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

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0. General

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 0 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***0***			
	Open point: 0.1 RMS to use the agreed new template for the list of endpoints See reporting table 0(1)	No comments from the notifier		Addressed: EFSA has amended the LoEP

1. Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 1 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***1***			
	Data gap: 1.1 A reliable analysis of batches for the Kanesho Soil Treatment should be provided. See reporting table 1(8)	The multibatch studies from Kanesho did indeed contain some impurities above 1 g/kg which were not able to follow the full method validation process because specific analytical standards of these impurities were unavailable. However these peaks were positively identified by GC-MS and the g/kg values estimated against other similar chlorinated hydrocarbon substances for which analytical standards were available. Kanesho are committed to completing synthesis of analytical standard impurities and to providing validated methods of analysis and confirmation of multibatch studies. The notifier therefore respectfully requests that current proposed specification of Kanesho material is accepted.	**August 2009** RMS considers that technical specification from Kanesho should be considered only as provisional. As these impurities are declared well above 1 g/Kg, validated analytical methods are required according to Directive 96/46/ECC	Data gap: A reliable analysis of batches for the Kanesho Soil Treatment source should be provided
	Open point: 1.1 EFSA to consider the tolerance range of the a.s. content in the formulation, when writing the conclusion	A formulation consisting of the technical material + one coformulant, with no balance ingredient is unusual which is why the standard process of setting a specification is proving more difficult.	**August 2009** RMS agrees with the notifier	Addressed. The tolerance range for the 1,3-D content of the EC product is acceptable as being 920 – 955 g/kg

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	See reporting table 1(16)	It may be useful to consider the lowest 1,3-D technical specification would be 96.5% and the highest could be up to 98.5%. The EC formulation (EF-1478) consists of a blend of 96% of 1,3-D technical and 4% co-formulant. Therefore the theoretical minimum content of 1,3-D in the EC product would by 96 * 0.965 = 92.64% and the theoretical maximum would be 94.56%. Therefore on these assumptions the theoretical tolerance range of 1,3-D would be 926 to 946 g/kg. However, as with FAO tolerances, these need to be wider to cover variation in manufacturing additions and in analytical tolerances. On that basis we could consider a 1,3-D content of 920 – 955 g/kg as a reasonable tolerance range for the EC product.		

2. Mammalian toxicology

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 2 Open points: ***4*** Points for clarification: ***0*** Data gaps: ***0***			Section 2 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 2.1 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 reporting table 2(6)	The DAS material does not contain impurities 8a and 8b above 1 g/kg (range is 0.01 to 0.27 g/kg, or 0.001 to 0.027% w/w).	**August 2009** Regarding the impurities, with the available information provided by notifier 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 four 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?.	PRAPeR TC 17 (2 September 2009) Open point still open: Further mutagenicity testing is needed for the Kanesho source. For both sources, comparison and compliance of the specification with the toxicological batches should be demonstrated. Written procedure: Open point still open

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			- The need of application the new refined manufacture method proposed by DAS, that achieved technical material with no impurities above 0.1% - The application of mitigation measures to reduce the hazard until this method becomes fully operational. These four issues should be discussed by the experts **9 September 2009** 1,3-D specifications were different depending on the two notifers: DAS and Kanesho. According to Data gap: 1.1 technical specification from Kanesho should be considered only as provisional. As these impurities are declared well above 1 g/Kg, validated analytical methods are required according to Directive 96/46/ECC. Thus, this data gap should be clarified before the mutagenicity testing for impurities required in the TC 17. The proposed technical specifications for DAS are new, whereas the genotoxicity studies were done by ancient batches, thus RMS considers to be improbable that Notifier could establish a correspondence between batches. **RMS has performed an assessment of impurities according**	

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			to "Manual on development and use of FAO and WHO specifications for pesticides" (2006), and the final conclusion was that the impurities showed no toxicological relevance. Furthermore, in DAS technical specifications, impurities 8a, 8b and 8c are below than 1g/Kg. **RMS considers also that DAS proposed a new refined manufacture method to decrease all the impurities below 0.1%.**	
	Open point: 2.2 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 reporting table 2(12)	The 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 in the EU seems overly conservative and should be removed	**August 2009** 1.3 D 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 vivo genotoxic agent for somatic cells due to findings of DNA fragmentations, but not a mutagenic agent. 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 appropriate margin of safety (1000) between ADI and irreversible effects. These irreversible effects were noted in rats at dose of	PRAPeR TC 17 (2 September 2009) Open point fulfilled: The SF to use for ADI calculation is 100; the ADI is 0.025 mg/kg bw/day; the ARfD value was confirmed as 0.2 mg/kg bw/day.

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			12.5 mg/kg/day and in mice at 101 mg/kg/day. Irrespective of the classification reached in ECB, the irreversible effects occurred, thus the ADI agreed in EPCO ensures sufficient margin for both effects. **09 September 2009** Due to reasons exposed above (August 2009), RMS still considers more appropriate to give an additional safety factor (200) to prevent the apparition of irreversible effects, irrespective of the classification agreed in ECB.	
	Open point: 2.3 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 See reporting table 2(13)	The notifier supports the second option proposed by the RMS to calculate AOEL for 1,3-D because it avoids unnecessary route-to-route extrapolation by using inhalation toxicity to calculate an inhalation AOEL, i.e. *" 2: Convert an inhalatory value in rat to an inhalatory value in human according to:* *ppm(h) =ppm(rat)* resp rate (rat) * t (rat)* *resp rate (h) * t (h)* *t*: time of exposure.* *- time of exposure human (according draft Technical Guidance Document*	**August 2009** In EFSA conclusion page 15 stated that "The NOAEL for systemic chronic toxicity was considered to be 20 ppm" but it does not imply that this value is the correct to select the AOEL. RMS does not understand why notifier considers more appropriate an inhalatory NOAEL from a chronic study to select an AOEL, when an inhalatory short term study (with a NOAEL established) is available and was accepted. As was established in DAR (point B 6.10.2.3), agreed in EPCO 23 (point 2.5) and appeared in Addendum 3	PRAPeR TC 17 (2 September 2009) Open point fulfilled: The AOEC is 0.45 mg/m^3 (0.1 ppm)

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		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 * 45 L/Kg bw/hr * 6 hr * 5 :* *17.5 L/Kg bw/hr * 8 hr * 5* *= **0.19 ppm = 0.87 mg/m^3** " However, the correct **short-term** inhalation NOEL to use is not 10 ppm from the 90-day rat study but 20 ppm from the chronic rat study (EFSA Conclusion, page 15). Therefore, the correct inhalation AOEL is **1.8 mg/m^3**	Sept 2005, the lowest relevant **inhalation NOAEL** is 10 ppm from the 13-weeks inhalation study in rat. A SF of 100 was considered and different calculations to establish the AOEL can be performed (point 2(13)): 1: AOEL = NOAEL / FS. Then: 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. Then: AOEL ppm(h) = = 0.1 * 45 L/Kg bw/hr * 6 hr * 5 : 17.5 L/Kg bw/hr * 8 hr * 5 **= 0.19 ppm = 0.87 mg/m^3** **09 September 2009** Taking into account the comments received after the TC, RMS considers definitive the AOEC=0.45 mg/m^3 agreed in TC 17. With this value RMS has recalculated the risk assessment for operator, worker and bystander exposure	
	Open point: 2.4 The operator, worker and bystander exposure to 1,3-D	It is not clear to the notifier why the issue of OPEX is being raised again when it was not listed as a critical area	**August 2009** 1) Operator: Taking into account the 1,3-D physico-chemical properties and	PRAPeR TC 17 (2 September 2009) Open point still open: RMS to recalculate the whole risk

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	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? See reporting table 2(17)	of concern or data gap in the EFSA review report. Nevertheless the key points about the protected uses of the drip irrigation EC product are:- 1. Dermal application is not a major factor as operator only has to place a tube into a drum. There is no exposure during application as the operator will always be remote from the glasshouse where the application is taking place. The risk assessment in the dossier does not cover accidents or spillages and of course it is recognised that in such cases then special emergency procedures and PPE equipment may apply. 2. After the application in greenhouses it is not normal for people to re-enter until it is time for planting – normally at least 3 weeks after application. The notifier accepts that good Stewardship practices of adding notices to prevent accidental r e-entry should always be used. The notifier has proposed that if re-entry is required between 0 and 7 days after application then respirators with organic filters should be worn, 3. Prohibition of bystanders immediately outside the	the mode of application in field/greenhouse, dermal exposure of 1,3-D is not anticipated. Moreover, field studies corroborated that inhalation was considered the main route of exposure. We do not consider necessary to asses dermal exposure in mixing/loading and application of 1,3-D. By one hand, the European models cannot provide with appropriate estimations and by the other hand, specific 1,3-D field studies proved that dermal exposure was negligible. However, we find that dermal exposure can occur, therefore, it is important to focus on what PPEs are necessary to avoid excessive exposure when incidental tasks appear. 2) Re-entry. Since levels of 1,3-D are high during the first week after exposure, we coincide with Notifier in highlighting the risks associated in re-entry within this period. As PPE is necessary, we consider that the Experts must agree on whether the certified masks and gloves can provide sufficient protection against temporary high levels of 1,3-D. 3) We find that a realistic evaluation of	assessment for operator, worker and bystander exposure considering the new AOEC and eventually consider a higher percentile from the field studies. Written procedure The operator and worker exposure during drip irrigation activities is below the AOEL with the use of PPE and RPE; the estimated exposure levels for a bystander at >7 m from the site of application are below the AOEL, for closer distances are exceeding the AOEC. During soil injection activities the operator, worker and bystander exposure estimates show levels below the AOEC (operator and worker wearing RPE). Open point fulfilled

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		greenhouse is not required as there is no expectation that an incidental bystander would be one metre from the greenhouse for 8 hours. 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 For field uses of injection product the key points are:- 4. The 1,3-D in drums is transferred to farmers bulk tank by pump and closed transfer system and so the likelihood of dermal contact during routine application is minimal. The risk assessment in the dossier does not cover accidents or spillages and of course it is recognised that in such cases then special emergency procedures and PPE equipment may apply. Good stewardship practices that the notifier has put into place with extensive operator training programmes also covers best practices and PPE needs when	bystander exposure showed that no risk is expected after 1,3-D application in open field or greenhouses. In those places (greenhouses) where bystanders are expected to pass near a recently applied 1,3-D greenhouse, it would be useful to discuss what measures may be applied. **09 September 2009** Taking into account the new AOEC, a new addendum has been prepared to assess operator, worker and bystander exposure.	

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		maintaining of application equipment. The notifier believes that all of the concerns that have been raised under this open point can be dealt with by an appropriate risk management review at Member State level. i.e. **by ensuring effective Product Stewardship programs are in place** in each Member State where 1,3-D has been approved. The notifier has developed and implemented improved training programs for Operators and Distributors throughout Europe and we are ready to accept that providing Member States with specific evidence of such programs should be a condition of any future Annex III product approval for a soil fumigant. The notifier recognises that continued high investment in human health and environmental Stewardship programs are a key part of any soil fumigant future approvals and uses.		

3. Residues

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 3 Open points: ***2*** Points for clarification: ***0*** Data gaps: ***0***			
	Open point: 3.1 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 comment 2(6)) See reporting table 3(1)	The notifier has now presented information from residue trials on fruiting vegetables (using both injection and drip application techniques) that demonstrates that the typical range of **impurities will not be present at levels above an LOQ of 0.01 mg/kg**. We have also conducted a toxicological evaluation of the various impurities, using the only guideline available, from the FAO/WHO manual, and demonstrated that none would be significantly more toxic than the parent 1,3-D. 1,3-D MRL's are also based on an LOQ and set at 0.01 mg/kg. The TMDI of 1,3-D is 1.12% of the ADI (0.0125 mg/kg bw) or 89 times less (100/1.12) than an acceptable exposure. In other words, an impurity would have to be at least 89-times more toxic than 1,3-D, which is toxic by ingestion and has an ADI based on carcinogenicity, to reach an unacceptable exposure. In summary, the absence of residues alone (not to mention the need for an impurity to have toxicity almost 2-orders of	**August 2009** RMS concluded that, according the calculation of contributions of impurities to the mammalian toxicology of 1,3-dihloropropene products, based on the Manual of development and use of FAO and WHO specifications for pesticides Feb 2006, impurities which may occur in 1,3 Dichloropropene do not contribute to the potential toxicity of these products (MTIhaz is clearly below 1,10); none impurity was found to be relevant. These conclusions, linked with the results of the residue trials, in which the level of residue of 6 impurities was measured in tomato fruits and all of them was below the LOD confirm that the risk for consumers is negligible. **RMS CONSIDERS THIS OPEN POINT CLOSED**	Open point still open See open point 2.1

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		magnitude greater than 1,3-D) means impurities can not be a risk to consumers.		
	Open point: 3.2 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 reporting table 3(11)	We support the comments of the UK in the reporting table 2(10); "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." See also points highlighted above on open point 3.1.	**August 2009** Although impurities 9a and 9b (oxiranes) 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 (MTIhaz) (see 3(1)) indicates that these three impurities were found to be "non-relevant", since MTIhaz were clearly below 1,10. Therefore the potential risk for consumers is very low and the risk assessment performed for 1,3 D could cover the risk for impurities since the fact the impurities which may occur in 1,3 Dichloropropene do not contribute to the potential toxicity of 1,3D, none impurity was found to be relevant. Furthermore according the technical specifications of DAS the level of these three impurities is < 1 g/kg. **RMS CONSIDERS THIS OPEN POINT CLOSED**	Open point still open See data gaps in section fate and behaviour

4. Environmental fate and behaviour

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 4 Open points: ***8*** Points for clarification: ***0*** Data gaps: ***7***			Section 4 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***7***
	Open point: 4.1 RMS to provide the additional detail attached to the reporting table in relation to figure 8.6.2.1-3 in an addendum. See reporting table 4(1)	The Notifier has no further comment to add.	**August 2009** ES: Figure 8.6.2.1-3 has been included in addendum 4	PRAPeR TC 15 (1 September 2009) Open point fulfilled
	Data gap: 4.1 Applicant to provide an explicit description of the relationship used to describe the 3 phase partition as utilised in the DripFume model. See reporting table 4(1)	The pesticide model was modified from a generic two-dimensional finite element code CHAIN 2D, a public domain free program from the U.S. Salinity Laboratory (Simunek and van Genuchten, 1994), tailored for simulating fumigant fate and transport in the soil and volatilization into the atmosphere. Briefly, a governing equation is used for computing fumigant transport in unsaturated subsurface soil in both solution and gaseous phases. The model assumes nonequilibrium interaction between the solution and adsorbed concentrations, and equilibrium interaction between the solution and gaseous concentrations. A linear relationship was used for	**August 2009** RMS has checked again the report Nº: GH-C 5358 (Masterfile:MK 42) for any evidence of these relationships and they are described in the second paragraph of the page 41 of the report. Therefore this Data Gap can be considered addressed Additionally, RMS contacted with the corresponding author of the article published in Computers and Electronics in Agriculture 56 (2): 111-119 who confirmed that the linear phase partition was computed as: Cg=Kh*Cl Cs=Kd*Cl	PRAPeR TC 15 (1 September 2009) Data gap closed. With hindsight it Is clear that this was inappropriately ascribed as a data gap in column 4 of the reporting table, as the information was clarified as having been present in the applicant's dossier provided with the resubmission application.

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		chemical partition between the three phases. Degradation was considered in the solution and adsorbed phases, but not in the air, using a first-order decay having the same rate constant	Cl =Cf where Cg is gas phase concentration, Cl is liquid phase concentration, Cs is solid phase (adsorbed) concentration Cf is concentration of 1,3-D in the drip system during the time of application Kh is the dimensionless Henry's constant Kd is the adsorption coefficient This clarification has been included in the addendum 4. **RMS considers this point addressed**	
	Data gap: 4.2 The reference 'Computers and Electronics in Agriculture archive Volume 56 , Issue 2 (April 2007) Pages 111-119 ISSN:0168-1699 should be added to the dossier. See reporting table 4(1)	The notifier has now provided this publication reference (in electronic format) to EFSA, DG SANCO and all Member States Authorities.	**August 2009** Spain as RMS does not agree with this data GAP. This is a public literature reference which was used by RMS to support the assessment (see addendum 3 page 6) The article is based on the report DripFume: a Visual Basic Interface Program for simulating soil Fumigatoin by Drip irrigation Dow Agroscience report Nº: GH-C 5358 (Masterfile:MK 42) already included in the dossier The reference has been included in the list of references at the end of the chapter. See addendum 4 **RMS considers this point addressed**	PRAPeR TC 15 (1 September 2009) Data gap open 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. Written procedure The data gap is included in the updated EFSA conclusion.

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			09 September 2009 In the TC-15; It was concluded that this is a formal data gap as the reference should be added to the dossier. The expert from the RMS did not agree with the data gap and considered it not essential to finalise the assessment	
	Data gap: 4.3 The references 'Simunek, J. and M. Th. van Genuchten. 1994. The CHAIN_2D Code for Simulating Two-Dimensional Movement of Water, Heat, and Multiple Solutes in Variably-Saturated Porous Media, Version 1.1. Research Report No. 136' and 'U. S. Salinity Laboratory, USDA, ARS, Riverside, California . Available from the following website: http://www.ars.usda.gov/Services/docs.htm?docid=8914' should be added to the dossier. See reporting table 4(3)	The notifier has now provided this publication reference (in electronic format) to EFSA, DG SANCO and all Member States Authorities.	**August 2009** ES: Spain as RMS does not agree with this data GAP. This is the manual of the model CHAIN 2D code. It is a public reference used by RMS to clarify the concerns arisen during the Peer Review. It was mentioned in the report Wang, D., Knowles, S., Knuteson, J (2005) Report Nº: GHE-P-11175 (Masterfile: K83) Annex point/reference IIIA 9.2.3/03 already evaluated in the addendum 3. It has been included in the list of references at the end of the chapter. See addendum 4 **RMS considers this point addressed** **09 September 2009** PRAPeR TC 15 concluded that this is a formal data gap. The expert from the RMS did not agree	PRAPeR TC 15 (1 September 2009) Data gap open 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. Written procedure The data gap is included in the updated EFSA conclusion.

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			with the data gap and considered it not essential to finalise the assessment	
	Data gap: 4.4 The reference 'Aller, L et al 1997 EPA/600/2-87/035' should be added to the dossier. See reporting table 4(7)	The notifier has now provided this publication reference (in electronic format) to EFSA, DG SANCO and all Member States Authorities.	**August 2009** ES: Spain as RMS does not agree with this data GAP. This is a public reference used by RMS to clarify the concerns arisen during the Peer Review. It was mentioned in the report Hughes, G., Price, O., Humphrey R., Knowles, S. (2006). Report number: GHE-P-11388 (Masterfile MK56) Annex point reference IIA 7.4/06, IIIA 9.2.1/05 already evaluated in the addendum 3. It has been included in the reference list at the end of the chapter. See addendum 4 **RMS considers this point addressed** **09 September 2009** PRAPeR TC 15 concluded that this is a formal data gap. The expert from the RMS did not agree with the data gap and considered it not essential to finalise the assessment	PRAPeR TC 15 (1 September 2009) Data gap open The reference 'Aller, L et al 1997 EPA/600/2-87/035' should be added to the dossier. Written procedure The data gap is included in the updated EFSA conclusion.
	Open point: 4.2 Member state experts to discuss and agree whether they consider the available	FOCUSsw models were not designed and deemed appropriate for such a highly volatile active due to the use practice and properties of the molecule.	**August 2009** ES: This model is an alternative to evaluate the environmental fate and behaviour of fumigants and address	PRAPeR TC 15 (1 September 2009) Open point fulfilled. New open point proposed (see below):

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	surface water exposure assessment in the additional report (addendum 3) is sufficient to conclude the EU level surface water exposure assessment. See reporting table 4(8)	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. The notifier agrees with RMS comments in the reporting table rev 1.1.	the PECsw calculation of fumigants. RMS conducted a FOCUS SW modelling for D scenarios with comparison purposes. The results showed the calculation made by notifer can be considered a worst case with respect the estimation of lateral flow and relevant for risk assessment. Therefore, the latter can be considered relevant for risk assessment	RMS to provide in an addendum a detailed water balance description (daily water balance; proportion of precipitation moving vertically out of the soil column and lateral movement and evapotranspiration) used in the DripFume / CHAIN 2D model used in the SW assessment for 1,3-D.
	New open point: 4.9 RMS to provide in an addendum a detailed water balance description (daily water balance; proportion of precipitation moving vertically out of the soil column and lateral movement and evapotranspiration) used in the DripFume / CHAIN 2D model used in the SW assessment for 1,3-D.		**09 September 2009** CHAIN 2D code was one of the models evaluated by FOCUS SW working group in the report SURFACE WATER MODELS AND EU REGISTRATION OF PPP (6476/VI/96) The WG concluded that CHAIN 2_D code has the potential to be one of the most useful models in the context of modelling drainage system inputs to surface water since it is fully 2-dimensional. As stated in FOCUS SW work group document the algorithms of CHAIN 2D_code defines finite elements for spatial distribution and implicit finite differences for temporal discretization of Richards equation for water flow. Finite elements for spatial distribution and Crank-Nicholson finite differences for temporal discretization of the	PRAPeR TC 15 (1 September 2009) Open point open Written procedure Open point open Useful information was provided by the RMS in addendum 5 dated September 2009, on the process descriptions in the model to parameterise the water movement. However the requested information on the actual water balance that the model had calculated in the actual simulations that were carried out by the applicant was not provided. Note in the draft of the conclusion that EFSA sent out for the written procedure no consequence was discussed in relation to this open point remaining open (i.e. the open point was not converted to a data gap). No comments were received from

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			convection-dispersion equation for solute transport. Hydrological model is based on Richards equation for unsaturated water flow and the drain flow is a Simplified representation of nodal drains using results of electrical analogue experiments. Runoff is not considered by the model and the Potential evapotranspiration is input by user. Actual evapotranspiration is calculated as a function of root distribution and soil water pressure head. The details of the water balance description is summarised in addendum 5.	member states indicating that they disagreed with the conclusion of the text as drafted in relation to the PEC calculated with CHAIN 2D being appropriate. Therefore though the point remains open, the pertinent PEC are agreed and accepted as being reliable for use in the EU level exposure assessment.
	Open point: 4.3 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 usefulness of the French data is therefore still compromised.	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 and use practice. The notifier is continuing with Ground water monitoring studies throughout the EU as part of Stewardship program for 1,3-D and to ensure that this type of data is available (post Annex 1) to enable Member State authorities to be satisfied on 1,3-D uses specific to their country uses.	**August 2009** ES: The information included in the addendum 3 updated is a summary of the soil and hydrogeology characteristics of the regions of study. It is not clear for RMS what details are still needed to clarify EFSA's concerns. No data on cropping have been found in the French study. However, RMS considers that this is not essential to consider the study valid because evidence of use of 1,3-D was submitted by the notifier for the five regions monitored. See addendum 3	PRAPeR TC 15 (1 September 2009) Open point open 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 usefulness of the French data is therefore still compromised. Written procedure Open point fulfilled

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	See reporting table 4(18)		and addendum 4	The EFSA conclusion reflects this conclusion and retains a data gap in relation to the French groundwater monitoring program.
	Data Gap: 4.5 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. See reporting table 4(19)	With respect the notifier provided additional information in June 2009 relating to GAP's that were approved in each Member State along with the number of years that these approvals had been in existence. This was information already in the public domain and only supports the previous information provided as part of the original resubmission where a table of data on volume uses of 1,3-D by country/region/location and proximity to GW wells monitored. (see open point 4.4)	**August 2009** ES: Spain as RMS does not agree with this data GAP. Nothing is mentioned throughout the regulation regarding statements to clarify concerns during the Peer Review. In this case, and in order to clarify the EFSA's concerns, notifier submitted a summary of the existing labels in European MS already included in the document C of the original dossier. **Addressed** **09 September 2009** The expert from the RMS did not agree with this data gap.	PRAPeR TC 15 (1 September 2009) Data gap open Information on use rate recommendations over the groundwater monitoring duration or in the preceding years to the commencement of monitoring is required for the regions monitored. This information was provided by the RMS in the revised Vol 3-B8 (June 2009) but in line with Commission Regulation (EC) No. 33/2008 neither additional information, nor the submission of new studies can be accepted in relation to stage 2 active substances. This is a formal data gap. Written procedure The data gap is included in the updated EFSA conclusion.
	Open point: 4.4 RMS to update table 8.10.1.2-1 to include the units for the sales figures for Italy, France and the UK where the the units are missing, in an	The notifier is ready to support the RMS with further information or clarification on this point if appropriate.	**August 2009** ES: The information has been included in the addendum 4 Addressed.	PRAPeR TC 15 (1 September 2009) Open point fulfilled

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	adendum, if this information is available. See reporting table 4(19)			
	Data Gap: 4.6 A groundwater exposure assessment for process impurity 13 that could be considered by the peer review is not available.This information was provided by the RMS in the revised Vol 3-B8 (June 2009) but in line with Commission Regulation (EC) No 33/2008 neither additional information, nor the submission of new studies can be accepted in relation to stage 2 active substances. See reporting table 4(21)	The levels of impurity 13 in DAS source of 1,3-D technical are very low at between 0.34 to 0.49 g/kg (0.03 - 0.05% w/w). The impurity 13 was not detected in any of the ten batches from the 2 sources from Kanesho. The notifier accepts that the information provided in June 09 was late in the process but it did confirm that impurity 13 would show similar volatilisation to the other impurities and will likely show similar trends to monitoring data from the other 6 monitored impurities.	**August 2009** ES: Spain as RMS does not agree with this data GAP. Nothing is mentioned throughout the regulation regarding statements to clarify concerns during the Peer Review. Notifer states that impurity 13 is likely to behave similarly in the environment than the rest of the impurities monitored. RMS confirms notifier's statement by calculating the phys-chem properties of impurity 13 with EPIwin 3.1 software. (See open point 4.5) The output of the model is included in addendum 4. Addressed **09 September 2009** The expert from the RMS did not agree with this data gap.	PRAPeR TC 15 (1 September 2009) Data gap open 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. Written procedure The data gap is included in the updated EFSA conclusion.
	Open point: 4.5 RMS to add the Atkinson calculation for process impurity 13 in an addendum. Though this is additional	EPI suite data shows that Impurity 13 expected to behave similarly to parent and other impurities.	**August 2009** ES: RMS has calculated the phys chem properties of impurity 13 by using EPIwin 3.1 software, in which the Atkinson DT50 calculation is included	PRAPeR TC 15 (1 September 2009) Open point fulfilled.

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	information, the fact that the calculated atmospheric half life is above the trigger of 2 days, this makes this calculation potentially adverse. See reporting table 4(21)		The calculation was included in addendum 4 point 8.11.2 Open point closed	
	Data gap: 4.7 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. See reporting table 4(22)	The submission of information of on hydrolysis products of process impurities is not a normal part of a 91/414 process. In our original resubmission we provided a rationale of why we chose the impurities we did for GW evaluation. This was based on a) these were the impurities which had a reasonable half-life in water b) the impurities covered the range of types of impurities found in DAS and Kanesho technicals (chloroalkanes, chloroalkenes, etc) None of these impurities except for 1,2-Dichloropropane was found at levels above 0.1 ppb in any of the wells that were monitored. The impurity 1,2-Dichloropropane was only found in one well (Timbaki) at levels between 0.11 and 0.25 ppb. As only the 1,2-D impurity was seen in one of the sampling with none of the other process impurities seen (including closely	**August 2009** ES: RMS accepts notifer's statement Spain as RMS does not agree with this data GAP. Nothing is mentioned throughout the regulation regarding statements to clarify concerns during the Peer Review. In this case, notifier submitted a statement to explain the general behaviour of hydrolysis of an halogeno alkanes and oxiranes based on a background knowledge on organic chemistry and biochemistry . The RMS has included it in addendum 3 updated as it is currently request by EFSA PRAPeR Unit. See open point 4(6) Addressed **09 September 2009** The expert from the RMS did not agree with this data gap.	PRAPeR TC 15 (1 September 2009) Data gap open 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. Written procedure The data gap is included in the updated EFSA conclusion.

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		related 1,3-dichloro-propane and 1,2,2-trichloropropane both of which are present at higher levels in the 1,3-D technical product), a non-1,3-D source of 1,2-D was suggested for the presence of this impurity around the Timbaki well. 1,2-D has been used extensively in the past by other industries e.g. as a degreasing agent. The notifiers believe we have provided sufficient weight of evidence to demonstrate that the impurities that occur in 1,3-D technicals do not pose an environmental risk,		
	Open point: 4.6 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	The notifier confirms that the information we provided in June 2009 on hydrolytic stability of the oxiranes (reporting table 4(22)) was from the open and well documented literature. The notifier provided the main modelling information on reactivity of oxirane impurities in report GHE-P-11692 that was provided in the original resubmission dossier.	**August 2009** ES: Oxiranes (impurites 9a and 9b) are epoxides. In Organic Chemistry, it is well known that epoxides are very unstable, and rapidly transform to alcohols. **09 September 2009** The expert from the RMS did not agree with this conclusion and the related data gap.	PRAPeR TC 15 (1 September 2009) Open point closed New data gap proposed (see below): Measured data (water solubility, vapour pressure, Koc, hydrolysis for impurities 9a, 9b, 10, 11, 12, 13 or other related impurities) are missing and would be needed to further validate the QSAR estimates. At the very least published information should be considered and an argumentation on how this can be extrapolated to any missing information is needed.

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	etc.) cannot be considered by the peer review. See reporting table 4(23)			
	New data gap: 4.8 Measured data (water solubility, vapour pressure, Koc, hydrolysis for impurities 9a, 9b, 10, 11, 12, 13 or other related impurities) are missing and would be needed to further validate the QSAR estimates. At the very least published information should be considered and an argumentation on how this can be extrapolated to any missing information is needed.		**09 September 2009** The expert from the RMS did not agree with this data gap.	PRAPeR TC 15 (1 September 2009) Data gap open Written procedure The data gap is included in the updated EFSA conclusion.
	Open point: 4.7 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	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 impurities would be	**August 2009** ES: It should be also specified that estimations with Atkinson's approach are only based on the reactivity of the molecule with OH radicals. Thus, the SETAC Pellston Workshop expressed the limitation of Atkinson approach to evaluate the long range atmospheric transport potential of chemicals. It should be taken into account that in the atmosphere there are other processes which could be influenced by other	PRAPeR TC 15 (1 September 2009) Open point open EFSA to highlight in the conclusion that there are indications that there may be concerns on 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, information can be found in addendum 4 to Vol. 3 B-8).

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	an attachment to column 3 of the reporting table) . See reporting table 4(24)	infinite in the atmosphere. Air monitoring for the parent showed typical maximum off site PECair concentrations of 500 µg/m3. Impurity concentrations would be in the range 0.05 to 0.6 µg/m3 just off site and significantly lower away from the treated area. Furthermore 1,3-D treatments are made on a very limited agricultural land area of the European Union.	phys chem properties and limit the transport. For example, all the impurities reported are halogen alkanes of short chain (C3-C6) with a solubility > 100 mg/L, which could limit their transport in the troposphere when react with H_2Ov . On the other hand, despite Atkinson's DT50, it was demonstrated that impurities 4 and 5 are rapidly hydrolysed. Finally, it is well known in Organic chemistry the instability of epoxides (impurity 9). Therefore, These properties should be taken into account in the evaluation of the potential long range atmospheric transport of the impurities **09 September 2009** The expert from the RMS did not agree with this open point	Written procedure Open point fulfilled The EFSA conclusion indicates the concerns raised by the potential for long range active transport of process impurities.
	Open point: 4.8 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	Notifier agrees with RMS - - 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	**August 2009** ES: The current guidance for evaluating the non target plants is calculating the exposure from BBA drift values. This practice is not valid for fumigants, which are applied by injection or drip irrigation in bare soil and are transported by diffusion	PRAPeR TC 15 (1 September 2009) Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	calculated with the CHAIN 2_D model based, on the information as reported in the additional report ecotoxicology section. See reporting table 4(26)	evaluate the environmental fate and behaviour of fumigants	throughout the 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 in-field 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 where a limit transport of 1,3-D was observed. In any case if the standard procedure is followed, for the field use a buffer zone of 5 m is necessary to obtain an a safe use for NTP (224x0.57/300= 0.4256 mg/kg) This in line with the conclusion obtained with CHAIN_2D code calculation.	
	New open point 4.10: RMS to check the consistency of the endpoints		**09 September 2009** **ES:** The LoEp dated on March was based on the EFSA conclusion LoEp. In	PRAPeR TC 15 (1 September 2009) Open point open

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	provided in the new formatted LoEP dated August 2009 against the version dated March 2009 (at least soilDT50s seem to be different).		August 2009, the LoEp was adapted to the new format of the EPCO manual with some differences from the end points of 2006 RMS has looked through LoEp (August 2009) and updated in order to keep the consistency with the LoEp contained in the EFSA conclusion of 2006. Following explanations on the origin of the differences are given 1.- **Route of degradation in soil** the end points for 10ºC and 40 % MWHC has been eliminated. 2.- **Rate of degradation in soil.** - Two tables were included according to the EPCO manual new template: the first one refers to the dissipation DT50 of 1,3-D and the second one to degradation DT50 values. The latter one has been deleted - The endpoints for 20ºC and 20% MWHC has been added to the table - The discrepancy between the normalised DT50 of the LoEp of March 2009 and August 2009 is because of the moisture value used in the normalization; in the DAR was considered FOCUS standard values and in August 2009 the experimental data given in the DAR were taken into	Written procedure Open point fulfilled. Appropriate amendments were made in the LoEP provided by the RMS dated Sept 2009.

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			account. -Notifier used an average DT50 of 9.54 d for modelling. RMS has checked that the experimental DT50 values used for normalization differ from the ones given in the experimental report, despite the source of the values cited is the experimental report summarised in the DAR. It is expected that this deviation does not have a relevant impact in the result of the risk assessment because it is based on higher tier studies. - Regarding metabolites only the end points taken from the study conducted with the parent compound were included in the LoEp of August 2009. The LoEp has been changed including the DT50 of the studies conducted with metabolite3-chloroallyl alcohol as test item. **3.- Adsorption/desorption** In the LoEp of August 2009 the value of Kd and Koc were added according to the new EPCO template i **4.- Mobility in soil** A footnote is added as it is stated in the LoEp of EFSA conclusion (2006). **5.- Hydrolysis**	

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			The different experimental pH have been included **6.- Photolysis in water** The statement of not photodegradation was changed in the LoEp of August 2009 for the experimental DT50 and the irradiation conditions as stated in the new EPCO template. **7.- Water sediment studies** Changes were made according to the new EPCO manual template. In the LoEp of EFSA conclusion(2006) the distribution between the water and sediment phases are those ones at the end of the study. In the loEp of August 2009 it refers to the maximum % AR found in each of the phases as stated in the EPCO manual template. The LoEp has been updated including both distributions fractions Regarding metabolites, DT50 values differ in both LoEP. In 2006 the DT50 from the studies conducted with metabolites as test item were included. In 2009 the end points were taken from the study conducted with the parent compound. The LoEp has been updated according to the end points	

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			from 2006.	

5. Ecotoxicology

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 5 Open points: ***9*** Points for clarification: ***0*** Data gaps: ***0***			Section 5 Open points: ***3*** Points for clarification: ***0*** Data gaps: ***3***
	Open point: 5.1 RMS to update LoE. The refined TER for earthworm eating bird (short-term) should be corrected to 320. See reporting table 5(1)	The Notifier has no further comment to add.	**August 2009** LoEP from march.2009_rev_24.06.09 has been checked, and the refined TER for earthworm eating bird (short-term) is > 2800 instead of 320. Not changes have been made. In more detail, for birds: LC_{50} st > 1264 mg/kg bw/d ETE = 0.44 TER = > 1264/0.44 = > 2800 **Open point closed.** **09 September 2009** LoEP amended.	PRAPeR TC 16 (2 September 2009) Open point open RMS to update the LoE. Written procedure Open point closed. LoE has been updated
	Open point: 5.2 Member State experts should discuss the relevant long-term end point for mammals.	The Notifier believes this point requires clarification and that the ecologically relevant NOEL, based on short-term effects on body weight, should be 15 mg/kg/day.	**August 2009:** Background information regarding to relevant NOEL to be used for risk assessment on mammals is depicted in Addendum 5_B9_ECOTOX_ADDITIONAL	PRAPeR TC 16 (2 September 2009) Open point closed Experts agree with RMS in using the 5 mg/kg bw/day based on body weight as a relevant endpoint for risk assessment. Using this endpoint the long-term risk to

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	See reporting table 5(5)	A NOEL of 15 mg/kg/day is supported by the available information provided in the Notifiers resubmission document and Section B.9.3.1 of the DAR (See attached supporting information, this information has been removed for procedural reasons).	REPORT_1-3D_MARCH 2009_24_06_09, pages 43-46. In summary, **Notifier proposal: the ecologically relevant NOEL, based on short-term effects on body weight (less of two weeks), should be 15 mg/kg/day.** The results of different studies (14-day, 90-day and 2-year) have been considered together, and the effect on body weight considered with respect to an appropriate environmentally relevant exposure period for wild mammals to 1,3-D. Thus, the NOEL of 15 mg/kg/day was established. This endpoint 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). **RMS does not agree with notifier proposal because effects in body weight can be detected late (after two weeks).** Effects in body weight after two weeks are observed in the rat 90-day oral	mammals is acceptable.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			study (Haut et al., 1993, summarized in the DAR). Thus, effects on body weight were detected after 49 days exposure to 5 and 15 mg/kg_{bw}/day in males. Effects at 50 and 100 mg/kg_{bw}/day were detected in males within 7 days of exposure. Females were less affected, with no effects even after 90 days at 5 mg/kg_{bw}/day, and effects at 15 mg/kg_{bw}/day only detected after 84 days. **RMS proposal is to use for refinement the relevant NOAEL 5 mg/kg bw/d.** This endpoints was based on the results from 90d-oral exposure study (Haul et al, 1993) in rat. Thus, the no-observed-adverse-effect level (NOAEL) for male rats and the no-observed effect level (NOEL) for female rats based on body weight was determined to be 5 mg Telone II/kg body weight/day. This endpoint was based on body weight change as ecological relevant endpoint and, it may have some relevance to breeding success of wild mammals e.g. establishing breeding site, pairing and mating. This proposal is in line with EFSA opinion (EFSA	

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			Journal (2006) 344, 1-22). Specifically, for endpoints such as changes in body weight, the PPR Panel recommended to evaluate the endpoint for the exposure period relevant to the ecotoxicological assessment. Furthermore, in the opinion it is stated that a way to refine the risk is by considering an endpoint from a study with a short period of exposure such as the 28-d or 90-day exposure study. Having in mind that for intended uses of 1,3-D in field long-term exposure it is not expected, and therefore endpoints from a study with shorter period of exposure should be suitable option for refinement. For transparency, the information provided by the notifier in this table and further discussions are included in addendum VI_ECOTOX_ADDITIONAL REPORT_1-3D_AUGUST 2009. **RMS would like to indicate that using both endpoints the out-put of long term risk assessment for mammals will not change.** **Open point closed.**	

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	Open point: 5.3 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? See reporting table 5(6)	The scenario evaluated is fully representative of the Annex I GAP for fruiting vegetables. The study clearly illustrates that small mammal activity on Telone treated fields is reduced due to the pre- and post-injection agricultural operations, and that potential for in-field exposure is therefore negligible. The study illustrates that, in reality, small mammals will not feed exclusively on treated fields (i.e. PT $\neq$ 1) for periods sufficient to affect growth (i.e. 6 weeks or more; See comment to Open Point 5.2), are not appropriate.	**August 2009**: Addressing the questions raised in the open point 5.3: **Can the study be considered valid?** A summary of the study is depicted in Addendum 5_B9_ECOTOX_ADDITIONAL REPORT_1-3D_MARCH 2009_24_06_09, pages 49-54. Rapporteur member state has been re-evaluated the study in terms of usefulness. All this information has been summarized in addendum VI_ECOTOX_ADDITIONAL REPORT_1-3D_AGUST 2009. In summary, Usefulness, the study gives information about wildlife mammals species exposed in the area treated with Telone II and surrounding fields, and indirectly assess in some extent the food available within the treated area. This is an important question that was a reason of concern in the first-tier assessment.	PRAPeR TC 16 (2 September 2009) Open point closed The risk to mammals was addressed based on field residue studies in invertebrates, therefore this study should be considered as a support to the conclusion.

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			The endpoint of study was to determine species and abundance of small mammals on Telone treated fields compared to adjacent habitats before and after, and subsequent to tomatoes planting. The study shows that, as not crop plants are grown at the time of Telone II treatment, the species potentially feeding on the treated field are omnivores (e.g. *Apodemus*) and insectivores (e.g. shrews) as was expected for tomato crops. Furthermore, the study shows that small mammals will not feed exclusively form the treated area during long-term periods, due to depletion in food availability (e.g. not plants) and agronomic operations (e.g. injection, soil sealed, and crop planting after 14 days). **Under RMS opinion the study contain useful information in identifying wildlife mammals species that can be exposed to 1,3-D residues. Relevant species are insectivorous and omnivores mammals.** How representative is the study? The type of ecosystem is relevant for	

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			the local situation, thus the study focused on fields which were due to be planted with a fruiting vegetable crop and with representative surrounding habitats of South Europe. The study is performed in the intended crop (tomatoes). Four field trial areas were selected for the study. The adjacent trapping areas are diverse, representing different ecosystems (woodland, grassland strip, tree plantation, narrow row of trees). The product of concern is applied at the maximum doses rate (190L/ha), and the method of application is by injection (relevant for actual situation, GAP). **RMS agrees with notifier, and would like to point out that the scenario evaluated is fully representative of the Annex I GAP for fruiting vegetables in South European conditions for 1,3-D.** <u>Is the preference for 1,3-D treated fields is low that not risk is expected?</u> RMS would like to point out that for outdoor uses, the application of 1,3-D is injected into the soil profile, typically	

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			at a depth of 15 - 20 cm, followed by capping to help seal the soil to maximise efficacy and minimise volatile losses. Typically, the soil is then harrowed to "open" the soil before the crop is planted, with a minimum interval between soil treatment and crop planting of 14 days. This interval between treatment and crop planting is necessary because 1,3-D is phytotoxic at the high initial soil concentrations achieved immediately following injection. In this scenario, after telone application is expected that the presence of wildlife in Telone treated bare soil is reduced due to the pre- and post-injection agricultural operations, and the low levels of food available in bare soil. Therefore, the potential for in-field exposure for mammals is low (PT lower than 1).This assumption is confirmed in the field study submitted Blanckenhagen, F. (2006). **Under RMS opinion the preference of mammals for 1,3-D treated field is expected to be low, and therefore the potential risk associated for**	

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			wildlife mammals with the use of 1,3-D should be acceptable. **Open point closed.**	
	Open point: 5.4 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? See reporting table 5(8)	The Notifier agrees with the comments of the RMS, in the reporting table rev 1.1, point 5(8), and has no further comment to add.	**August 2009**: For transparency, comments coming from notifier and RMS comments added in this evaluation table have been summarized in addendum VI_ECOTOX_ADDITIONAL REPORT_1-3D_AGUST 2009. Field residue study Small (2007) A summary and evaluation of study is depicted in Addendum 5_B9_ECOTOX_ADDITIONAL REPORT_1-3D_MARCH 2009_24_06_09, pages 16-22. EPCO expert's meeting considered that a new study representative for the supported GAP (spring/summer applications under Mediterranean conditions) was needed. Therefore, a further field study (Small, 2007) has been conducted, in which residue levels of 1,3-D in arthropods and earthworms were determined following use of 1,3-D at 224 kg a.s./ha under	PRAPeR TC 16 (2 September 2009) Open point closed Based on the limited data available for death and alive invertebrates in this study, the experts' meeting concluded there is no base to expect a higher concentration in dead invertebrates for South Europe for this particular crop and application method.

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			Mediterranean conditions. **Under RMS opinion the study (Small, 2007) should be considered acceptable for risk assessment. The study is considered as a realistic study representative of agriculture sites of the South of Europe where Telone is applied.** Addressing the questions raised in the open point 5.4: - Is there a bias in the estimated concentration, based on a potential higher residue concentration in dead insects, which may compose a higher proportion of bird diet than expected from the residue study? In the study pitfall traps were used to collect arthropods. This technique is the most practical method to collect ground dwelling arthropods. They have of course the disadvantage of collecting only active and moving individuals, but, on the other hand, pitfall traps are the only method to selectively collect only arthropods. To improve the sampling protocol, if dead arthropods were seen the personnel collected them. According to Appendix 5, the number of death arthropods was low, and therefore	

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			residue levels in most of the sites sampled accounted mostly for alive arthropods. Maximum residue levels for arthropods were 1.52 mg/kg. This value was used for risk assessment and not unacceptable risk was expected. To address if death arthropods has high level of residues, and address if bias on the low side due to the use of pitfall traps as collection method, RMS would like to refer to Fischer and Bower (1997) data set on arthropod residues and Brewer et al (1997) (Appendix II in Sanco 4145/2000). In Brewer's study residues for both adult insects (3.3 mg/kg) and larvae (2.1 mg/kg) were below the average of the Fischer and Bowers data set (5.1 mg/kg). This finding is inconsistent with the potential concern that Fischer and Bowers data are biased on the low side due to the use of pitfall traps as collection method. RMS would like to point out that limited information is available to conclude how much residue levels is expected in death arthropods compare to live arthropods, and if pitfall traps protocol	

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			is really bias in the low side. <u>Is reasonable to consider that birds/mammal have a bias for live arthropods/earthworms?</u> It is an important question from an academic point of view, and that may have a potential impact in risk assessment of birds and mammals. But, in the current guidance document on risk assessment for birds and mammals, SANCO/4145/2000 this question is not addressed specifically. Reference to this question is made in appendix 28 of EFSA opinion (birds and mammals risk assessment, 2008). Unfortunately, limited information is available and specifically addresses the impact of insecticides (e.g. spray applications), therefore extrapolation to other pesticides and application types increases the uncertainties. RMS would like to point out that the type of application of 1,3-D is not comparable to conventional spray applications. For transparency, a copy of appendix 28 is inserted below: ***Knock down samples during application***	

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			It can be assumed for insecticides (and other pesticides with insecticidal side effects like some fungicides) the highest initial residue loading occurs on those arthropods which are killed during or immediately after application of the product. These individuals are normally missed *during the sample events for foliage dwelling arthropods (because they are already dead and have fallen on the ground) and will not be found in pitfall traps (because they can no longer move).* ***It is unclear to what extent those arthropods are used as food items by birds and mammals. At least some reports can be found in the scientific literature describing the uptake of dead and/or moribund arthropods by birds.*** *Thus, in principle this scenario should not be overlooked and a respective sample of those arthropods affected directly from the product application should be obtained* ***whenever possible****.* RMS would like to point out: • It is unclear to what extent death arthropods are used as food items by birds and mammals. • The use of 1,3-D as a soil	

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

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			compaction (not spraying), and therefore low levels of residue should be expected. • In the field study submitted (Small, 2007), residue levels used for risk assessment of 1,3-D account for dead/alive arthropods/earthworms residues. Death arthropods/earthworms were collected when seen it. At this level of information it is not possible to know if dead arthropods/earthworms have more 1,3-D residues because for analytical purposes samples were combined in order to get enough sampling to conduct the analysis. Due to low number of animals and its level of residues (1,3-D) analysed it is unlikely that birds and mammals have a higher proportion of residues coming from dead insects in the diet. Impact on risk assessment To address uncertainties on risk assessment calculations, and to account for higher levels on death arthropods it is assumed 5 times more of residue levels (Estimated residue	

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			levels 7.50 mg/kg). Using this theoretical residue levels acceptable acute and short-term risk to birds is expected. Also, acute risk to mammals is acceptable. Residue levels expected in earthworms are lower, therefore risk calculations for birds/mammals eating insects covers potential risk in birds/mammals eating earthworms. **Open point closed.**	
	Open point: 5.5 Confirmation of PECsw is pending the fate expert meeting. See reporting table 5(13)	Notifier has no comment.	**August 2009** If PECsw are confirmed in fate section the risk to aquatic organisms is expected to be low from the intended outdoor uses of 1,3-D in South Europe.	PRAPeR TC 16 (2 September 2009) Open point closed As PECsw are confirmed in fate section the risk to aquatic organisms is expected to be low from the intended outdoor uses of 1,3-D in South Europe
	Open point: 5.6 Both growth rate and biomass are normally reported for algae and higher plants and the lower endpoint should be used in the aquatic risk assessment according to the Aquatic Risk Assessment Guidance Document. In the current risk assessment TER values for the parent do indicate a large margin of	Notifier will provide the estimated EbC50 (area under the curve), EyC50 (based on final frond number and ErC50 (growth rate based on frond number) as requested.	**August 2009:** Notifier has provided endpoints for aquatic plants based on growth rate, biomass, and yield. This information has been included in Addendum 6_B9_ECOTOX_ADDITIONAL REPORT_1-3D_AGUST_2009. The lowest endpoint has been used for aquatic risk assessment. The lowest end-points are: 13.6 mg/L (E_bC_{50}) for	PRAPeR TC 16 (2 September 2009) Open point closed New data gap proposed (see below) EFSA would reflect that the new information has been submitted and evaluated by the RMS but cannot be taken in to account due to Regulation 33/2008. The lack of data will not affect the outcome of the aquatic risk assessment, but the data gap is maintained for formal reasons.

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	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). See reporting table 5(16)		1,3-D; 0.454 mg/L (EC_{50}) for 3-CAA; 0.26 mg/L (EC_{50}) for 3-CACA. The only change that results from this is that the lowest end-point for 1,3-D changes from 14.56 mg/L to 13.6 mg/L - this is not significantly different and will have no impact on the risk assessments. For the alcohol and acid metabolites, the lowest calculated end-points are essentially the same as those previously used by the RMS for the risk assessments. The outcome of aquatic risk assessment for aquatic plants did not change. The aquatic risk assessment has been updated in the LoE and in the Addendum 5_B9_ECOTOX_ADDITIONAL REPORT_1-3D_AGUST_2009, pages 12-19. **Open point closed.**	
	New data gap: 5.1 EFSA would reflect that the new information has been submitted and evaluated by the RMS but cannot be taken in to account due to Regulation 33/2008. The lack of data will not affect the			PRAPeR TC 16 (2 September 2009) Data gap open Written procedure Data gap still open

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	outcome of the aquatic risk assessment, but the data gap is maintained for formal reasons.			
	Open point: 5.7 Member State experts should discuss the use of the field study by Small (2006) in the risk assessment for NTA. See reporting table 5(19)	The scenario evaluated was fully representative of the Annex I GAP for fruiting vegetables and represented a typical injection application scenario for Telone. The report documents that the injection of Telone took place under GLP inspection (page 6), the injection equipment was calibrated prior to use (page 22), and the measured application rate was 199.34 L/ha (page 13). . All other aspects of the study were conducted in GLP compliant facilities and were subject to all the normal procedures of record keeping, calibrations and SOP compliance required by GLP. Key phases were audited by an independent GLP auditor as was the final report. It is the notifier opinion that the study is suitable for risk assessment, has been conducted under realistic conditions for an exception product and if of the same high quality as all other fully compliant GLP studies. The experimental constraints	**August 2009:** A summary and evaluation of study is depicted in Addendum 5_B9_ECOTOX_ADDITIONAL REPORT_1-3D_MARCH 2009_24_06_09, pages 59-71. RMS opinion is that results coming from this study can be used for risk assessment besides some shortcomings of the study can be highlighted. A shortcoming of the study was that concentrations of the compound in the soil are not measured, so it is not clear the actual exposure in the study. Also not positive control was used. These shortcomings can be explained by the experimental constraints associated with type of application that is not comparable to conventional spray application. RMS agrees with notifier that scenario evaluated was fully representative of the Annex I GAP for fruiting vegetables and represented a typical injection application scenario for Telone.	PRAPeR TC 16 (2 September 2009) Open point closed New data gap proposed (see below): The statically power of the study should be confirmed before the results can be used to address the risk to NTA tomato crops in the south of Europe. Additional data gap proposed relevant at Member state level (see below). Further data are required to address the risk to non-target arthropods for other potential uses.

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		associated with this type of application method should not be underestimated (i.e. specialist application equipment, in furrow injection at 25-30 cm depth, soil closing with a roller immediately after application, operator safety considerations (during application and for post-injection sampling). This type of application is not comparable to conventional spray applications and the same expectations regarding analytical confirmation of soil concentrations or use of toxic standards cannot be applied.	In the field study, not statistical significant effects were observed for macroarthoprods and microarthopods investigated in Telone II treated and untreated plots at any of the post-treatment sampling intervals for an application rate of 224 kg as/ha. However, effects on earthworms were observed. These effects on earthworms were transient, lasting less than 6 months, with no difference in earthworm abundance between treated and untreated plots detected at 6, 9 or 12 months post-treatment. Results from the field study on arthropods are in line with results from risk assessment based on lab studies. The extended laboratory studies indicated that soils treated with single application of Telone II at 329 kg a.s./ha may pose a high risk to some soil dwelling arthropods, as indicated by the study with *Folsomia candida*. The application rate evaluated in this study was 1.5-fold higher than that proposed for Telone II, and so is expected to be an overestimate of the likely risk to soil organisms. Nevertheless, the studies with all	

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			species of arthropods tested indicated that 1,3-D has low residual toxicity. Observed effects 1 day after treatment (DAT) were below 30% for *H. aculeifer*, *P. cupreus*, *A. bilineata* and *Pardosa* spp. 1 DAT 78% effect on mortality was observed for *F. candida*. No adverse effects of Telone II treated soil were observed when *F. candida* was introduced 22 days after treatment of the soil. Therefore, it is expected that for those species affected during soil treatment, recolonization will be possible within a short period following treatment. Furthermore, **according to intended uses of telone only 1 application per year is proposed. Full recovery of soil non target arthropods and earthworms is expected before next application. If uncertainties remaining may be this should be flagged at member state level.** **Open point closed.**	
	New data gap: 5.2 The statically power of the study should be confirmed before the results can be used to address the risk to NTA tomato crops in the south of			PRAPeR TC 16 (2 September 2009) Data gap open Written procedure Data gap still open

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	Europe.			
	New data gap: 5.3 Further data are required to address the risk to non-target arthropods for other potential uses. This won't affect the EU Risk assessment but should be addressed at Member State level			PRAPeR TC 16 (2 September 2009) Data gap open
	Open point: 5.8 EFSA to flag in the conclusion that washing water from cleaning tools should not be disposed into surface water. See reporting table 5(27)	The Notifier has no further comment to add.	**August 2009**: not further comment	PRAPeR TC 16 (2 September 2009) Open point open EFSA to flag in the conclusion that washing water from cleaning tools should not be disposed into surface water. Written procedure Open point closed Concern for disposal of cleaning water has been included in conclusion.
	Open point: 5.9 RMS to update the LoE. TER calculations should be provided for all aquatic organisms groups for the parent substance. See reporting table 5(31)	The Notifier has no further comment to add.	**August 2009**: RMS has been checked LoEP for active substance and TER calculations are provided for all aquatic organisms, selecting the more sensitive species of each group. New endpoints and TER calculations from open point 5.6 have been updated in the LoEP.	PRAPeR TC 16 (2 September 2009) Open point open RMS to include a footnote in the aquatic TER tables to explain the method of estimating PECsw.

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			Open point closed **09 September 2009** LoEP ammended	