reported in Tables C.1.2.3-4 (Dow) and C.1.2.3-5, C.1.2.3-6 (Kanesho). The proposed specification of Kanesho Soil Treatment should be considered only as provisional until a reliable analysis of batches is available. The new research at pilot scale was conducted to determine that a further reduction in the maximum levels of chlorinated impurities is technically and economically feasible and it will be considered only in the case the current commercial production at Stade (German) is not accepted. See comments from 1(4) above	

<table>
<tr><th colspan="5">Identity (B.1, Annex C)</th></tr>
<tr><td>No.</td><td>Column 1
Reference to DAR (vol., point, page)</td><td>Column 2
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Data requirement or Open point (if data point not addressed or fulfilled)</td></tr>
<tr><td>1(12)</td><td>Additional report to Vol. 4, Table C.1.2.3-4 Five batch data, p. 25</td><td>EFSA: the manufacturing dates of the batches are missing</td><td>Notifier:
The manufacturing dates for Report A81 (page 25, Dow Stade material) are shown below:-
<table><tr><td>TSN003419-0001</td><td>March 14, 2008</td></tr><tr><td>TSN003419-0004</td><td>March 3,2008</td></tr><tr><td>TSN003419-0005</td><td>Feb 29 , 2008</td></tr><tr><td>TSN003419-0007</td><td>March 17, 2008</td></tr><tr><td>TSN003419-0008</td><td>March 12, 2008</td></tr></table>
RMS: Data introduced in Addendum 3 Annex C_rev (C.1.2.3-1)</td><td>Addressed.</td></tr>
<tr><td>1(13)</td><td>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</td><td>EFSA: clarification is needed if the US source still has not to be considered for Annex I inclusion</td><td>Notifier:
Dow AgroSciences has confirmed to RMS that they wish only Stade Germany material to be considered for Annex 1 Inclusion. See Annex C, Addendum III, Vol IV, C1.2.

At this stage DAS are only seeking approval for the technical grade 1,3-dichloropropene manufactured at Stade in Germany. At a later date DAS will consider submitting a separate dossier for the 1,3-D manufactured in Texas,</td><td>Addressed:

See also comment 1(11)</td></tr>
</table>

Identity (B.1, Annex C)				
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			USA using the equivalency process required by the European Union. **RMS:** Agree with the notifier. In addition, from the documentation provided, RMS understood that there are two different technical material produced in US: The commercial production for which approval is not sought at this stage and will be evaluated at a later date following the equivalency process. The new pilot plant that was conducted to determine that a further reduction in the maximum levels of chlorinated impurities is technically and economically feasible and it will be considered only in the case the current commercial production at Stade (German) is not accepted.	
1(14)	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	**RMS:** See comment 1(11) above about sources uses for setting the specification(s) RMS considers that the discussion of specifications in an expert meting is not necessary. The proposed specification of Dow AgroSciences is acceptable from an analytical point of view (see 5-batch analysis from Stade, Germany, Table C.1.2.3-4). The proposed specification of Kanesho Soil Treatment should be considered only as provisional until a reliable analysis of batches is available (see 5-batch analysis from Tavaux and Rheinberg, Table C.1.2.3-5	Addressed: See also comments 1(11) and 1(8)

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			and C.1.2.3-6). None of the impurities, apart from 1,2-dichloropropane, were found of tox/ecotox relevance (sections 7 and 9 of the DAR)	
1(15)	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)	Notifier: (1) Dow AgroSciences: Proposed spec is based on 5 batch analysis shown in Table C.1.2.3.4. (2) Kanesho Proposed spec is based on 5 batch analysis shown in Tables C.1.2.3.5 and C.1.2.3.6. Also see C.1.2. (page 8, paragraph2). At this stage both of the notifiers, Dow AgroSciences and Kanesho Soil Treatment, have not submitted a joint specification to cover both DAS and KST sources. However both notifiers remain ready to make such a proposal if the review of this resubmission dossier deems it to be appropriate. **RMS:** Agree with notifier. See also comments 1(11) and 1(14) above about sources uses for setting the specification(s)	Addressed: The specifications are presented in vol.4. See also 1(11), 1(14) and 1(10)
1(16)	Additional report Vol.1 1.4.5.1a Identity and	EFSA: it is true that the FAO tolerance for formulations above 50 % is ±25	Notifier: Dow AgroSciences thinks that the comments from	Open point:

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	content of a.s., p. 10	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.	EFSA are valid. This will likely need further discussion but initial proposal from DAS would be a range of 915 – 960 g/kg to cover process and analytical method variation as well as variation in level of purity of 1.3-D technical. **RMS:** Although the product has a very high amount of technical material and a small amount of co-formulant, a manufacturing process is involved. Therefore RMS considers that a tolerance to take into account the manufacturing, sampling and analytical variations can be set. If we take as nominal content the mean value of analysis of batches (978 g/Kg in Table C.1.2.3-4) and we apply the FAO tolerances of ±25 g/kg, the result is a tolerance range of 914-964 g/kg, in line with the notifier proposal. Nevertheless RMS considers that in this case 914 or 915 g/Kg is a very low limit for the active substance in the formulation taking into account that the minimum declared purity of the technical material is 965 g/Kg and the contribution of the surfactant is only 40 g/Kg. A narrower tolerance range should be considered.	EFSA to consider the tolerance range of the a.s. content in the formulation, when writing the conclusion
1(17)	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	**RMS:** Amended	Addressed: The typo was amended
1(18)	Additional report Vol.1	EFSA: the absence of the mass unit (g)	**RMS:** Amended	Addressed:

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	1.5.3.2b Proposed application rates., p. 14	in 1180 as/L is probably a typo		The typo was amended
1(19)	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	Notifier: Information on Vol.1 2.1.1 identity, p. 18 needs to be corrected. Notifier confirms the following: (1) Dow AgroSciences: Minimum specified 1,3-D purity (sum of cis and trans isomers): 965 g/Kg Minimum specified *cis*-1,3-D content: 450 g/Kg Minimum specified *trans*-1,3-D content: 320 g/Kg (2) Kanesho Soil Treatment: Minimum specified 1,3-D purity (sum of cis and trans isomers): 965 g/Kg Minimum specified *cis*-1,3-D content: 450 g/Kg Minimum specified *trans*-1,3-D content: 320 g/Kg **RMS:** Amended	Addressed: The correct values were introduced
1(20)	Vol. 4, page 11, impurities exceeding 1g /kg	Notifier 2-chloro-4_methylpentane Max content should be 2 g/kg and not 12 g/kg. See 5 batch analysis summary on page	**RMS:** Amended	Addressed: The value has been corrected

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		25		
1(21)	Vol. 4, page 17, summary of Dow AgroSciences and Kanesho specifications	Notifier **Table C.1.2.2-1.** 2, chloro 2-methylpentane should be max of 3 g/kg and not 4 g/kg for DAS specification. Cis 1,3,3 trichloropropene should be max of 3 g/kg and not 4 g/kg for DAS specification See 5 batch analysis summary on page 25	**RMS:** Amended	Addressed: The values have been corrected

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(22)	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 conclusion.	Notifier: For the hydrolysis study, GHE-P-11384 by Eversfield & Knowles, samples were stored in GC glass vials contained within a headspace analyser. So there would have been extremely low levels of ambient laboratory lighting from a fluorescent source since the vials are enclosed in a vial rack and are capped with a septum to prevent direct overhead lighting. The levels of light simulated levels which would be experienced during routine chromatographic analysis of a groundwater sample. The analytes which were more stable to hydrolysis during the method development were included in the groundwater monitoring study. **RMS:** Agree with notifier. The impurities were not found in the groundwater monitoring study. Impurities of 1,3-D are not expected to persist in the environment.	Addressed: The impurities were not found in the groundwater monitoring study

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(23)	Vol 3 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.	Notifier: The pH of a 1% solution was 5.33 after 1 minute but continued to be measured and had stabilised at pH of 3.17 after 10 minutes. In addition, because the pH was <4 the acidity (HCl content) was measured before and after storage: Before storage -- 30.4 ppm HCl After 24 month storage -- 30.4 ppm HCl All of the above data is included in this report FOR-04-041(Masterfile MA88). RMS: Agree with notifier. The value before stabilization was reported in the DAR. The value is now corrected in Addendum 4 B2	Addressed: The pH of a 1% solution was 5.33 after 1 minute but continued to be measured and had stabilised at pH of 3.17 after 10 minutes
1(24)	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	**RMS:** Amended	Addressed: Names were amended

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(25)	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	**RMS:** Amended	Addressed: The name was corrected
1(26)	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	**RMS:** Amended	Addressed: The names were corrected

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(27)	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 Germany	**RMS:** Amended	Addressed: The names were corrected
1(28)	Vol. 1, page 12, 1.5.4.a, Information on authorisations in EU Member States	**Notifier** Please amend table to reflect all DAS and Kanesho authorisations See table in column 4	**RMS** Amended	Addressed: Table amended
1(29)	Vol. 1, page 14, 1.5.4.b Information on authorisations in EU Member States	**Notifier** Please amend table to reflect all DAS and Kanesho authorisations See table in column 4	**RMS** Amended	Addressed: Table amended

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(30)	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	**RMS:** Amended	Addressed: Footnotes have been amended

Further information (B.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Classification and labelling (B.4)

For comments on classification and labelling see the relevant sections.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(31)	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.	Notifier: Unless advised otherwise, DAS are of the opinion that the only relevant impurity in 1,3-D technical is 1,2-Dichloropropane. Therefore the only validated method required to be presented for impurities in formulations is for 1,2-Dichloropropane. DAS have presented this method (Master file Index O45 ,DAS –AM-05-008) and this validated method has been reviewed by RMS. **RMS:** The identity of the relevant impurity 1,2-Dichloropropane has been confirmed by MS in 5-batch analyses (Latham A. 2008, II A 1.11.1/02). The specificity of methods for impurities has been discussed in expert meetings and it has been concluded that "the requirement: *data to confirm the identity of impurities* *revealed by chemical analysis,* should **no longer be applied** to analytical methods submitted under section 4.1 and that specificity of these methods could be adequately addressed by retention time match to authentic reference standards. The experts agreed that information relating to confirmation of identity was required under section 1.10/1.11". Therefore this issue has been addressed	Addressed: The conclusion of PRAPeR 36: Specificity of the analytical method for the determination of the impurities in the active substance as manufactured (requirement 4.1) can be suitably addressed by retention time match with reference standards. *Confirmation of identity of impurities should be addressed under section 1.10/1.11.*

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(32)	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.	**RMS:** The impurities are not included in the residue definition for monitoring purpose (see sections B.7 and B.8) and therefore a method for monitoring is not needed. Regarding the specificity of the method for pre-registration, these compounds have a low molecular weight and therefore the requirements of the guidance documents regarding the presence of 2 ions with m/z > 100 can not be met. Nevertheless RMS considers that the validation data are sufficient for the acceptability of the method.	Addressed. Taking into account the molecular mass of the a.s., the argumentation of the RMS can be accepted

2. Mammalian toxicology

Toxicokinetics (B.6.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Acute toxicity (B.6.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(1)	Vol. 3, B.6.4,	DE: In the whole, data suggest that	Notifier:	Addressed.

Rapporteur: Spain (ES)

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	Genotoxicity	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).	On the whole, data suggest that in vitro effects are related to this phenomenon. More importantly, all of the test guideline-compliant/higher tier mammalian ***in vivo*** genotoxicity studies on 1,3-D, conducted to GLP regulations, were negative including: - mouse bone marrow micronucleus test at oral doses up to 380 mg/kg bw - mouse lung and rat liver 32P-postlabeling analysis of DNA adducts - transgenic 'Big Blue' mouse assay in lung and liver - rat dominant lethal test These studies show that 1,3-dichloropropene does not represent an in vivo genotoxic hazard and this is why it was not classified for genotoxicity during its latest review by ECB and all EU MS. **RMS:** Agree. No new information about genotoxic potential of 1,3D has been received after EPCO 23. Althought, as the notifier stated, all mammalian *in vivo* test according to GLP regulations were negative, important considerations to these studies were summarized in Adendum 2 (March 05) and discussed in EPCO 23 (May 05), which agreed that 1,3D is an *in vivo* genotoxic agent for somatic cells, acting directly or after activation by	As the official classification in EU concluded not to classify 1,3 dichloropropene as R40 and R68, this will be reflected as well in the revised EFSA conclusion.

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			cytochrome P450, and gluthathione protects against the genotoxicity. See also 2(17)	
2(2)	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.	Notifier: For genotoxicity, refer to response 2(1). For carcinogenicity, there are six (6) test guideline and GLP compliant studies so there is no need to refer back to older (NTP) studies compromised by test material, design, methodology and health status issues and deemed '**unacceptable'** by the EU review under 91/414/EEC. **RMS:** notifier has not submitted any additional data to clarify the uncertainties observed in relation to the mutagenic and carcinogenic properties described in the Conclusion on the peer review of 1,3dichloropropene (EFSA, 2006). EPCO 23 proposed to classify 1,3 Dichloropropene as mutagenic Cat 3 R68 and as carcinogenic Cat. 3 R 40. However the final decision of ECB, that has the legal competition to take decision about classification, was not to classify 1,3 Dichloropropene as human carcinogenic Category 3, R40 neither a mutagenic Category 3, R68. Nevertheless, with the available data, RMS considers that the reference values (agreed in EPCO 23 and reported in Conclusion's EFSA 2006) should be considered as definitive to	Addressed. See 2(1)

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			ensure an adequate margin of safety respect to irreversible effects. Earlier studies, contained epichlorihydrin, were evaluated, however they were not considered for risk assessment.	
2(3)	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?	Notifier: The ECB review of 1,3-D was, like all reviews of pesticides, based on the 91/414 DAR. These were submitted by the RMS as addenda on carcinogenicity, genotoxicity and acute toxicity (ECBI/27/05 Add 1, 2 and 3, respectively). RMS: The working team on ECB has informed us that they had original studies, 91/414 DAR, Addendum I and II, and the data included in CIRCA. With this information they prepared a series of documents, with their conclusions, that were sent to be discussed in ECB. Essentially, the conclusions reached were the same: concerning carcinogenicity, 1.3 D (without epichlorhydrin) induced benign tumors in 3 or 6 studies, with presence of preneoplastic lesion, lack of a clear mechanism to explain the tumor formation, a likely DNA toxicity and structural analogy to known carcinogens; with respect to genotoxicity the results suggested that 1.3 D could be an in	Addressed. See 2(1)

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			vivo genotoxic agent for somatic cells due to findings of DNA fragmentations, but not a mutagenic agent. MS had different positions about if the weight of evidence was sufficient to classify the test substance for both effects. After a voting, ECB agreed no to classify the substance for carcinogenic or mutagenic effects. Maybe, authorization of 1,3D with adequate reference values to avoid the irreversible effect and certain mitigation measures to reduce the hazard could be proposed (See also 2(9)).	

Long-term toxicity and carcinogenicity (B.6.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(4)	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	Notifier: DE (BfR) were represented at the meeting where ECB and MS concluded that 1,3-D was not an in vivo mutagen and did not merit classification as a carcinogen so the basis for the ECB decision should be known.	Addressed. See 2(1)

Long-term toxicity and carcinogenicity (B.6.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		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.	However, to clarify, as mentioned in response 1(1) all test guideline-compliant/higher tier mammalian ***in vivo*** genotoxicity studies on 1,3-D, conducted to GLP regulations, were negative. These studies show that 1,3-D does not represent an in vivo genotoxic hazard and this is why it was not classified for genotoxicity during its latest review by ECB and EU MS. Regarding carcinogenicity, it's important to remember that of six (6) test guideline-GLP compliant studies, cancer (i.e., malignancies) did not occur in any study; three (3) had no tumours at all; Treatment-related tumours in the other 3 studies were all benign and limited to a single tissue and in 2 studies, to a single sex: respiratory tract tumours in male B6 mice, which occur with high incidence, and urinary bladder tumours in female CD-1 mice, which may not be neoplastic. This is why 1,3-D was not classified with R40. **RMS:** see 2(1) and 2(2)	

Long-term toxicity and carcinogenicity (B.6.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(5)	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?	Notifier: The RMS used the 91/414 DAR for the ECB review – see response 2(3). **RMS:** see 2(3)	Addressed. See 2(1)

Reproductive toxicity (B.6.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Neurotoxicity (B.6.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(6)	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).	Notifier: Impurity 8a is [redacted] and the proposed specification is <1 g/kg for DAS and 6 g/kg for Kanesho material. Impurity 8b is [redacted] and the proposed specification is <1 g/kg for DAS and 4 g/kg for Kanesho material. Impurity 8c is [redacted] and the proposed specification is <1 g/kg for DAS and 5 g/kg for Kanesho material. DAS review of literature search and QSAR analysis included these compounds and conclusion was that they do not pose any additional risk compared to the parent molecules i.e. they are not relevant impurities. RMS: Agree The only toxicological information submitted with respect to the impurities 8a, 8b and 8c was estimates of rat oral LD_{50} values made using the commercially available, statistically-based, QSAR computer model TOPKAT™ . It should be discussed if this information is sufficient taking into account the tecnical especifications for Kanesho material regarding	Open point: The toxicological properties of the new technical specifications for 1, 3-D technical as proposed in the addendum 3 to the Annex C (March 2009), including toxicological consideration of the several impurities present and the compliance to the batches tested in the mammalian toxicity data package, to be discussed by the experts. See also 2(7) (8) (9) (10) (11) (24)

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			these impurities and the very high application rates of the product. **However, according the comments 1(11); 1(14) and 1(15) The proposed specification of Kanesho Soil Treatment should be considered only as provisional until a reliable analysis of batches is available.**	
2(7)	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.	RMS: Agree Notifier: Agree.	See open point in comment 2(6)

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(8)	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 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. 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.	RMS: Agree Notifier: Agree.	See open point in comment 2(6)
2(9)	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	Notifier: Agree. RMS: Agree. A total of 18 impurities (+ 1,2	See open point in comment 2(6)

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		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 their method of manufacture only if necessary	Dichloropropane) have been identified in the 5 batches analysis of DAS and Kanesho. Technical specifications were revised according to these data. Moreover, the company has proposed further refine their method of manufacture if necessary. Research and pilot plant process studies indicated that a technical material with no impurities above 0.1% (and above of 0.01% of 1,2 Dichloropropane) can be achieved. Since DAS estimate that it would take up to a maximum of 3 years to construct and make fully operational a plant that could manufacture to this lower impurity specification, mitigation measures to reduce the hazard can be proposed, for example: technology to minimize spillage during the application, restriction to use in zones with shallow groundwater and vulnerable soils, lowered maximum application rates, prohibition of use in areas overlaying karst geology...	

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(10)	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	RMS: Agree. See also comment 2(9) Notifier: Agree.	See open point in comment 2(6)

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		reasonably practicable (ALARP) approach would seem appropriate for these impurities.		
2(11)	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. 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	Notifier: The DAS material and proposed spec contains 4 impurities > 1 g/kg and 12 impurities <1 g/kg – see Table C.1.2.3-4 of Vol 4 Additional report. The Kanesho material contains 6 impurities at >1 g/kg and 7 impurities <1 g/kg – see Tables C.1.2.3-5 and C.1.2.3-6 of Vol 4 additional report. A detailed QSAR analysis of all present impurities has been conducted and a comparison of the relevance of these impurities versus that of the parent 1,3-D has been conducted. The FAO/WHO manual guidance on relevance of impurities was used for this assessment. The conclusion is that these impurities will not pose any additional toxicological risk. RMS: Regarding the impurities , with the availble information provided by notifier	See open point in comment 2(6)

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		missing.	and from the results of the calculations according to the FAO Manual, we concluded that the impurities which may occur in 1,3-dichloropropene products do not contribute toward the potential toxicity of these products. Nevertheless, according to a MS comment (point 2 (6)), several structural alerts (Mutagenicity, carcinogenicity, hepatotoxicity, nephrotoxicity) for some impurities (8a,8b,8c) showed by the QSAR Screening (DEREK analysis) had not been considered in the risk assessment. For these reasons, regarding the impurities, there are two key points: - Is the information provided suffcient to establish its toxicolgical relevance? and - what is the most correct approach taken to calculate the (additional) hazard by impurities?. These two issues should be discussed by the experts	

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(12)	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) .	Notifier: This statement that an extra 2X safety factor was applied to the LOEL for tumours per se, giving a 1000X safety factor for the ADI against this end point, is correct. However, the use of an extra safety factor against liver tumours in rats that were not statistically identified and which were not deemed sufficient to trigger cancer classification seems overly conservative and should be removed. RMS: EPCO 23 agreed an ADI=0.0125 based on NOAEL of 2-year study in rats (2,5 mg/kg/day) and a safety factor of 200, to ensure an appropiate margin of safety (1000) between ADI and irreversible effects. These irreversible effects were noted in rats at dose of 12.5 mg/kg/day and in mice at 101 mg/kg/day. Irrespective of the clasiffication reached in ECB, the irreversible effects occurred, thus the ADI agreed in EPCO ensures sufficient margin for both effects.	Open point: The ADI of 1,3-D to be confirmed by the experts The ARfD of 1,3-D to be confirmed by the experts See also 2(25)
2(13)	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.	Notifier: The NL comment is correct but why mention only the human respiration rate? If the correct human respiration rate is used then the correct rat respiration rate should also be used based on the EU AOEL guidance document (45l/kg/hr or 1.14 m^3/kg/day).	Open point: The AOEL of 1,3-D to be confirmed by the experts, in particular taking into account the derivation of the inhalatory AOEL in humans: the method has to be agreed on by the experts

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		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 calculation a mean respiration volume for humans was used (mean over 24 h) which is too low for the working population. A higher value for respiration during effort (working hours) should be used: 10 m^3/**8** hours, which is about 0.14 m^3/kg/**8** hours.	Furthermore, the inhalation AOEL should be calculated correctly. Why calculate it from oral data when valid, accepted inhalation data are available? The lowest relevant inhalation NOEL is 20 ppm from the chronic rat inhalation study, not 10 ppm estimated by EPCO 23 from an oral-systemic AOEL. If the correct NOEL is used in a correct calculation method using correct animal and human respiration rates the inhalation AOEL is 0.4 ppm or 1.8 mg/m3. If the incorrect method agreed by EPCO 23 is used (i.e., an inhalation NOEL of 10 ppm calculated from an oral-systemic AOEL) but with the correct respiratory inputs the inhalation AOEL is 0.2 ppm or 0.9 mg/m3. Slightly different values can be determined, often based on rounding errors or slightly different inputs; the above rationale and figures are explained in 'ToxDoc 1' attached. RMS Agree As was established in DAR (point B 6.10.2.3), agreed in EPCO 23 (point 2.5) and appeared in Addendum 3 Sept 2005, the lowest relevant inhalation NOAEL is 10 ppm (9.72 mg/kg bw/d) form the 13-	See also 2(15) (25)

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			weeks inhalation study in rat. From this value, different calculations to establish the AOEL can be performed: 1: AOEL = NOAEL / FS. Then: AOEL = 9.72 mg/kg bw/d / 100 = AOEL = **0.1 mg/kg bw/d** or AOEL= 10 ppm/100 = **0.1 ppm = 0.45 mg/m^3** 2: Convert an inhalatory value in rat in an inhalatory value in human according to: $ppm(h) = ppm(rat) * \frac{resp\ rate\ (rat)}{resp\ rate\ (h)} * \frac{t\ (rat)}{t\ (h)}$ t*: time of exposure. - time of exposure human (according draft Technical Guidance Document ECB Nov 2005, humans work : 8 hr/day and 5 days/week), - respiratory rate (human during effort: 10 m^3/8 hr = 17.5 L/Kg bw/hr (according internat. occupational exposure limit setting practice) and 45 L/Kg bw/hr for rat in accordance the AOEL Guidance). Then : $ppm(h) = 0.1 * \frac{45\ L/Kg\ bw/hr}{17.5\ L/Kg\ bw/hr} * \frac{6\ hr}{8\ hr} * \frac{5}{5}$ **= 0.19 ppm = 0.87 mg/m^3**	

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			The most correct way to establish the AOEL should be discussed by the experts.	
2(14)	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.	RMS: See point 2 (13), 2 (25) Notifier: See response 2(13) and 2(15).	See open points in comments 2(12) and 2(13)

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(15)	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 the Notifiers comments 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)	RMS: See point 2 (13) Notifier: See response 2(13).	See open point in comment 2(13)

Toxicity of the product(s) (B.6.11)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(16)	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.	RMS: Agree Notifier: Agree.	Addressed. Classification and labelling of the preparation is a Member State issue

Dermal absorption (B.6.12)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Toxicity of non-active substances (B.6.13)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(17)	Vol. 1, 2.3, Impact on human and animal health, Vol. 3, Appendix 1, List of end points and Addendum III (September, 2005)	DE: a) 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 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). b) 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. c) 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. d) In addition, measured concentrations outside	Notifier: a) The supported method of application (drip irrigation in greenhouses) is designed to exclude potential dermal exposure. As exposure is limited to the introduction of Telone into irrigation system (i.e. there is no conventional mixing and loading, there is no contact with the product). The operator simply places a tube into the drum In addition the operator wears PPE which further limits the any potential for dermal exposure. No exposure during drip application occurs as the operator will always be outside the greenhouse. Incidental exposure will only occur if there is a leakage in the irrigation system-which will not occur if the irrigation system is checked before use. In terms of open field application, a closed transfer system will employed eliminating dermal contact b) There should be no necessity to set an acute reference dose as the workers are required to wear respirators with organic filters during application and for a period of 7 days post application. No key tasks exist during this period that would result in potential exposure up to 75.61 mg/m^3. Any incidental tasks (e.g repair of the irrigation system occurs only during application and for a very limited period (Refer to section 2.19).	Open point: The operator, worker and bystander exposure to 1,3-D to be discussed and confirmed by the experts. In particular with regard to: • Operator: The need of determining dermal exposure to 1,3-D during the proposed intended uses (drip irrigation in greenhouses and soil injection in greenhouses and fields) Need of PPE to limit the exposure below the proposed AOEL Field studies presented • Re-entry: Appropriateness of the presented assessment Need of re-entry interval? Need of environmental monitoring assessment? Field studies presented • Bystanders: Is bystander exposure foreseen in such a scenario?

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		greenhouses (1 m) are also above the AOEL (particularly 0-6 hours after application). Therefore, prohibited areas for bystanders are necessary. e) Re-entry should be allowed only, if no active substance is detectable above reference values. f) Hence, application should be restricted to well-trained authorised personnel only.	c) There is no necessity to monitor the air concentrations as the workers are required to wear respirators with organic filters during application and re-entry for a period of 7 days after application (as proposed by the notifier). d) No prohibition area for bystanders is required as although the concentration of 1,3-D was monitored immediately (one meter) outside the greenhouse. The value of 1.4 mg/m^3 relates to a 4 hour interval, when considered in conjunction with the second 4 hour concentration of 0.16 mg/m^3, the 8 hour average concentration is 0.78 mg/m^3, The next 8 hour period (4 to 12 hours) average concentration is 0.3 mg/m^3 There is no expectation that an incidental bystander would be one metre from the greenhouse for 8 hours. Therefore the apparent exceedence of the proposed AOEL of 0.3 mg/m^3 AOEC based on air concentrations alone is not significant; it is dependant on the duration of exposure. e) A re-entry of 7 days has been proposed by the notifier as a conservative value. f) Agreed and this is a requirement of the Stewardship Program.	

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			RMS: a) The study B.6.14.1.3 in the DAR evaluated both inhalation exposure and systemic exposure for 6 operators in mixing/loading task, leading to the conclusion that, generally systemic exposure correlated well with inhalation exposure. Therefore, dermal exposure can be considered negligible. However, we introduced in the text that for some unusual tasks, such as incidental task (see operator 1) systemic exposure did not correlate very well with inhalation exposure, probably due to dermal exposure?, that can be avoided with protection measures. But, as the Notifier suggested, accidental tasks can be avoided if the irrigation system is checked. b) We do not consider that the risk assessment can provide reliable evaluation of the risk for operator when using data from operator exposure from incidental tasks. c) We do agree that after a short period from 1,3-D application, the levels of exposure can be higher than AOEL, however, when GAPs, (in this case, a good revision of the irrigation system) is carried out, it is not predictable the need to enter into the greenhouse.	

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			d) We do agree that any bystander passing near a greenhouse recently treated can be exposed to levels higher than the AOEC. However, as with other PPP, bystander risk always was realistically calculated for those passing at >7 mt. For 1,3-D application (irrigated, injected), bystanders walking at the realistic distance was exposed to values lower than the AOEC proposed. e) There is no re-entry activities after 1,3-D application. f) We do agree with the statement	
2(18)	Vol. 3, Appendix 1, List of end points and Addendum III (September, 2005)	DE: Representative uses include outdoor and greenhouse applications. However, risk assessment was performed for greenhouse applications only!	RMS: Outdoor evaluation was performed for telone injected. See Monograph B.6.14.6 Notifier: This is incorrect, a separate risk assessment was conducted for open field use.	See open point in comment 2(17)

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(19) Rapporteur: Spain (ES)	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.	RMS: Operator re-entry tasks are not anticipated when the irrigation system is revised previously, and we consider more practical to make sure about this aspect. In addition, we do not consider appropriate perform a risk assessment for unusual task, such as repairing during 1,3-D application, since operator exposure values is variable, depending of several factors (time of re-entry, time after application, type of activity, etc…). Notifier: Although the concentration of 1,3-D was monitored immediately after application (4 hours). There is no expectation that the worker would re-enter the greenhouse at this time (re-entry would only be required if there was a leak in the irrigation system). Re-entry to address a leak would typically take less than 10 minutes (B6.14.1.1). The proposed AOEL is based on an 8 hour exposure, therefore the 12 mg/m^3 for 10 minutes would be equivalent to 0.25mg/m^3 over 8 hours. Finally the value of 242 mg/m^3 can be considered atypical as due to a technical issue that resulted in a	See open point in comment 2(17)

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(20) Rapporteur: Spain (ES)	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/m^3 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.	RMS: We do agree that bystander passing close to an 1,3-D application site could be exposed to levels higher than AOEC, and measures to avoid exposure should be taken. However, bystander exposure was made following other approaches (more than 7 meters), in which case, no risk for bystanders was anticipated. Notifier: Although the concentration of 1,3-D was monitored immediately (one meter) outside the greenhouse. The value of 1.4 mg/m^3 relates to a 4 hour interval, when considered in conjunction with the second 4 hour concentration of 0.16 mg/m^3, the 8 hour average concentration is 0.78 mg/m^{3,} The next 8 hour period (4 to 12 hours) average concentration is 0.3 mg/m^3 There is no expectation that an incidental bystander would be one metre from the greenhouse for 8 hours. Therefore the apparent exceedence of the proposed AOEL of 0.3 mg/m^3 AOEC based on air concentrations alone is not significant.	See open point in comment 2(17)

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(21)	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?	RMS: Considering that field studies involve certain variability, and that these studies are specific for 1,3-D, we are not sure if new studies can reduce variability. Therefore, we consider that these studies (MG48 and 49) can provide approximate data of 1,3-D exposure. Notifier: Air concentrations reported in MG48 and MG 49 cover a range of *ca.* 50 fold and as such can be considered to be indicative of the potential variation in air concentrations.	See open point in comment 2(17)

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(22)	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 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.	RMS: We do agree that all the activities involved in 1,3-D application (injection) require the use of RPE to minimise the risk. Notifier: Soil Injection reports cover outdoor and greenhouse application. However, the notifier no longer supports the use of Injection -greenhouse application and the work task of installation of sheeting. The notifier agrees that work on bed shaping would require RPE.	See open point in comment 2(17)

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(23)	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/m^3 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/m^3 for this duration? This is important to enable assessment Of risk to those living next to the treated area.	RMS: See point 2 (20) Notifier: Please refer to section 2(13) on the errors associated with the calculation of the AOEC concentration of 0.3 mg/m$^{3..}$ The correct value is 0.4 ppm or 1.8 mg/m^3. This value is for a daily lifetime exposure and bystanders will not be exposed on a continuous basis for a lifetime as applications are only annual or bi-annual. In addition, further refinements should be made to the breathing rates in the calculation of AOEC to reflect the overall breathing rate for residential bystanders.	See open point in comment 2(17)

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(24)	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.	RMS: This assessment is not possible due to the limited information available regarding the impurities present in the batches used in the toxicological studies.	See open point in comment 2(6)
2(25)	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.	RMS: Irrespective of the clasiffication reached in ECB, the irreversible effects occurred, thus the ADI agreed in EPCO 23 ensures sufficient margin to avoid them. See 2(12), 2(1), 2(2) Notifier: USEPA have a totally different classification system to the EU and this is an EU review. ECB and EU Member State experts (not just ECB) agreed no cancer classification for 1,3-D. On this basis, use of an extra safety factor against this end point for the 1,3-D ADI seems inappropriately conservative and should be removed. See Responses 2(2), 2(3), 2(4) and 2(12).	See open points in comments 2(12) and 2(13)

3. Residues

Storage Stability (B.7.0)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(1)	Vol. III B.7.6 Residues resulting from supervised trials	FR: As 1,3,3-trichloropropene 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?.	Notifier: At the time that the notifiers resubmission dossier was assembled it was not certain whether 1,3,3-trichloropropene would be declared relevant. However residues would again be expected to be <0.01 mg/kg, as for parent 1,3-D. The TMDI of 1,3-D is 0.57% of the ADI or 175 times less than an acceptable exposure. Therefore in the worst case the exposure through diet would still be a very low percentage of the TMDI. **RMS (June 2009):** 1,3,3-Trichloropropene, was considered as non toxicologically relevant according to the information reported by notifier and assessed in the Addendum IV.B-6. March 2009. An estimation of rat oral LD50 value of 1,3,3-trichloropropene of 337,6 mg/kg using the commercially available, statistically-based, QSAR computer model TOPKATtm. So that, 1,3,3-trichloropropene should be considered as not toxicologically relevant. According that, 1,3,3-	Open point Need for assessment of potential and actual consumer exposure to toxicologically relevant impurities pending the outcome of the discussion on impurities by the expert meeting in toxicology (refer to open point in commnet 2(6)) See also comments in 3(8) and 3(13)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			trichloropropene should be considered as not toxicologically relevant (see Addendum IV.B-6. March 2009). Moreover, according to Addendum IV.B-6. March 2009, calculation of contributions of impurities to the mammalian toxicity of 1,3-dichloropropene products (Manual of development and use of FAO and WHO specifications for pesticides, Feb.2006) concluded that impurities which may occur in 1,3-dichloropropene do not contribute to the potential toxicity of these products. No impurity was found to be relevant, since the greatest contribution of an individual impurity was estimated to be 0.26% (MTIhaz= 1.0026) for 1,3-dichloropropane.	

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(2)	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.	Notifier: Information on the concentration of each impurity used in residue trials is provided in Volume 4, Table C.1.2.3.7, pages 33-34. **RMS (June 2009):** Information about used impurities is provided in volume 4, point c.1.2.3-3. Regarding the batch used in the residue trials for Telone II (test substance TSN106192), a certificate of analysis was submitted and all the six analysed impurities were found in the used batch. Regarding the batch used in the residue trials for Telone EC (test substance TSN106192), the impurity content was not quantified directly, although it could be assumed to be similar to the batch of Telone II, since Telone EC was produced from the batch of Telone II (TSN 106191).	Addressed

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(3)	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.	Notifier: Whole peppers and whole tomatoes were the matrix analysed. **RMS (June 2009):** Whole fruits of tomatoes and peppers were the analysed matrixes for the trials in which 6 impurities were determined.	Addressed
3(4)	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.	Notifier: Method CEM-3339 (CEMS-3629, GHE-P-11736, Ref. OR35) was used to determine the impurities and the method is fully validated. This method is reported in Vol 3, B.5.2.2, pages 17-19 of the additional report. **RMS (June 2009)** Agreed with notifer's answer.	Addressed

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(5)	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.	Notifier: Information on the concentration of each impurity used in residue trials is provided in Volume 4, Table C.1.2.3.7, pages 33-34.The batch used for Telone II injection and Telone EC residue trials was TSN 106191. **RMS (June 2009):** Information about used impurities is provided in volume 4, point C.1.2.3-3. Regarding the batch used in the residue trials for Telone II (test substance TSN106191), a certificate of analysis was submitted and all the six analysed impurities were found in the used batch. Regarding the batch used in the residue trials for Telone EC (test substance TSN106192), the impurity content was not quantified directly, although it could be assumed to be similar to the batch of Telone II, since Telone EC was produced from the batch of Telone II (TSN 106191).	Addressed

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(6)	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?	Notifier: ND refers to the individual impurities. The LOD or <LOD (0.003 or <0.003 mg/kg) are only numerical values and the individual results should not be added since it would give higher false result for total residues of impurities. **RMS (June 2009):** ND refers to the individual impurities. The LOD is a numerical value based in 30% of the LOQ.	Addressed
3(7)	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.	Notifier: Method CEM-3339 (CEMS-3629, GHE-P-11736, Ref. OR35) was used to determine the impurities and the method is fully validated. This method is reported in Vol 3, B5.2.2, pages 17-19 of the additional report. **RMS (June 2009)** Agreed with notifer's answer	Addressed

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(8)	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.	Notifier: Many of the low level impurities present in 1,3-D technical have been found to have short half-lives in water due to hydrolysis. 1,3-D is applied to soil at least 3 weeks before planting and therefore choice of impurities to include in residue studies were based on covering the range of type of impurities and avoiding those which rapidly degrade in water. Additional information on the choice of impurities can be found in the responses in the environmental fate section (related to groundwater monitoring studies). **RMS (June 2009):** Regarding impurity 6, see 3(1).	Refer to open point in comment 3(1)
3(9)	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).	**RMS (June 2009):** This information has been noted in the assessment.	Addressed

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Livestock feeding (B.7.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Succeeding/Rotational crops (B.7.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(10)	Appendix 1.4 (LoEP)	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.	**RMS (June 2009):** Agree, LoEP has been updated	Addressed

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(11)	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.	Notifier: These 2 impurities have a maximum of 1 g/kg as a proposed specification. The product is injected into bare soil at least 3 weeks before planting. The estimated vapour pressures of these [redacted] are around 21-22 mbar at 50 deg C and so they are still reasonably volatile (parent molecules are 105-147 mbar). Based on low levels present, the actual application practices, and the estimated phys-chem properties the exposure risk from these oxiranes should be low. (see response 4 (23) highlighting rapid degradation of these [redacted] . **RMS (June 2009):** Although impurities 9a and 9b [redacted] are predicted to have lower vapour pressures than 1,3-D, and impurity 13 is structurally dissimilar, the calculation of the maximum theoretical increase in hazard (MTI_{haz}) (see 3(1)) indicates that these three impurities were found to be “non-relevant”, since MTI_{haz} were clearly below 1,10.	Open point No experimental data is available on the vapour pressure of the impurities (see 1(9)). Need for further consideration of potential consumer exposure to structurally dissimilar impurities with different physical chemical properties is pending the outcome of the discussion by the expert meeting in environmental fate and behaviour See also comment in 3(12)

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(12)	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.	Notifier: A table of phys-chem data, including vapour pressure data, has also now been provided to RMS (literature, estimated, lab measurement etc) See response 1(9). **RMS (June 2009):** The assessment will be based on the non-relevance of the impurities. As shown in Addendum IV-B.6-March 2009, no impurity was found to be "relevant" and the greatest contribution of an individual impurity was estimated to be 0.26% (MTIhaz= 1.0026) for 1,3-dichloropropane. Regarding clarification of sources for vapour pressure and phy.-chem. property data, see 1(9).	See open point in comment 3(11)

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(13)	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 1,3,3-dichloropropene whereas in the residue section it was.	Notifier: At the time that the notifiers resubmission dossier was assembled it was not certain whether 1,3,3-trichloropropene would be declared relevant. However residues would again be expected to be <0.01 mg/kg, as for parent 1,3-D. The TMDI of 1,3-D is 0.57% of the ADI or 175 times less than an acceptable exposure. Therefore in the worst case the exposure through diet would still be a very low percentage of the TMDI. **RMS (June 2009):** See 3(1)	See open point in comment 3(1)

4. Environmental fate and behaviour

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Adsorption,desroptionand mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

PEC in soil (B.8.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(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.	Notifier: Wang report, GHE-P-11175: Weather data source on P.5 of report (www.weatherbase.com) Etain, France for Northern Zone and Almeria, Spain for Southern Zone. Model publication: Computers and Electronics in Agriculture archive Volume 56 , Issue 2 (April 2007) table of contents Pages 111-119 Year of Publication: 2007 ISSN:0168-1699 **24 June 09** **RMS:** the linear relationship for chemical partition between the three phases was not found in the report GHE-P-11175 or in Wang et al (2007). For the weather data source, see notifier comment above.	Open point RMS to provide the additional detail attached to the reporting table in relation to figure 8.6.2.1-3 in an addendum. Data gap Applicant to provide an explicit description of the relationship used to describe the 3 phase partition as utilised in the DripFume model. Data gap The reference 'Computers and Electronics in Agriculture archive Volume 56 , Issue 2 (April 2007) Pages 111-119 ISSN:0168-1699 should be added to the dossier.
4(2)	Vol. 3, B.8.10.1.1, Monitoring data on Groundwater,	FR: When does the application occur on the Tymbaki and Irapetra basins? Considering the high mobility of the a.i,	Notifier: Applications in Tymbaki and Ierapetra basins take place July – November.	Addressed

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	Monitoring conducted in Greece	and the possibility of preferential pathways to the GW (see comment on page 87), this point might be of importance.	**24 June 2009** **RMS:** no comment	
4(3)	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.	Notifier: See Wang report, GHE-P-11175 Model publication: Computers and Electronics in Agriculture archive Volume 56 , Issue 2 (April 2007) table of contents Pages 111-119 Year of Publication: 2007 ISSN:0168-1699 **24 June 09** **RMS:** RMS conducted a FOCUS SW modelling for D scenarios with comparison purposes. The results showed to be comparable to the calculation made by notifer. Therefore, the latter can be considered relevant for risk assessment. Details on how lateral transport is accounted for in the model can be found in: Simunek, J. and M. Th. van Genuchten. 1994. The CHAIN_2D Code for Simulating Two-Dimensional Movement of Water, Heat, and Multiple Solutes in Variably-Saturated Porous	See data gap at comment 4(1) Data gap The references 'Simunek, J. and M. Th. van Genuchten. 1994. The CHAIN_2D Code for Simulating Two-Dimensional Movement of Water, Heat, and Multiple Solutes in Variably-Saturated Porous Media, Version 1.1. Research Report No. 136' and 'U. S. Salinity Laboratory, USDA, ARS, Riverside, California . Available from the following website: http://www.ars.usda.gov/Services/docs.htm?docid=8914' should be added to the dossier.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Media, Version 1.1. Research Report No. 136, U. S. Salinity Laboratory, USDA, ARS, Riverside, California . Available in the following website: http://www.ars.usda.gov/Services/docs.htm?docid=8914	
4(4)	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?	Notifier: Simulated rainfall event was timed to coincide with the estimated peak 1,3-D flux to the atmosphere which is worst case (GH-C 5046). Maximum runoff was 90 mm/day in the US study. FOCUS R-scenarios ranged from 8-40 mm/day. **24 June 09** **RMS:** agreed with notifer's answer **See also comment 4(5)**	Addressed
4(5)	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.	Notifier: FOCUSsw models were not designed and deemed appropriate for such a highly volatile active due to the use practice and properties of the molecule. The lateral flow model has been independently developed by academics to best describe the behaviour of 1,3-D in the field based on field measurements and run-off has been assessed using a more extreme run-off field experiment. 0.002% 1,3-D runoff was the result of	Addressed

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			combined natural and simulated runoff. The value of PECsw 2.24 ug/L from 0.003% runoff (50% higher than value determined under worst case condition) has been used in the aquatic risk assessment and gives a PECsw below the level of ecotoxicological concern. **24 June 09** **RMS:** agreed with notifer answer The reason of not conducting a FOCUS modelling with scenarios R is a known bug of SWASH in communication with PZRM, which says that values of 100 Pa and more for the saturated vapour pressure are replaced by 0.000 in Efate screen of PRZM shell without notice. When the user does not check the screens in the PRZM shell, but immediately presses the write button, the value of > 100 Pa is maintained and PRZM will crash. 1,3-D is a fumigant with a vapour pressure of 3920 Pa Because of the limitation of FOCUS PRZM for running with fumigants, the only alternative possible is to conduct a experimental trial under real conditions of use or by an alternative modelling The notifer has submitted an experimental study conducted in USA which was already evaluated and discussed in the EPCO expert meeting 21. In this meeting it was concluded **that a justification on**	

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			extrapolation of values from the U.S. trials. This information was submitted and evaluated in the new addendum 3 and considered valid by RMS. **See also notifer answer in comment 4(4) and comment 4(10)**	
4(6)	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).	Notifier: Representative wells in close proximity to the treated areas have been monitored in the EU over 4 years in 5 countries in high 1,3-D use areas, 5 regions per country. The vulnerability of each well has been assessed with respect to soil type, slope, hydrogeology, groundwater depth and recharge, GHE-P-11388. ~6000 samples taken from ~125 different wells (which were selected by independent academic experts) across a range of soil types, weather conditions and use practices provides a "weight of evidence" which is indicative of the behaviour of 1,3-D following typical use. A significant financial investment (> 2 million Euros) has been spent developing a 1,3-D dataset which monitors wells in high use areas. If there was a significant GW water contamination issue, there would be trends in the data indicating a risk. **24 June 09** **RMS:** During the peer review information on	Addressed

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			the use of 1,3-D in the regions of study were request. Details of this information is summarised in the addendum 3. Details of the locations of boreholes are given in the previous addenda. Moreover, a vulnerability of the boreholes was submitted. See comment 4(7)	
4(7)	B.8.10.1.4 Borehole vulnerability assessment	NL: more detail on the method used for ranking vulnerability of the individual boreholes per country.	Notifier: See report by Greg Hughes, O Price, R Humphrey, GHE-P-11388. **24 June 09** **RMS:** The approach followed to evalaute the vulneerability of the boreholes is based on DRASTIC approach. The DRASTIC index method is one of the most commonly used approaches to assess groundwater vulnerability to pollution. It can be found in the following website: **http://yosemite.epa.gov/water/owrccatalog.nsf/9da204a4b4406ef885256ae0007a79c7/9f6b7f250b4fbc4585256b0600723559!OpenDocument** Details of the different factor rankings have been included in the addendum. 3	Data Gap The reference 'Aller, L et al 1997 EPA/600/2-87/035' should be added to the dossier.
4(8)	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	**24 June 09** **RMS:** This model is an alternative to evaluate the environmental fate and behaviour of fumigants and address the PECsw calculation of	Open point Member state experts to discuss and agree whether they consider the available surface water exposure assessment in the

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		further evaluation.	this type of substances. RMS conducted a FOCUS SW modelling for D scenarios with comparison purposes. It showed the calculation made by notifer can be considered a worst case with respect the estimation of lateral flow and relevant for risk assessment. See comments 4(1), 4(3), 4(9)	additional report (addendum 3) is sufficient to conclude the EU level surface water exposure assessment. See reporting table comments 4(1), 4(3), 4(5), 4(8), 4(9) and 4(12).
4(9)	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.	**24 June 09** **RMS:** RMS conducted a FOCUS SW modelling for D scenarios with comparison purposes. The results showed that the calculation made by notifer can be considered a worst case with respect the estimation of lateral flow and relevant for risk assessment. Chain 2D code was one of the models reviewed by FOCUS SW group. Deatils on how lateral transport is accounted for in the model can be found in http://www.ars.usda.gov/Services/docs.htm?docid=8914	See open point at comment 4(9) and data gap at comment 4(3).
4(10)	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	Notifier: Blackburg, Virginia is in the Mesic temperature regime (USDA system for the classification of soils for temperature and moisture regimes). Mesic soil temperature regimes	Addressed Temperature was discussed in the additional report (volume 3).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		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 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.	extend across Northern Europe and large parts of Southern Europe. It is therefore considered appropriate for assessing the run-off given the worst case nature for rainfall and slope/soil type. 0.003% run-off was previously accepted and was used in the DAR. **24 June 09** **RMS:** agreed with notifer's answer The study was already evaluated and discussed in the EPCO expert meeting 21. In this meeting it was concluded that a justification on extrapolation of values from the U.S. trials. This information was submitted and evaluated in the new addendum and considered valid by RMS.	
4(11)	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	Notifier: The value of 500 µg/m3 was considered conservative given that deposition of interest will be to waterbodies away from the applied field (not onto treated field). As the typical maximum off site PECair was used and 100% was considered by deposition, a worst case evaluation has been conducted. **24 June 09** **RMS:** Details on volatilization studies are given in previous addenda already evalauted and peer reviewed . The bystandar monitoring was	Addressed

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		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.	conducted in a region of greenhouses. The experimental results were used for the proposed use in greenhouses, which was accepted in the EPCO Peer review. For field uses it was considered more appropriate to use experimetal data from volatilization studies already evaluated and peer reviewed. As mentioned in the orignal comment, it is assumed that 100% is deposited in a liter of water This is considered a worst case taking into account Henry's Law constant for 1,3-D	
4(12)	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 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).	Notifier: FOCUSsw models were not designed and deemed appropriate for such a highly volatile active due to the use practice and properties of the molecule. The lateral flow model has been independently developed by academics to best describe the behaviour of 1,3-D in the field based on field measurements. **24 June 09** **RMS:** FOCUS SW was conducted for scenarios D with comparison purposes. See comments 4(3) and 4(8) Agreed with notifier's comment	See open point at comment 4(8).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(13)	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 systems', but then information is only presented for exposure at distances of 1m and 3m from the crop. No information is presented for 5m?	Notifier: From the PECsw results from the Drip Fume modelling and field measurements evidence suggest that 5m PECsw acceptable to mitigate drainage. GHE-P-11175 shows that there is no movement of 1,3-D >5m. **24 June 09** RMS: Details are given in tables 8.6.2.1-4 and 8.6.2.1-5 of the addendum 3	Addressed

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(14)	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.	Notifier: The application rate for the 4 relevant U.S. sites were in the range 112 L/ha – 233 L/ ha so the PECair concentrations are relevant to the EU applications. **24 June 09** RMS: agreed with the notifier's answer Information on aplication rates can be found in previsous addenda already evaluated.	Addressed

Definition of the residues (B.8.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(15)	Vol. 3, B.8.10.1, groundwater monitoring study	UK: One of the reasons given for positive findings of 3-chloroacrylic acid at the Spanish site was the 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	Notifier: 3-chloroacrylic acid at the Spanish site was found adjacent to treated field well CC-2 ~2 m (stepped terrace) to tobacco plantings (application rate >300kg/ha and not covered by Annex I submission), CC-4 ~20m to tomatoes (max 224kg/ha). Groundwater depth was ~6m. Information on the depth of the individual wells or groundwater is presented in the individual reports or GHE-P-11388. It should be noted that use practice at this site was also questioned. Ratings applied to differing depths to groundwater for each well in ADAS report, Appendix 3, GHE-P-11388 See following table from report for	Addressed

<table>
<tr><th colspan="5">Other comments</th></tr>
<tr><td>No.</td><td>Column 1
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Comments from Member States or applicant</td><td>Column 3
Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier</td><td>Column 4
Data requirement or Open point (if data point not addressed or fulfilled)</td></tr>
<tr><td></td><td></td><td>compared to 16m for UK) not information for individual wells.</td><td>more detailed depth data.

<table><tr><th>Depth to Groundwater Class (m)</th><th>Rating</th></tr><tr><td>0 - 1.5</td><td>10</td></tr><tr><td>1.5 - 4.5</td><td>9</td></tr><tr><td>4.5 - 9.0</td><td>7</td></tr><tr><td>9.0 - 15</td><td>5</td></tr><tr><td>15 - 22</td><td>3</td></tr><tr><td>22 - 30</td><td>2</td></tr><tr><td>>30</td><td>1</td></tr></table>
24 June 2009
RMS: The addendum has been updated with information on the GW levels see appendix 8.1 of addendum 3.</td><td></td></tr>
<tr><td>4(16)</td><td>Vol. 3, B.8.10.1, groundwater monitoring study</td><td>UK: Overall, the UK would want to evaluate more detailed data at MS level before relying on this monitoring for a national regulatory decision.</td><td>Notifier:
Recommendation from Annex I would be that GW is thought to be a MS state issue. The monitoring data presented in Annex I was designed to show that safe use is possible given the “weight of evidence” available from 5 EU countries which include a diverse dataset of pedoclimatic conditions/soil type</td><td>Addressed</td></tr>
</table>

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			and use practice. **24 June 2009** **RMS:** Agreed with notifier's answer Details on the design the monitoring programme and analytical method are given in previous addenda already evaluated and peer reviewed. Details on grundwater level can be found in comment 4(15). Details on hydrogeolocial aspects can be found in the orginal reports and summarised in the previous addenda and annex 8.1 of addendum 3. Details on the use of 1,3-D the study areas was included in addendum 3 as request in the EFSA conclusion.	
4(17)	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.	Notifier: There is detailed information contained in the reports GHE-P-11707, GHE-P-11693, GHE-P-11388 and Letter report to RMS, July 2006 Ref. K86. **24 June 2009** **RMS:** Details on the boreholes have been included in the addendum 3	Addressed
4(18)	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	Notifier: There is additional information on the groundwater depth, hydrogeology class, slope, organic carbon and soil texture in the well vulnerability study for each of the French monitored wells, GHE-P-11388. There are 4 other countries which have	Open point EFSA to update the conclusion to indicate that for the French groundwater monitoring limited clarifications have been provided in annex 8.1 of addendum 3 but that the detail is not that which is necessary and still there is no information at all on cropping. The

<table>
<tr><th colspan="5">Other comments</th></tr>
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Comments from Member States or applicant</td><td>Column 3
Evaluation by (RMS) rapporteur and
- if available - (Co-RMS) Co-rapporteur / response from the Notifier</td><td>Column 4
Data requirement or Open point (if data point not addressed or fulfilled)</td></tr>
<tr><td></td><td></td><td>French data is compromised.</td><td>detailed data which has been accepted so an Annex I assessment for safe use can still be made.
24 June 2009
RMS: The information of the French monitoring has been included in the addendum 3 (see annex 8.1)</td><td>usefulness of the French data is therefore still compromised.</td></tr>
<tr><td>4(19)</td><td>Vol. 3, addendum 3 B.8.10.1.2, Evidence of 1,3-D use in the areas of monitoring pages 88-90</td><td>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.</td><td>Notifier:
A spreadsheet is provided to the RMS which summarises the label rates for all crops and EU Member States

These label rates have remained stable for at least the last 10 to 15 years. It must be noted that the recommended rates vary depending on soil type (light soils have lower rates than heavy soils); but the table below provides lowest and highest rate used in field use. In most cases the use rates are similar to, or higher than, the Annex 1 supported use rates.
<table>
<tr><td>Country</td><td>Min rate L/ha</td><td>Max rate L/ha</td></tr>
<tr><td>Belgium</td><td>150 (S Beet)</td><td>340 (various)</td></tr>
<tr><td>France</td><td>150</td><td>500</td></tr>
</table></td><td>Data Gap
Information on use rate recommendations over the monitoring duration or in the preceding years to the commencement of monitoring is required for the regions monitored. This information was provided by the RMS in the revised Vol 3-B8 (June 2009) but in line with Commission Regulation (EC) No 33/2008 neither additional information, nor the submission of new studies can be accepted in relation to stage 2 active substances.

Open point
RMS to update table 8.10.1.2-1 to include the units for the sales figures for Italy, France and the UK where the the units are missing, in an adendum, if this information is available.</td></tr>
</table>

Other comments

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			<table><tr><td></td><td>(S Beet)</td><td>(orchards)</td></tr><tr><td>UK</td><td>225 (Potatoes)</td><td>225 (Potatoes)</td></tr><tr><td>Italy</td><td>100 (herbaceous crops) 225 (Vegetables)</td><td>475 (Vines, citrus, orchards)</td></tr><tr><td>Spain</td><td>90 (S Beet) 150 (vegetables)</td><td>475 (Vines, citrus, orchards)</td></tr><tr><td>Greece</td><td>90 (vegetables)</td><td>200 (potatoes and ornamentals)</td></tr></table> **24 June 2009** **RMS:** The information has been included in the addendum 3	
4(20)	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	Notifier: 1,2-dichloropropane was not registered in Greece. However as indicated 1,2-D has non-agricultural uses (including lubricants, degreasing agents and unleaded petroleum	Addressed

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		after January 2004 in line with the pertinent non inclusion 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?	products). As only the 1,2-D impurity was seen in one of the sampling regions (Timbaki well B13HER007) with none of the other process impurities seen (including closely related 1,3-dichloro-propane and 1,2,2-trichloroproane both of which are present at higher levels in the 1,3-D technical product), a non-1,3-D source of 1,2-D is suggested for the presence of this impurity around the Timbaki well. **24 June 2009** **RMS:** Agreed with notifier's comment	
4(21)	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 (oxiranes) 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 1,3-D and for this moiety there are not even any QSAR values	Notifier: The proposal was to monitor for a range of 1,3-D impurities which were: - stable in water to allow a robust analytical procedure to be validated - representative of a range of compound classes within the profile of impurities The alkene impurities 10, 11a, 11b and 12 are likely to behave similarly to other alkenes that have been monitored. Based on the phys-chem properties of these impurities, they are expected to behave in a similar manner in the environment. Impurity 13 phys-chem properties have been	Data Gap A groundwater exposure assessment for process impurity 13 that could be considered by the peer review is not available.This information was provided by the RMS in the revised Vol 3-B8 (June 2009) but in line with Commission Regulation (EC) No 33/2008 neither additional information, nor the submission of new studies can be accepted in relation to stage 2 active substances. Open point RMS to add the Atkinson calculation for process impurity 13 in an addendum.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		reported? This impurity (13) would also have been a good candidate to have been monitored for?	compared to the other 12 impurities covered in GHE-P-11692 using the EPISuite QSAR software tools. These data show that impurity 13 is likely to behave similarly in the environment and that volatilization is likely to be the major dissipation route for most of this compound. Therefore impurity 13 will likely show similar trends to monitoring data from the other 6 monitored impurities. **24 June 2009** **RMS:** Accepted. The addendum 3 has been updated Regarding to [redacted] see comments 4(22) and 4(23)	Though this is additional information, the fact that the calculated atmospheric half life is above the trigger of 2 days, this makes this calculation potentially adverse. .
4(22)	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.	Notifier: The impurities are all closely related short chain simple chlorinated hydrocarbons. The mechanisms for substitution reactions and dechlorination have been widely reported in the literature. The hydrolytic instability of alkenes and oxiranes is well documented in the literature. 1. The **hydrolysis of a halogenoalkane**	Data gap An assessment of the potential hydrolysis products of process impurities 4, 5a, 6, 7 and 8b and their potential to leach to groundwater that could be considered by the peer review is not available. This information was provided by the RMS in the revised Vol 3-B8 (June 2009) but in line with Commission Regulation (EC) No 33/2008 neither additional information, nor the submission of new studies can be accepted in relation to stage 2 active substances.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			forms an alcohol. $RCl + H_2O \rightarrow ROH + H^+ + Cl^-$ Haloalkane dehalogenase is followed by Haloalcohol dehalogenase/epoxide hydrolase and then mineralisation Once dechlorinated many of the impurites will be <C4 with C,H, O only so may be considered to be non-relevant.	

Other comments				
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			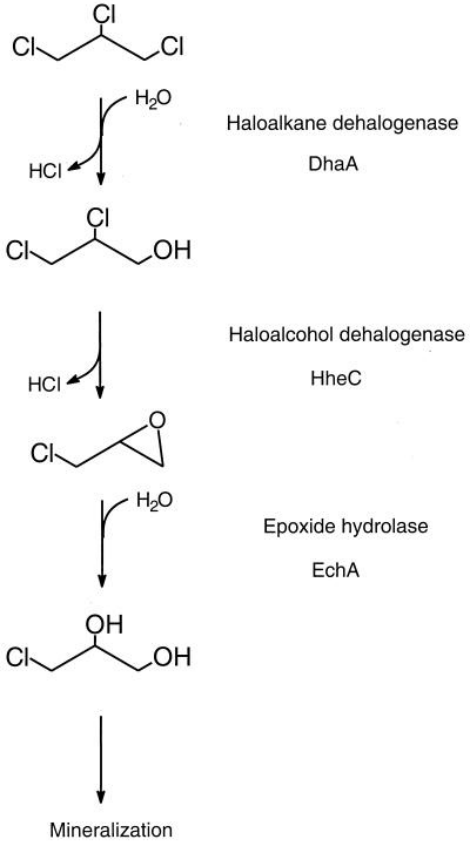 Furthermore, it is well documented that oxiranes are reactive and undergo rapid hydrolysis to form	

Other comments				
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			diols. Closely related oxiranes degrade rapidly with DT50 in water ~ 7 days (pH 4- 10) so impurities 9a/b are unlikely to pose a long-term groundwater risk. **24 June 2009** **RMS:** Accepted. This argument has been included in the addendum.	
4(23)	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 (oxiranes) 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) than measured for 1,3-D and estimated for the more closely structurally related impurities. Not even QSAR information was presented for compound 13?	Notifier: 6 impurities 9a, 9b, 10, 11 and 12 (that are not currently covered at all by any monitoring exercise) are included in the QSAR evaluation and are likely to behave similarly in the environment to the other impurites. Volatilization is likely to be the major dissipation route for most of these compounds. Furthermore, it is well documented that oxiranes are reactive and undergo rapid hydrolysis to form diols. Closely related oxiranes degrade rapidly with DT50 in water ~ 7 days (pH 4- 10) so impurities 9a/b are unlikely to pose a long-term groundwater risk. QSAR information for Impurity 13 **24 June 09** RMS: accepted	Open point Member state experts to discuss if they can accept the available QSAR estimates and the associated case for low groundwater exposure asssessment for the process impurities 9a, 9b, 10, 11, 12 that will be applied at 22 to 110 g/ha. Note for this discussion the additional information that was provided by the notifier in the reporting table with regard to the oxiranes (9a and 9b, reactivty, half lives etc.) cannot be considered by the peer review.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(24)	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.	Notifier: From the Atkinson calculations the potential for long range transport exists. However due to the high volatility of these compounds and considering the behaviour of the parent which is present at 1000-10000 times higher concentrations, no adverse impact is expected. Taking the worse case for air concentrations for the parent, no aquatic risk was seen. For longer range transport vapour dispersion of these volatile impurites would be infinite in the atmosphere. **24 June 2009** **RMS:** Only impirities 3 5a, 5b have a maximum declared contain > 1 g/kg. The long range transport cacapity of the rest of the impurites is considered low. According to WHO, Impurity 3 has several industrial uses and it is rarely found in water. Information on the impurities 5a and 5b was not found. On the other hand, notifer presented data from a Pilot plant in which all impurites are ≤ 1g /kg	Open point EFSA to highlight in the conclusion that there are concerns for the potential long range atmospheric transport for 10 of the process impurities that will have application rates of up to 28 to 340g/ha (including impurity 13, potentially adverse new information provided by the applicant as an attachment to column 3 of the reporting table) .
4(25)	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?	Notifier: Correct name is : 2-chloro-3-chloromethyl oxirane. **24 June 2009** **RMS:** The name has been changed in the addendum 3	Addressed

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(26)	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.	**24 June 2009** **RMS:** This comment comes from ecotox section (comment 5(29)). The current guidance for evaluating the risk on non target plants is calculating the exposure from BBA drift values. This practice is not valid for fumigants, which are transport by diffusion. CHAIN 2_D code is an alternative to evaluate the environmental fate and behaviour of fumigants. No comments was received regarding to the PECsoil calculation in fate section. The calculation with CHAIN_2D code is made for the top 30 cm . If the results at 0.1 m of the edge of the field (191- 221 mg/kg) are compared to the worst calculation made for infield according to the current guidelines (if 30 cm depth is considered the initial PECsoil would be 62.8 mg/kg for an application rate of 283 kga.s/ha), they can be considered a worst case. This conclusion is confirmed by field dissipation studies .	Open point Member State experts to discuss if they can agree the PEC soil off crop as presented in section B.9.8.2 of the additional report (addendum 5, section B.9, ecotoxicology) that was calculated with the CHAIN 2_D model based, on the information as reported in the additional report ecotoxicology section.

5. E cotoxicology

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(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	Notifier: Agree with comment for birds; Vol. 3, Table 9.1.4-2, for birds Tier 2 TER: Insectivorous acute = 88 Insectivorous short-term > 790 Earthworm-eating acute = 320 Earthworm-eating short-term >2800 Also, note that the Vol. 3, Table 9.1.4-2 herbivorous bird acute Tier 2 TER > 91000 (not >9100) For mammals, the Tier 2 acute TER values for herbivorous mammals are presented in the LoEP (Acute oral (plant intake) Tier 2 TER > 46700). RMS: LoEP, table with TER values for birds and mammals has been amended. RMS agrees with notifier comments.	Open point: RMS to update LoE. The refined TER for earthworm eating bird (short-term) should be corrected to 320.
5(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	RMS: not comment.	Addressed. See open point in 5 (5) and 5 (10)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(3)	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.	RMS: The study is considered acceptable for risk assessment. The NOEC was established at the highest doses tested of both exposure periods.	Addressed.
5(4)	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.	Notifier: The study to look at residues in plants was conducted using tomato as a surrogate plant to enable a worst-case assessment to be conducted. Seedlings were introduced (as they would be under conventional use scenarios) after the minimum time period following soil treatment (i.e. at the time when any residues in soil would be greatest). The study indicated that the compound is either no longer present in the soil, or if present, it is not systemic and hence the risk to birds and mammals from the consumption of plants which may grow in treated soil will be negligible. It is agreed that the available information for NMS and SMS indicates that residues in earthworms differ; not surprisingly, environmental factors (soil type, temperature, moisture content) and GAP (time between soil capping and introduction of crop) will affect the presence and activity of earthworms within the treatment zone, and	Addressed See open point in 5(8).

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		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. 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.	the period of exposure to 1,3-D. In the NMS study, the soil was treated in Autumn and capped for several months before the crop was planted in the Spring. Under such conditions earthworm presence and activity in the treatment zone would be higher than in the SMS study which was conducted during Spring in sandy soils, where the crop was introduced two weeks after soil treatment. Therefore, for uses in NMS then the appropriate GAP, and associated environmental factors, must be considered further when considering the magnitude of residues in soil organisms. RMS: The study conducted in SMS was conducted according to the intended use of 1,3-D in South Europe. It is a realistic approach. It is agreed 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. This is an important point to consider for risk assessment. The risk assessment was conducted according to intended uses on South Europe. The supported application rates are up to 283 kg 1,3-D/ha for indoor uses and up to 224 kg 1,3-D/ha for outdoor uses, with a maximum	

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			of one application per year. Typically the soil is treated with 1,3-D and then left for a minimum of 14 – 21 days before a fruiting vegetable crop (seedlings) is transplanted into the soil. Furthermore, the EPCO expert's meeting indicated that the residue data should be collected under conditions representative of Mediterranean conditions. During Annex I evaluation the study conducted under NMS was not considered to be relevant to the supported Annex I use for fruiting vegetables in SMS. RMS agrees that the study conducted in NEU conditions is more relevant for NE conditions. However, according to the GAPs for Annex I inclusion of 1,3-D only South Europe was considered.	
5(5)	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?	Notifier: See Notifier comment 5(10). RMS: The long-term oral toxicity endpoint (NOAEL: 2.5 mg a.s./kg bw/d) listed in the EFSA Scientific Report (2006) was taken from the 2 year dietary study in rats (Depression of in life body weights). The selection of endpoint focused on body weight change was based on the PPR Panel opinion on the choice of endpoints to assess the long term risk to mammals was subsequently	Open point: Member State experts should discuss the relevant long-term end point for mammals. See also comments 5(9) and 5(10)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			adopted in 2006 (The EFSA Journal (2006) 344, 1-22). In this opinion the PPR Panel recommended that while all available toxicity studies should be considered when assessing the risk for mammals, the main focus should be on studies that directly assess reproductive performance. Furthermore, some of the more sensitive endpoints, such as histopathological effects, not accompanied by clinical or physiological changes, were not considered relevant as they will have little or no impact on total individual reproductive success. In addition, and probably more appropriate in the case of 1,3-D, the NOEL should be chosen from studies with a treatment duration close to the expected exposure duration in the field, or if longer-term studies are used the NOEL should be chosen for the treatment duration closest to the expected exposure duration in the field. Specifically, for endpoints such as changes in body weight, the PPR Panel recommended to evaluate the endpoint for the exposure period relevant to the ecotoxicological assessment. According to the PPR Panel opinion, effects on body weight may have some relevance to breeding success of wild mammals (e.g. establishing breeding site, pairing and mating) and so should be considered. These are therefore considered further in the	

Birds and mammals (B.9.1 and B.9.3)				
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			context of the treatment duration closest to the expected exposure duration in the field as advised by the PPR Panel.	
5(6)	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.	Notifier: The scenario evaluated was relevant to the Annex I GAP and clearly illustrated that small mammal activity on 1,3-D treated fields is reduced due to the agricultural operations. Thus, this illustrates that in-field exposure on bare, treated soils is low and so any assumption that small mammals will feed exclusively on treated fields is incorrect. RMS: The field study submitted **Blanckenhagen, F. (2006)** by the notifier is considered relevant for risk assessment of telone. The aim of this study was to identify those wild small mammal species that may be active on fields during the period immediately following soil injection with Telone II, and to determine their habitat preference including their food source / choice. The data were analysed to determine the relative abundance of small mammal species on agricultural fields and in the surrounding habitats during the period immediately before fumigation, immediately after fumigation, and approximately 14 days after a typical vegetable crop (in this case tomato	Open point: Use of the field study submitted Blanckenhagen, F. (2006) should be discussed by Member State experts. E.g: - Can the study be considered valid? - How representative is the study? - Is the preference for 1,3-D treated fields so low that no risk is expected?

Birds and mammals (B.9.1 and B.9.3)				
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			seedlings) is planted. Since no crop plants are grown at the time of Telone II treatment, the species potentially feeding on the treated field are omnivores (e.g. wood mice) and insectivores (e.g. shrews). Based on available data it is expected a low preference of wood mice for the fields where Telone II is applied. The field study contains valuable information for risk assessment refinement on mammals.	
5(7)	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?	Notifier: There were no statistically significant differences in growth of male bobwhite quail between the control group and exposed groups. The range of maximum weight increase or loss during the study for all treatments is comparable to that in the control birds. Therefore the statement that "*growth of male bobwhite quail in the control gr. (both 20w and 7w exposure) is low compared to the growth of exposed males*" is not supported. RMS: RMS agrees with notifier comments. Not significant differences were detected between	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			growth of male bobwhite quail in the control gr. (both 20w and 7w exposure) compared to the growth of exposed males.	
5(8)	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 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. 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	Notifier: The personnel collected what was present; if dead arthropods or earthworms were seen then they were collected. The analysis was based on live/dead arthropods/earthworms as collected; presumably birds or mammals would consume in the same ratio assuming no bias or choice by a bird/mammal. In reality, birds/mammals are expected to show bias for live arthropods/earthworms which will attract attention, due to their movement, more than dead arthropods/earthworms. In addition, dead arthropods/earthworms will quickly dessicate on the soil surface and will be less attractive as food. RMS: In the summary of report is indicated that "All samples of earthworms and arthropods were sorted, counted and weighed. Where seen dead arthropods and earthworms were also collected, counted and weighed. All samples were frozen and shipped on dry ice to CEMAS for analysis of 1,3-D residues. Therefore the results of analysis are based on dead/alive arthropods/earthworms as collected.	Open point: The validity or the residue study in insects and earthworms should be discussed .by Member State experts - Is there a bias in the estimated concentration, based on a potential higher residue concentration in dead insects, which may compose a higher proportion of bird diet than expected from the residue study? - Is reasonable to consider that birds/mammal have a bias for live arthropods/earthworms?

Birds and mammals (B.9.1 and B.9.3)				
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			EFSA question: 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? For transparency Appendix 5 of the original report is inserted in the Addendum where the number of death earthworms and arthropods is analysed. Residue levels used for risk assessment account for dead/alive arthropods/earthworms residues. At this level of information it is not possible to know if dead arthropods/earthworms have more 1,3-D residues because for analytical purposes samples were combined in order to get enough sampling to conduct the analysis. Due to low number of animals and its level of residues of 1,3-D analysed it is unlikely that birds and mammals have a higher proportion of residues coming from dead insects in the diet.	
5(9)	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	Notifier: See Notifier comment 5(10) In addition, EFSA is referred to the ADME information for 1,3-D. Pharmacokinetic data	See open point in 5(5).

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		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?	for 1,3-D, illustrated that the active substance is rapidly absorbed from the gastrointestinal tract (absorption half-life of 1.3 - 4.7 min); once absorbed, peak blood concentrations of 1,3-D are reached within 15 minutes of dosing, and this is followed by a more than 10-fold decrease in blood concentration within 30 and 60-min post-dosing. In rats, the rapid elimination from the bloodstream occurs consisting of an alpha phase half-life of 2.8 – 6.1 min. Following acute (and repeated) oral dosing, the predominant routes of metabolism and excretion of 1,3-D were via the urine (*ca*. 50-60%), faeces (*ca*. 15-20%), and expiration of carbon dioxide (*ca*. 15-17%). The principle route of excretion, via the urine, had an elimination half-life of less than 6 hours for both rat and mouse. The ADME study indicated that 1,3-D is primarily metabolized (detoxified) in rats and mice by conjugation with glutathione, with no parent compound identified in the urine. Lesser amounts undergo hydrolysis to produce carbon dioxide. Thus, we can be sure that effects will not occur after 90 days from short term (less than 14 days) exposure. **RMS:** Furthermore, see point 5 (10) column 3. In the rat 90-day oral study (Haut et al., 1993, summarized in the DAR) effects on body	

Birds and mammals (B.9.1 and B.9.3)				
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			weight were only detected after 49 days exposure to 5 and 15 mg/kg$_{bw}$/day in males. Effects at 50 and 100 mg/kg$_{bw}$/day were detected in males within 7 days of exposure. Females were less affected, with no effects even after 90 days at 5 mg/kg$_{bw}$/day, and effects at 15 mg/kg$_{bw}$/day only detected after 84 days. An important point to consider is that following the 4-week recovery period, rats fed 100 mg/kg/day showed definitive signs of recovery in most of the parameters examined including body weight. ADME information for 1,3-D. Pharmacokinetic data presented by notifier is in agreement with absorption, distribution, excretion and metabolism in mammals (see below): **Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)** Rate and extent of absorption ‡: Rapid and complete, based on urinary, faecal and CO2 excretion in rat and mouse, accounting >90% dose after 48 h of single oral administration of 1 and 50 mg/kg and 1 and 100 mg/kg, respectively. Inhalation route: rat: >73-79% human: cis-isomer: 72-80% and trans isomer: 77-82% within 15 min after cessation of exposure (based on expired air concentrations) Distribution ‡: At 48 hours post-dosing, practically eliminated. About 6% of the dose remained in tissues and carcass of rat, in which highest values were found in non-glandular stomach, glandular stomach, bladder, liver and kidneys. Potential for accumulation ‡: No evidence of accumulation in rats or humans Rate and extent of excretion ‡: Oral administration in rat (50 mg/kg): 93.5% eliminated within 48 h, mainly via urine (61.3%), faeces (17.1%) and CO2 (15.1%). Inhalation route in human: 89-99% within 24 h. Mainly via urine (cis isomer-75%, trans-isomer-25%) Biphasic excretion. Half-lives: cis-isomer: phase 1-4.2 h; phase 2-12.3 h; trans-isomer: phase 1-3.2 h; phase 2-17.1 h	

Birds and mammals (B.9.1 and B.9.3)				
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5(10)	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/kgbw/day). The notifier would like to reiterate that a precautionary, and ecologically relevant, NOEC is 15 mg/kgbw/day as supported by the available information provided in Section B.9.3.1. See Column Further explanation in the notifiers comments	RMS: Taking into account the intended use and time of application of 1,3-D, the 90 days oral exposure study is suitable for risk assessment. Based on the results from 90d-oral exposure studies in rat the no-observed-adverse-effect level (NOAEL) for male rats and the no-observedeffect level (NOEL) for female rats based on body weight was determined to be 5 mg Telone II/kg body weight/day. Furthermore, the NOAEL of 5 is in agreement with the information provided by the notifier based on the assessment presented on effect of 1,3-D on body weight of rats during first 2 weeks exposure to 1,3-D in long-term studies. Therefore, NOAEL of 5 mg/kg_{bw}/day basis on body weight effects may have some relevance to breeding success of wild mammals (e.g. establishing breeding site, pairing and mating) and so should be considered for risk assessment.	See open point in 5(5).

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(11)	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.	RMS: see point 5 (14), only effects on length are significant. It has been indicated in the table 9.2.5-1.	Addressed.
5(12)	Vol. 1, LoEP, Toxicity data for aquatic species	FR: There are typo errors in the names of green algae: write ***Selenastrum capricornutum*** instead of *capricornotum*, and ***Skeletonema costatum*** instead of *Skeletonenam constatum*	RMS: typos amended.	Addressed.
5(13)	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.	RMS: Under RMS opinion all the comments regarding PECsw calculation have been addressed or fulfilled, See comments 4(1); 4(4); 4(5); 4(8); 4(9); 4(10); 4(11); 4(12); 4(13)	Open point: Confirmation of PECsw is pending the fate expert meeting.
5(14)	Vol. 3, Adenda V, B.9.2.5, Chronic toxicity to invertebrates, Mirino et al., 2007	EFSA: It's not clear from Table 9.2.5-1 if the effects on length are significant.	RMS: The length data did not meet the normality and homogeneity assumptions, therefore, the determination of a NOEC for length was made using a Kruskall-Wallis test and if significant, was followed by a Wilcoxon Rank Sum test. Statistical Significant differences were ($p < 0.05$) established for 5.08 and 10.1 treatments. This statistical difference has been indicated in Table 9.2.5-1.	Addressed.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(15)	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.	**Notifier**: The EFSA values were for EC50. Following the request of EFSA, the toxicity end-points for algae were calculated in terms of biomass (E_bC_{50}) and growth rate (E_rC_{50}) using the cell counts reported in the original studies. The *Skelotonema* results for 1,3-D and 3-chloroallyl alcohol should be reported as 5 day values (not 4 days). **RMS**: As indicated by notifier the differences between values calculated are due to the way the calculations were made: New calculations are: E_rC_{50} (growth rate), E_bC_{50} (area under the growth curve), The values reported on the DAR and EFSA report were calculated as EC_{50} (final cell density). The typo error indicated by notifier has been amended.	Addressed.
5(16)	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	Notifier: This is a new request, time will be needed to get the data re-analysed to give end-points as growth rate and area under the curve. If the RMS confirms this is a requirement, the notifier will action accordingly.	Open point: Both growth rate and biomass are normally reported for algae and higher plants and the lower endpoint should be used in the aquatic risk assessment according to the Aquatic Risk Assessment Guidance Document. In the current risk assessment TER values for the parent do indicate a

Aquatic organisms (B. 9.2)				
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			RMS: RMS agrees with notifier that this is a new request. Furthermore, according to aquatic risk assessment aquatic plants are not an area of concern. This is not a critical endpoint that could change the output of risk assessment. In EFSA report is stated: *An aquatic risk assessment for the use via drip irrigation (indoor use) with the initial PEC_{sw} values, agreed in the EPCO 21 expert meeting on Fate and behaviour, is available in addendum 3 of September 2005. The EFSA agrees with the presented risk assessment but considers it not necessary to conduct a chronic risk assessment for algae and Lemna gibba as these studies are not long term studies.* For consistency reasons with previous aquatic risk evaluations for 1,3-D on aquatic plants (basis on 14d LC50), RMS opinion is not necessary to have the *Lemna* endpoints based on both as growth rate and biomass.	large margin of safety. However, for 3-chloroacrylic acid a TER of 84 does not provide an extensive margin of safety. Changes in GAP uses at national level and providing the endpoint based on both growth rate and biomass may change the conclusion of the risk assessment. For consistency with other active substances endpoints should be provided based on both growth rate and biomass for the active substance and the two metabolites. The aquatic risk assessment should be updated accordingly (in the LoE).
5(17)	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).	RMS: typographical error amended.	Addressed.

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(18)	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.	RMS: The information has been included.	Addressed.
5(19)	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.	Notifier: It is agreed that analytical confirmation of exposure is expected in these types of studies with conventionally applied (sprayed) pesticides. However, In the case of a soil injected, volatile, fumigant, sampling of the soil to measure 1,3-D would have been extremely difficult due to the nature of the application (injection and capping of soil surface) and the equipment required to sample 1,3-D accurately from the soil (to minimize potential volatile losses – e.g. see non-conventional soil sampling methods used for field dissipation and leaching study, MK09). The difficulty associated with accurately measuring 1,3-D soil concentrations were considered disproportionally high compared to the value the data would provide to satisfy the study objective. The study was conducted to GLP, and all aspects of the application were checked and documented in the final report (batch of material used, preparation and calibration of application equipment, application volumes used, etc).	Open point: Member State experts should discuss the use of the field study by Small (2006) in the risk assessment for NTA. See also comment 5(21) and 5(23).

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			The use of a toxic standard was not considered to be necessary in the study. The challenge of the study was to investigate the impact on a range of soil taxa (earthworms, soil arthropod meso- and macro-fauna) for which no one product would serve as a suitable reference. The mode of application of 1,3-D is also unique which also makes finding a suitable and valid toxic reference difficult which would also mimic and validate the application method. Overall, the study compared 1,3-D treated and untreated fields on a field scale representing commercial conditions of use. **RMS:** A new detailed evaluation of study is included in the addendum June 2009. Note: In accordance with Sponsor, this trial is not GLP compliant.With the exception of Telone II application, which will be carried out by the farmer, and the arthropod taxonomy which will be carried out by University experts, and the collembola/earthworm taxonomy wich will be carried out by SynTech Research France, all other aspects of this trial will be carried out according to international GLP guidelines. RMS opinion is results of study can be used for risk assessment.	

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(20)	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.	RMS: It is agreed on the basis of data submitted and risk assessment calculated the risk to honey bees is expected to be low.	Addressed.
5(21)	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.	Notifier: See response to 5(19). The arthropod and worm data collected from samples taken during the study are fully presented and detailed table in Appendix 2. These data tables provide information on the types of organisms identified and the numbers found. A fully glossary of terms used are presented on P.61 and P.70 for the worm and arthropod data respectively to aid interpretation. When considering the conduct of the study it must be stressed that it was performed under realistic use conditions with respect to soil, location, crop and cultivation practices and hence represents the likely effects of 1,3-D when used under realistic conditions. RMS: a new summary of the study is depicted in	See open point in 5(19).

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			the Addendum of June 2009. Note: In accordance with Sponsor, this trial is not GLP compliant. With the exception of Telone II application, which will be carried out by the farmer, and the arthropod taxonomy which will be carried out by University experts, and the collembola/earthworm taxonomy wich will be carried out by SynTech Research France, all other aspects of this trial will be carried out according to international GLP guidelines. RMS opinion is results of study can be used for risk assessment.	
5(22)	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	Notifier: The risk assessment is a worst-case assessment based on a comparison of the $NOEC_{inhalation}$ (= 115 mg/m^3, measured) for bees exposed for 6 hours to 1,3-D vapour and the maximum reported air concentration (in-field and off-field). Since bees will not forage over bare soil for 6 hours, and since air concentrations measured under field conditions are generally 50 – 5000 fold lower than the maximum value used in the assessment, then the risk to bees is adequately addressed. It should be noted that the $NOEC_{inhalation}$ is more than 1000-fold higher than air concentrations generally measured under field conditions, which provides a very large margin of safety.	Addressed.

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			RMS: see point 5 (20). It is agreed on the basis of data submitted and risk assessment calculated the risk to honey bees is expected to be low.	
5(23)	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.	Notifier: When considering the conduct of the study it must be stressed that it was performed under realistic use conditions with respect to soil, location, crop and cultivation practices and hence represents the likely effects of 1,3-D when used under realistic conditions. Initial samples taken prior to start and at 21 and 42 days after treatment failed to collect collembola in both treated and untreated fields. This may have been due to recent cultural operations necessary in the fields and due to the hot weather driving collembola deep into the soil. These factors may have reduced the sampled collembolan numbers to low levels. Alternatively it may be that collembolan numbers are naturally very low at this time of year. For the first 3 samples a smaller soil core was used which did not lead to significant numbers being sampled. During this time (0-42 days) it is not possible to say whether 1,3-D had an adverse impact on collembola numbers. However, laboratory data would suggest that this is a possibility which cannot be excluded for the initial phase of the study (0 – 42 days). However, laboratory assays	See open point in 5(19).

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			in 1,3-D treated aged soil (21 days) indicated no effects on collembola. From 96 days and onwards sample methods were changed (larger and deeper soil samples). This change lead to small numbers of collembola (mostly *Hypogastrura brevis* and other Isotomidae) being sampled with numbers similar in both control and treated plots. From day 95 through to day 366 numbers of collembola sampled show a trend towards increasing numbers suggesting that prior to the 96 day sample numbers were low. Overall, given the limitations of the work it cannot be excluded that applied of 1,3-D under commercial growing conditions had an adverse impact on populations of collembola in soil for up to 96 days after treatment. From this point onwards collembola numbers were similar in both control and treated plots and continued to increase in number up to 366 days after treatment (i.e. approximately 1 year). Consequently, should effects have occurred the population was show to be able to recover in-field within 96 days after treatment. **RMS** agrees with notifier comments. A new summary of the study is depicted in the Addendum of June 2009.	

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 DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(24)	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?	Notifier: The study was not considered to be relevant to the supported Annex I use for fruiting vegetables in SMS. The study is relevant to some NMS scenarios and will be submitted to those MS where the GAP and environmental conditions are relevant (see comment 5(4)). **RMS:** The study was not submitted and therefore it was not evaluated.	Addressed
5(25)	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.	Notifier: Application of 1,3-D to soil will lead to reduced microbial respiration and nitrogen transformation. However, under field conditions it has been demonstrated that soil treated at 190 L/ha Telone II is unlikely to have any significant long lasting effects on soil respiration or nitrogen turnover, with recovery within no more than 4.5 months of treatment. **RMS:** Application of 1,3 –D to soil will lead to reduced microbial respiration and nitrogen transformation. For evaluation of 1,3-D in soil microflora two field studies are available: A) Field study showed that arable soil from N EU treated with Telone II at 300 L/ha	Addressed: It is considered sufficient that the LoE mentions the prolonged recovery for micro-organisms.

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 DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			(**equivalent to 363 kg 1,3-D/ha, which is more than 1.5-fold higher than the proposed rate supported for Annex I inclusion**) disrupted microbial respiration and nitrogen turnover. Soil respiration rates recovered to within 25% deviation from controls by Day 102 and nitrogen turnover recovered to a level of 25% deviation from control by Day 184. Therefore, the treated soil was considered to **have recovered** from the 1,3-D application within a **period of 184 d.** B) field study from S EU treated with 224 kg 1,3-D/ha, (1 x proposed rate): 1,3-D effects on soil microflora are unlikely to have any significant long lasting effects on soil respiration or nitrogen turnover, with recovery within no more than 4.5 months of treatment (136 days). In these studies not early sampling points were assessed, therefore **recovery** in field **extends 100 days**. According to intended uses of telone only 1 application per year is proposed. Full recovery of soil microflora is expected before next application. Recovery potential extends over 100 days but	

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
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			the effects are not long lasting under field conditions. May be this should be flagged at member state level.	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(26)	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	Notifier: See comment 5(30), Column 2. RMS: See comment (5 (30), column 3	Addressed.
5(27)	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.	RMS: In order to avoid potential water contamination RMS proposal is that washing water from cleaning tools should not be disposed of in to surface water. May be this subject should be flagged and dealt at MS level.	Open point: EFSA to flag in the conclusion that washing water from cleaning tools should not be disposed into surface water.

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(28)	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.	RMS: The current guidance for evaluating the non target plants is to calculate the exposure from BBA drift values. This practice is not valid for fumigants, which are transport by diffusion in soil. CHAIN 2_D code is an alternative to evaluate the environmental fate and behaviour of fumigants. No comments was received regarding to the PECsoil calculation in fate section. The calculation with CHAIN_2D code is made for the top 30 cm . If the results at 0.1 m of the edge of the field (191- 221 mg/kg) are compared to the worst calculation made for infield according to the current guidelines (if 30 cm depth is considered the initial PECsoil would be 62.8 mg/kg for an application rate of 283 kga.s/ha), they can be considered a worst case. This conclusion is confirmed by field dissipation studies..	Addressed.

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(29)	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 EC50 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.	RMS: It was a mistake. It is agreed that the NOEC for non-terrestrial plants is not relevant for risk assessment. These values have been deleted from LoEP.	Addressed.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(30)	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.	RMS: the name '3-chloroprop-2-en-1-ol' has been be replaced by '3-chloroallyl alcohol' to maintain consistency	Addressed

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(31)	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)	RMS: LoE has been updated according to template last updated in January 2009.	Open point: RMS to update the LoE. TER calculations should be provided for all aquatic organisms groups for the parent substance.
5(32)	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.	Notifier: All DAS batches showed levels of [redacted] below 1 g/kg (between 0.34 – 0.49 g/kg). This impurity is not observed in any of the Kansesho batches. DAS has now some ECOSAR information, which gives estimated fish LC50 = 2.343 mg/L, Daphnid EC50 = 6.446 mg/L, algae EC50 = 4.338 mg/L, earthworm LC50 = 294 mg/L. All of these are slightly higher (lower toxicity) than the corresponding end-points for 1,3-D, and so even if the actual toxicity is assumed to be 10x more than the ECOSAR estimates, the low exposure relative to parent would cancel out any (assumed) higher toxicity relative to parent. RMS: during addenda evaluation notifier did not	Addressed: For 3-chloro cyclomethylpentane it is assumed that the low exposure relative to the parent would cancel out any (assumed) higher toxicity relative to parent.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			submitted any ecotoxicological information about [redacted] Maximum levels in all batches indicated levels below 1 g/kg. According to the new data summarized in this table by the notifier, and assuming even if the actual toxicity is to be 10x more than the ECOSAR estimates, a relatively high toxicity is expected for fish and algae, respect to active substance. However, RMS agrees with notifier that the low exposure relative to parent would cancel out any (assumed) higher toxicity relative to parent.	