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	Section 1 Data requirements: ***15*** Open points: ***22***			Section 1 Data requirements: ***6*** Open points: - Data gaps: ***4***
	Open point 1.1: RMS to clarify the discrimination between [redacted] captan" (R290236). (see reporting table 1(2))	In the original dossier, one of the impurities found in Captan technical was incorrectly identified. The impurity labelled as [redacted] **Conclusion:** Based on the available data, it is most likely that the [redacted]	Apr. 05 Clarification is given in the new report (Grabarnik, 2005) submitted by the notifier. EP list amended. Oct. 05 Noted – The information has been included in addendum to vol.4. See general new open points	EPCO 25 (24.-26.05.2005): Open point closed, but refer to the two general open points. General new open point 1.23 set. Second general point 1.24 set. Data gap 1.16 identified. New open point 1.25 set.
	General new open point 1.23: RMS to present the evaluation of the new submitted information presented in the addendum to the dossier and all information in an addendum to the DAR. See open point 1.1. This open point was proposed at EPCO 25.		Oct. 05 Addenda to the DAR (vol.3 and vol.4) have been prepared and already sent to the EPCO-Team (BVL) by 21/06/05. Anyway, by carefully considering some points in this evaluation table, a revised addendum to vol.4 has been prepared (in purple colour the new changes).	EPCO 25(24.-26.05.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.

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	General new open point 1.24: RMS to clarify whether the document or addendum to the dossier (tabled at the meeting) was written by the RMS or the notifier. Furthermore, it should be distinguished between confidential and non confidential information. See open point 1.1. This open point was proposed at EPCO 25.		Oct. 05 The document tabled at the meeting was written by the RMS, but without distinguish between confidential and non-confidential information, due to our mistake. See general open point 1.23.	EPCO 25(24.-26.05.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.
1.16	Notifier (Makteshim) to submit validated analytical method for the impurity [redacted] See open point 1.1. This data gap was identified at EPCO 25.		Oct. 05 Noted	EPCO 25(24.-26.05.2005): Data gap identified. Evaluation Meeting (06.-09.02.2006): Data gap still open.

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	New open point 1.25: Depending on the assessment of the recently submitted data further data could be required. See open point 1.1. This open point was proposed at EPCO 25.		Oct. 05 See addendum to vol.4. No structure confirmation for [redacted] by the LC/MS analysis of captan technical (provided by Arysta in the new batch analysis report, Rose 2005). Because quantitation of [redacted] was based on response factor, due to the lack of a standard, linearity and accuracy have not been provided.	EPCO 25(24.-26.05.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point closed. Covered by data gap 1.16, since submitted method was not accepted by the RMS.
	Open point 1.2: RMS to clarify the biological activity of [redacted] (see reporting table 1(4))	See the comment above (Open Point 1.1, Reporting Table 1(2)). The [redacted] impurity in Captan technical. There is therefore no need to evaluate the relative biological activity [redacted] It should also be noted that the [redacted] is a sterically hindered and stressed structure which is likely to be unstable and unlikely to be formed during synthesis.	Apr. 05 See point 1.1	EPCO 25(24.-26.05.2005): Open point closed. New open point 1.26 set.

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	New open point 1.26: RMS to indicate clearly in the list of end points that only the [redacted] See open point 1.2. This open point was proposed at EPCO 25.		Oct. 05 Noted – EP list amended	EPCO 25(24.-26.05.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.
	Open point 1.3: RMS to clarify for transparency and better comprehensibility the reason/background for the given minimum purities, which are higher than the FAO value (e.g. based on actual batch analysis or due to "tox/ecotox" effects). (see reporting table 1(10))	Specification for purity: Makhteshim: 92.0% w/w Arysta Paris: 91.0% w/w	Apr. 05 The given minimum purity provided by Arysta (91,0%) is in accord with the actual batch analysis (new Doc J) and with FAO specification (910 g/Kg ± 30 g/Kg). The given minimum purity provided by Makhteshim is 92,0%, while on the basis of actual batch analysis this value is higher (95%). Further explanations will be provided by the notifier: in fact, based to statistical quality control tests from the recent years, Makhteshim can raise the stated minimum purity of the Captan Tech. to 93%. This is a result of significant improvement of the manufacturing process over the years which consequently cause the increase of the active ingredient purity. Makhteshim will amend the composition statement in a new DOC. J that will be provided.	EPCO 25(24.-26.05.2005): Open point closed. New open point 1.27 set. Message to toxicology and ecotoxicology section: From the analytical point of view the technical materials cannot be regarded as equivalent.

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	continued Open point 1.3 RMS to clarify for transparency and better comprehensibility the reason/background for the given minimum purities, which are higher than the FAO value (e.g. based on actual batch analysis or due to "tox/ecotox" effects).		Oct. 05 A new DocJ updated May 2005 has been provided (information reported in the addendum to vol.4)	
	Message from EPCO 25 to toxicology and ecotoxicology section: From the analytical point of view the technical materials cannot be regarded as equivalent.			
	New open point 1.27: RMS to indicate the new minimum impurity in the list of end points. See open point 1.3. This open point was proposed at EPCO 25.		Oct. 05 EP list amended with the new minimum purity (not impurity)	EPCO 25(24.-26.05.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.

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	Open point 1.4: RMS to clarify the relevance of the given impurities. The acceptable maximum values for relevant impurities must be set and the maximum values given in the FAO specification should be mentioned in the row "FAO specification". (see reporting table 1(11))	The FAO limits for impurities are stated in both Arysta and Makhteshim Document J under annex Point IIA 1.10. This information is confidential and not for disclosure. This is consistent with the conclusions of the RMS that the data should not be included in the endpoint list.	Apr. 05 Folpet is the only relevant impurity of toxicological significance, whose maximum value has been set to be [redacted] PMM is the only impurity which has FAO specifications (Maximum of 10 g/kg). We disagree with the notifier comments regarding the FAO limits for impurities, that are clearly not confidential. EP list amended. Oct. 05 EP list amended	EPCO 25(24.-26.05.2005): Open point still open. RMS to amend the list of end points: Box of identity of relevant impurities: The first sentence has to be changed and for the PMM (perchloromethylmercaptan) the value has to be given and the maximum value from Folpet has to be given too. Message to toxicology and ecotoxicology section to confirm the proposed max value for Folpet of [redacted] as a relevant impurity. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.
	Message from EPCO 25 to toxicology and ecotoxicology section to confirm the proposed max value for Folpet of 10 g/kg as a relevant impurity.			

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1.1	Data regarding the boiling point or temperature of decomposition must be provided according to Directive 94/37/EC. (see reporting table 1(13))	Data are presented in the new Addendum under Point IIA 2.1.3. **Conclusion:** Captan decomposes on melting starting at 173°C.	Apr. 05 Data requirement addressed EP list amended Oct. 05 Data included in the addendum to vol.3. See new general open points	EPCO 25(24.-26.05.2005): Data requirement fulfilled, but refer to the two general open points.
	Open point 1.5: RMS should indicate in the list of endpoints that data are required (e.g. as open point). (see reporting table 1(13))		Apr. 05 Noted – EP list amended	EPCO 25(24.-26.05.2005): Open point fulfilled.
	Open point 1.6: RMS to amend the list of endpoints regarding the hazard classification and labelling symbol "T". (see reporting table 1(18))		Apr. 05 Noted – EP list amended	EPCO 25(24.-26.05.2005): Open point fulfilled.
1.2	A new batch analysis must be provided (Tomen source). (see reporting table 1(23))	Arysta have provided a new 5 batch report. This is summarised in the Arysta Document J under Point IIA 1.11.	Apr. 05 Data requirement addressed Oct. 05 Confidential information has been included in the addendum to vol.4.	EPCO 25(24.-26.05.2005): Data requirement still open Because this information hasn't been presented in a confidential addendum.

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1.2	*continued* A new batch analysis must be provided (Tomen source). (see reporting table 1(23))		See new general open points	Data requirement open for formal reasons. Evaluation Meeting (06.-09.02.2006): Data requirement fulfilled.
1.3	A new specification or a justification for the set limit must be provided (Makhteshim source). (see reporting table 1(23))	A new specification and justification for the set limit is provided in Makhteshim Document J (Annex Point IIA 1.11).	Apr. 05 Makhteshim justification provided Data requirement addressed Oct. 05 See new general open points	EPCO 25(24.-26.05.2005): Data requirement fulfilled, but refer to the two general open points. Data gap 1.17 identified.
1.17	A justification or a new maximum value of the impurity [redacted] must be given because the proposed value is not reliable from the presented batches. See data gap 1.3. This data gap was identified at EPCO 25.		Oct. 05 Noted	EPCO 25(24.-26.05.2005): Data gap identified. Evaluation Meeting (06.-09.02.2006): Data gap still open.

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	Open point 1.7: RMS to clarify the identity of the used pure material (incl. [redacted] (see reporting table 1(24))	EFSA noted that clarification is needed, regarding the identity of the used pure material. This issue has arisen because the impurity identified as [redacted]	Apr. 05 On the basis of the new data, the pure material used is very likely the [redacted] See open point 1.1	EPCO 25(24.-26.05.2005): Open point closed.
1.4	Spectra of relevant impurities have to be provided according to Directive 94/37/EC. (see reporting table 1(28))	Folpet spectra summary has been added to the amended Makhteshim Doc J; re-dated Mar 05. Referenced under Annex Point IIA 2.5.2.	Apr. 05 Data requirement addressed Oct. 05 Noted	EPCO 25(24.-26.05.2005): Data requirement still open All the relevant impurities have to be addressed. Thus spectra for PMM (perchloromethylmercaptan) are missing. Evaluation Meeting (06.-09.02.2006): Data requirement still open.
	Open point 1.8: a) RMS to clarify for transparency and better comprehensibility the given justification in respect to the given minimum purities of 920	(a) Specification for purity: Makhteshim: 92.0% w/w Arysta Paris: 91.0% w/w (b) Makhteshim have provided data to show that flammability and auto-flammability do not differ between	Apr. 05 a) Probably the comment to point 30 in reporting table was badly interpreted, because the given justification was in relation to the melting point test (vol.3, B.2.2.1): the test was considered	EPCO 25(24.-26.05.2005): a) Open point closed. b) Open point open for technical reasons see general open point in

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	g/kg and 910 g/kg, respectively. b) RMS to clarify whether the justification that the two technical materials will not reveal significantly differences in the physical and chemical properties is based on practical experiences or on a theoretical assessment. The acceptability on the argumention will be discussed in an expert meeting. (see reporting table 1(30))	sources of technical material.	acceptable taking account that the content of captan in technical material, once declared and determined, shall not differ from the declared by more than ± 30 g. b) Justification was initially based on a theoretical assessment, by comparing the results obtained for some physical and chemical properties (melting point, relative density) using technical or pure active substance, and further supported by the data provided by Makhteshim in the Addendum to dossier. This opinion is open to discussion Oct. 05 b) Evaluation of the data provided in the addendum to the DAR. See new general open points	open point 1.1. Evaluation Meeting (06.-09.02.2006): Open point (part b) fulfilled
	Open point 1.9: The need to conduct the studies regarding the flammability and auto-flammability with both technical materials should be discussed in an expert meeting. (see reporting table 1(32))	Makhteshim have provided data to show that flammability and auto-flammability do not differ between sources of technical material. **Conclusion:** Neither technical material is 'Highly Flammable' and neither self ignites.	Apr. 05 The new report by Turner (2005b) has been evaluated, accepted and included into the addendum. Open point fulfilled Oct. 05 Evaluation included in the addendum to vol.3. See new general open points	EPCO 25(24.-26.05.2005): Open point fulfilled, but refer to the two general open points.

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1.5	Notifier to clarify whether the formulations “Captan 80 WDG” and “Merpan 80WDG” are identical or not. (see reporting table 1(33))	“Captan 80 WDG” and “Merpan 80WDG” are the same material; this is stated in the Makhteshim ‘Merpan 80 WDG’, Annex III, Tier II, Section 1, Point 2 summary. (Merpan being the generic name used for the studies). Text to confirm similarity of Merpan 80WDG’ and ‘Merpan 83 WP has been added to new Makhteshim Doc J under Point IIIA 1.4.1.	Apr. 05 Data requirement addressed Oct. 05 Noted	EPCO 25(24.-26.05.2005): Data requirement still open. Notifier to provide the composition of the captan 80 WDG formulation. To be able to confirm that these formulations can be regarded as identical. Notifier Makteshim to clarify the content of captan technical and pure in the two formulations. “Merpan 80 WDG” and “Merpan 83 WP” (refer to tables 1.4.1-1 and -2 in Doc J, updated May 2005). Evaluation Meeting (06.-09.02.2006): Data requirement still open.
1.6	Notifier to clarify whether the formulations “Captan 80 WDG” and “Malvin 83” are identical or not (see reporting table 1(34))	“Captan 80 WDG” and “Malvin WG” are the same material; this is stated in the Tomen ‘Malvin WG, Annex III, Tier II, Section 1, Point 2 summary. (Captan 80 WDG is a generic name used for the studies). In addition Captan 80WG (YF7851) was used for several tests but only used exclusively for the Friability test.	Apr. 05 Data requirement addressed Oct. 05 Noted	EPCO 25(24.-26.05.2005): Data requirement still open. Notifier to provide the composition of the “captan 80 WDG” formulation. To be able to confirm that these formulations can be regarded as identical

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1.6	*continued* Notifier to clarify whether the formulations "Captan 80 WDG" and "Malvin 83" are identical or not (see reporting table 1(34))	Text to confirm similarity of 'Malvin WG' and 'Malvin 83 (WP)' has been added to new Arysta Paris Doc J under Point IIIA 1.4.1.		Notifier Calliope to clarify the content of captan technical and pure in the two formulations. "Captan 80 WDG"and "Malvin 83". Evaluation Meeting (06.-09.02.2006): Data requirement still open.
	Open point 1.10: The need for a measurement of the pH value of the in use concentration should be discussed in an expert meeting. (see reporting table 1(37))	A discussion of this issue is presented in the new Addendum under this Open Point reference. **Conclusion:** The need for a measurement of the pH at in-use concentrations is not necessary.	Apr. 05 Conclusions can be considered acceptable, also taking into account the new submitted study (Pollman, 2004) that demonstrates the reproducibility of the sprayer performance using Merpan 80WDG (evaluation of captan content in the spray tank). See also open point 1.12. Oct. 05 Evaluation included in the addendum to vol.3. See new general open points	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.
	Open point 1.11: RMS to clarify whether the physical stability (in terms of physical/technical properties) was examined **after** the accelerated storage.	A justification for non-submission of technical properties data from accelerated storage stability trial has been included in Point IIIA 2.7.1 in the Addendum.	Apr. 05 In the original study (Wells, 1996) the test substance was visually inspected after the accelerated storage for changes in physical characteristics (color, phase separation, crystallization and clumping) and no changes were	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.

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	(see reporting table 1(39))		observed. Justification for non sub-submission of technical properties is based on the fact that two-years ambient shelf life data are available (see addendum). Oct. 05 See new general open points	
1.7	Notifer to clarify the test conditions to determine the wettability for “Captan 80 WDG”. (see reporting table 1(41))	For Merpan 80 WDG the conditions of the test (swirling and without swirling) are clearly and correctly stated in the summary. All results are within the 1 minute acceptance limit and so no further comment is required. It is believed that the comment actually refers to Malvin WG where there is one undesirable result at the beginning of the storage stability study. This issue is discussed in the Addendum under Point IIIA 2.8.1. Wettability was acceptable after storage for 24 months and so the ‘before storage’ result is considered to be anomalous.	Apr. 05 Clarification acceptable Oct. 05 Noted	EPCO 25(24.-26.05.2005): Data requirement fulfilled. New open point 1.28 set.
	New open point 1.28: EFSA to indicate in its conclusion that a label like “Agitation must be used during mixing and loading and		Oct. 05 Noted	EPCO 25(24.-26.05.2005): Open point still open.

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	until spraying complete" should be considered. See data requirement 1.7. This open point was proposed at EPCO 25.			Evaluation Meeting (06.-09.02.2006): Open point fulfilled.
	Open point 1.12: The need for a sprayability study should be discussed in an expert meeting. (see reporting table 1(42))	Sprayability report is provided and summarised in the new addendum under Point IIIA 2.8.3/01. **Conclusion:** The spraying solution of Merpan 80 WDG was homogenous throughout the spraying operation the content of captan in the spray tank did not change during spraying.	Apr. 05 A new report (Pollmann, 2004) has been provided. The study is acceptable and it has been included into the addendum. Oct. 05 Evaluation included in the addendum to vol.3. See new general open points	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.
	Open point 1.13: The need for further investigation regarding the friability and attrition for "Captan 80 WDG" should be discussed in an expert meeting. (see reporting table 1(47))	This Annex point is intended to show the increase in dust content caused by attrition during transport and handling. In this case the data supplied (MT171, the measure of dust content) was conducted on the granules following attrition caused by routine transport and handling. This process is believed to meet the requirements of the Annex point before the CIPAC attrition resistance test was widely available. Makhteshim have now submitted a study, conducted to MT178, which confirms the earlier results that showed Captan 80 WDG is resistant to attrition. The Notifiers's conclusion is consistent	Apr. 05 A new report (Comb, 2001) has been provided. The study is acceptable and it has been included into the addendum. Oct. 05 Evaluation of the report included in the addendum to vol. 3. See new general open points	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.

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		with the conclusion of the RMS.		
1.8	Notifier to clarify the stability of the active substance in the spray tank until application. (see reporting table 1(48))	See Open Point 1.10, reporting table 1(37) and Open Point 1.12, reporting table 1(42) above. A Sprayability report is provided conducted with 'Merpan 80 WDG' and summarised under Point IIIA 2.8.3 of the new addendum which confirmed that the content of captan in the spray tank did not reduce during spraying. **Conclusion:** The spraying solution of Merpan 80 WDG was homogenous throughout the spraying operation. The content of captan in the spray tank did not change during spraying.	Apr. 05 A new report (Pollman, 2004) has been provided. The study is acceptable and it has been included into the addendum. Data requirement addressed. Oct. 05 Evaluation of the report included in the addendum to vol. 3. See new general open points	EPCO 25(24.-26.05.2005): Data requirement fulfilled, but refer to the two general open points.
	Open point 1.14: EFSA to highlight the concern of wettability of the formulation in its conclusion. (see reporting table 1(49))	This issue is addressed in the new Addendum under Point IIIA 2.8.1 It is believed that the comment actually refers to Malvin WG where there is one anomalous result. Wettability was acceptable after storage for 24 months and so the 'before storage' result is considered to be anomalous.	Apr. 05 Clarification of the existing data has been provided: acceptable. Oct. 05 Noted	EPCO 25(24.-26.05.2005): Open point closed. See data requirement 1.7 and new open point 1.28.
1.9	Data to confirm the identity of the impurities revealed by chemical analysis must be provided for folpet, perchloromethylmercaptan	Specificity of the impurity methods has been adequately addressed in the dossier. Specificity was confirmed by comparison of chromatograms of certified analytical standards and blank	Apr. 05 If the requirement of the Directive for confirmation of analyte identification relates to the initial confirmation of compound identity, this has been done	EPCO 25(24.-26.05.2005): Data requirement still open.

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	[redacted] to address the requirement of the Directive on the specificity of the method(s). (see reporting table 1(52))	solvent. Absence of interfering peaks is taken as confirmation of specificity. Regarding identity of the impurities, this has been confirmed by the use of certified reference standards in the validation procedures. There is no sound scientific basis on which to reject this argument. Confirmation of the identity of the impurities is inherent in the proven specificity of the method. The Directive does not directly require any further confirmation of the identity of the impurities. It should be noted that both applicants have supplied batch analysis reports which include mass spectrometric data on impurities.	for folpet (NMR and MS data have been included in the new Doc J from Makhteshim). In addition Arysta provided a batch analysis report (Rose 2005 in the new Doc J) which includes structure confirmation of [redacted] by LC-MS analysis. The same LC-MS approach was employed to identify all the other minor impurities in captan technical. Data for PMM should be provided. Oct. 05 Noted	Evaluation Meeting (06.-09.02.2006): Data requirement still open.
	Open point 1.15: RMS to clarify the origin of folpet in the technical material, if it is not formed in the manufacturing process or during storage. Depending on this information, the need for an analytical method for the determination of folpet in the formulation should be discussed in an expert meeting. (see reporting table 1(54))	The occurrence of folpet in the Makhteshim technical material is discussed in the Makhteshim Document J (Annex Point IIA 1.10).	Apr. 05 The origin of folpet has been explained in the Makhteshim Document J. We agree with EFSA conclusion that the need for an analytical method for folpet determination in the formulation should be discussed in an expert meeting. Oct. 05 The information has been included in the addendum to vol.4. See new general open point 1.23	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.

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	Open point 1.16: Analytical methods for the determination of residues in food could be required depending on the outcome of the discussion concerning the residue definition [see also 3(7), 3(8) and 3(9) in the reporting table] and the evaluation of the recently submitted methods. Open point relates to open points 3.6 and 3.7. (see reporting table 1(55))	Position paper summarised in new Addendum under Annex Point IIA, 4.2.1/07. The new report by Faessel (2004) is summarised in the new addendum under Point IIA 4.2.1/08. **Conclusion:** No additional data are necessary to fulfil the Annex point requirement. For animal tissues, it is considered unnecessary to conduct further work or confirmation when there are numerous existing chromatographic conditions available and an analytical method for monitoring purposes is not required due to the lack of residues of captan in edible animal tissues.	Apr. 05 A validation study of the analytical method for the determination of captan and tetrahydrophthalimide (THPI) in tomato processed fractions has been submitted (Faessel, 2004). The new report has been evaluated, accepted and included into the addendum. We agree with EFSA conclusions. Oct. 05 Evaluation of the report included in the addendum to vol. 3. See new general open point 1.23	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points. Data gap 1.18 identified.
1.18	A validated analytical method for the determination of THPI in food of plant origin (matrices with high water content) according to Directive 96/46/EC incl. an ILV. It seems that this data are already submitted, but the data gap is set for technical reasons due to the fact that no validation data for THPI		Oct. 05 Validation data for THPI have been included in the addendum to vol.3. ILV: A new study will be provided (no scheduled time)	EPCO 25(24.-26.05.2005): Data gap identified. Evaluation Meeting (06.-09.02.2006): The validation data presented in the addendum does not cover the requirements of Directive 96/46/EC and SANCO/825/00, therefore

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	are given. Notifier has to present an ILV according to Directive 96/46/EC. See open point 1.16. This data gap was identified at EPCO 25.			data gap still open.
1.10	Notifier to provide a validated analytical method for the determination of residues in air. (see reporting table 1(57))	Position paper included in Addendum. Referenced under Annex Point IIA, 4.2.4. **Conclusion:** It is concluded that the requirements of the Commission Directive 96/48/EC, in terms of method validity, have been adequately met and the method presented is suitable for monitoring. It is considered unnecessary to conduct further work on confirmation when there are numerous existing chromatographic conditions available.	Apr. 05 Data discussed in the position paper do not fulfil the point, because the previously submitted method (Jones and Freeman, 1994) has not been sufficiently validated. Specific studies are still required. Data requirement not addressed. Oct. 05 A new study will be provided (no scheduled time)	EPCO 25(24.-26.05.2005): Data requirement still open. Evaluation Meeting (06.-09.02.2006): Data requirement still open.
	Open point 1.17: DT_{90} values must be confirmed by the fate and behaviour section. Provided that the values will be confirmed, an analytical	An analytical method for the determination of captan in water in not required due to the extremely rapid hydrolysis. It has been calculated from hydrolysis data that the DT_{90} for captan is in the	Apr. 05 New evidences provided by the MDS seem to confirm that an analytical method is not required. This position is open to discussion.	Answer from EPCO 21: DT_{90} in water below three days is confirmed! EPCO 25 (24.-26.05.2005):

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	method is not required. ⇨ Discussion in expert meeting (fate and behaviour) Open point relates to open point 4.17. (see reporting table 1(65))	range 8 minutes to 1.3 days depending on pH. The details of the DT_{90} calculations are presented in "**Captan. Position Paper on Residue Analytical Methods** (April 2004)". The analytical methods guidance document SANCO/825/00 states that a monitoring method for water is not required for an active substance with a DT_{90} in water of less than three days. In addition, the results of the water/sediment study described under IIA, 7.2.1.3.2/01, demonstrated that captan was not detectable in the surface water 24 hours after application. Therefore, it is concluded that, as degradation of captan in water is extremely rapid, it would be practically impossible to monitor the active substance in the aquatic environment. Consequently, a monitoring method is not appropriate for captan.	Oct. 05 EP list amended	Open point closed.
1.11	A validated analytical method for the determination of residue in blood. (see reporting table 1(68))	Arysta Paris has commissioned a study. The report will be supplied in April or May 2005.	Apr. 05 New data will be evaluated. Data requirement not addressed. Oct. 05 A new study " Validation of an Analytical Method for the Determination	EPCO 25(24.-26.05.2005): Date requirement still open. Data gap 1.19 identified. Message to toxicology expert: The respective residue in blood should be confirmed. Is it feasible to require an

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1.11	*continued* A validated analytical method for the determination of residue in blood. (see reporting table 1(68))		of Captan in Human Body Fluids and Tissues". Thorn, M. (2005) GAB Report 20041453/01-RVAT" will be provided by the notifier.	analytical method for the determination of captan in blood? Evaluation Meeting (06.-09.02.2006): Data requirement still open.
	Message from EPCO 25 to toxicology experts: The respective residue in blood should be confirmed. Is it feasible to require an analytical method for the determination of captan in blood?			
1.19	Notifier to present an analytical method (including ILV) for the determination of residue in food of animal origin according to the residue definition provided than an MRL will be proposed. At the moment it looks like that it is likely that MRLs will be proposed.		Oct. 05 Noted	EPCO 25(24.-26.05.2005): Data gap identified. Evaluation Meeting (06.-09.02.2006): Data gap still open.

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	See data requirement 1.11. This data gap was identified at EPCO 25.			
	Open point 1.18: RMS to evaluate the comparability of the two technical materials. (see reporting table 1(73))	A comparison of the technical captan from both notifiers is presented in the Confidential Document J (Contains industrial and commercial secrets which are to be kept confidential from both applicants). **Conclusion:** Captan technical, produced by both applicants can be considered to be comparable for the purposes of safety evaluation.	Apr. 05 The pattern of impurities in the two technical materials is slightly different, both from a qualitative and quantitative point of view. Anyway, this difference is minimized in the plant protection products and I think that the two products can be considered comparable for the purposes of performance and safety evaluation. This position is open to discussion. Oct. 05 Evaluation included in the addendum to vol.4. See new general open points	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points. Message to toxicology and ecotoxicology section: The technical materials cannot be regarded as equivalent from an analytical point of view.
	Message from EPCO 25 to toxicology and ecotoxicology section: The technical materials cannot be regarded as equivalent from an analytical point of view.			

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
1.12	Data regarding the purity and source (commercially available or not) of the starting material must be provided according to Directive 94/37/EC. (see reporting table 1(74))	Data regarding the purity and source (commercially available or not) of the starting materials are provided in the Makhteshim Document J and the Arysta Document J under Point IIA 1.8.	Apr. 05 Data requirement addressed Oct. 05 Data have been included in the addendum to vol.4. See general open points.	EPCO 25(24.-26.05.2005): Data requirement open for formal reasons. See general open point in open point 1.1. Evaluation Meeting (06.-09.02.2006): Data requirement fulfilled.
1.13	New batch analysis must be provided. (see reporting table))	A new 5 batch analysis has been conducted by Arysta Paris and the report is presented in Arysta Document J under Point IIA 1.9.	Apr. 05 Data requirement addressed Oct. 05 Data evaluation has been included in the addendum to vol.4. See general open points.	EPCO 25(24.-26.05.2005): Data requirement open for formal reasons. See general open point in open point 1.1. Evaluation Meeting (06.-09.02.2006): Data requirement fulfilled.
	Open point 1.19: RMS to reflect on the different impurity pattern in the evaluation of the comparability of the two technical materials. (see reporting table 1(76))	A comparison of the technical captan from both notifiers is presented in the Confidential Document J (Contains industrial and commercial secrets which are to be kept confidential from both applicants). **Conclusion:** Captan technical, produced by both applicants can be considered to be comparable for the purposes of safety evaluation.	Apr. 05 See open point 1.18	EPCO 25(24.-26.05.2005): Open point closed. See open point 1.18.

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	Open point 1.20: RMS to indicate in the list of endpoints that a CIPAC method is available for the determination of captan in the technical material. (see reporting table 1(77))		Apr. 05 Noted – EP list amended	EPCO 25(24.-26.05.2005): Open point fulfilled.
	Open point 1.21: RMS to clarify the basis of the assumption that the CIPAC method for WP and DP formulations is also applicable for WG formulations. (see reporting table 1(77))	A comparison of the composition of captan WP and WG products is presented in the Confidential Document J (Contains industrial and commercial secrets which are to be kept confidential from both applicants). This concludes that WG formulations containing captan have very similar compositions to WP formulations containing captan. Both have closely similar active substance content, the same wetting/dispersing agents at the same or similar concentrations, and the remaining ingredients are inorganic minerals. The CIPAC technical and WP analytical methods (40/TC/M 3/-, 40/TC/M 4/-, 40/WP/M 3/- or 40/WP/M 4/-) consists of a simple non-aqueous extraction which would be unaffected by the minor differences in composition. It can therefore be assumed that the CIPAC method for WP and DP formulations is also applicable to WG formulations.	Apr. 05 Conclusions acceptable.	EPCO 25(24.-26.05.2005): Open point closed. At the moment, the CIPAC method for WP and DP formulations cannot be regarded as applicable for WG formulations

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1.14	Data to confirm the identity of the impurities revealed by chemical analysis must be provided to address the requirement of the Directive on the specificity of the method(s). (see reporting table 1(80))	Specificity of the impurity methods has been adequately addressed in the dossier. Specificity was confirmed by comparison of chromatograms of certified analytical standards and blank solvent. Absence of interfering peaks is taken as confirmation of specificity. Regarding identity of the impurities, this has been confirmed by the use of certified reference standards in the validation procedures. There is no sound scientific basis on which to reject this argument. Confirmation of the identity of the impurities is inherent in the proven specificity of the method. The Directive does not directly require any further confirmation of the identity of the impurities.	Apr. 05 See data requirement 1.9	EPCO 25(24.-26.05.2005): Data requirement closed. See data requirement 1.9.
1.15	Notifier to clarify the investigated fortification levels in the method for the determination of folpet and the impurities. (see reporting table 1(82))	Makhteshim Document J and Arysta Document J have been amended accordingly.	Apr. 05 Data requirement addressed. Oct. 05 Data included in the addendum to vol. 4. See general point 1.23	EPCO 25(24.-26.05.2005): Data requirement open for formal reasons. See general open point in open point 1.1. Evaluation Meeting (06.-09.02.2006): Data requirement fulfilled.

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	Open point 1.22: For transparency and better comprehensibility, RMS to confirm that the notifier has changed from Tomen to Calliope and in this context to confirm which formulations belongs to which notifier. (see reporting table 1(98))	Details of the amended names, organisations and contacts details are included in the new Addendum under Point IIA 1.1, IIA 1.2, IIIA 1.1 and IIIA 1.2. The formulation Merpan 80 WDG belongs to Makhteshim. The formulation Malvin WG belongs to Arysta Paris.	Apr. 05 The notifier has changed from Tomen to Calliope. The formulation Merpan 80 WDG belongs to Makhteshim. The formulation Malvin WG belongs to Arysta Paris. Oct. 05 See general open points.	EPCO 25(24.-26.05.2005): Open point still open for technical reasons. See general open point in open point 1.1. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.
	Message from EPCO 25 to the toxicology experts: To confirm that carbon tetrachloride has not to be regarded as a relevant impurity in the technical material of captan.			

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	New open point 1.29: RMS to amend the list of end point. - RMS to use the template given in EPCO manual E4 - p. 3 ff the confidential information has to be deleted. - RMS to indicate the new minimum impurity in the list of end points. - UV/VIS absorption box. The molar extinction coefficient is not correct. This open point was proposed at EPCO 25.		Oct. 05 EP list amended.	EPCO 25(24.-26.05.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.

2. Mammalian toxicology

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	Section 2 Data requirements: ***4*** Open points: ***18***			Section 2 Data requirements***: -*** Open points: ***2*** Data gaps: ***1***
	Open point 2.1: MS to discuss the canceriogenic properties in an expert meeting. (see reporting table 2(1))	The notifier response by Makhteshim and Calliope (2005) to comments made by Greece on the toxicology section of the DAR is summarised in the new addendum under Annex Point IIA 5.10/02. This paper summaries and refers to various other new studies which are submitted and summarised in the new addendum, under Points IIA, 5.5.3/01, 5.5.3/02, 5.5.3/03, 5.9.3/02, 5.9.3/03.	April 2005 The RMS deems acceptable the responses stated in the addendum made to the comments made by Greece. Neither the experimental data nor the epidemiological observations are sufficient to change the overall conclusions regarding the judgement of no cancer risk to man.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. Not carcinogenic in rat. Carcinogenic (duodenal tumours) in mice, non-genotoxic mechanism, clear NOAEL established. Proposal for classification of Category 3, R 40
	Open point 2.2: The setting of ARfD to be discussed at an expert meeting. (see reporting table 2(3))	The notifier contends that an ARfD is not applicable for captan. The arguments supporting this contention are presented in the paper by Gordon and Kinzell (2004) summarised in the new addendum under Point IIA, 5.10/01, supported by Moore and Creasey (2004) summarised in the new addendum under Point IIA, 5.8.2/06. Note: Moore and Creasey (2004) is a study on folpet but is directly applicable to captan.	April 2005 The RMS deems that the data summarised in the new addendum under Point IIA, 5.8.2/06 are applicable to Captan and support that the short term toxicity (irritancy) can result in a maternotoxic effect that in turn leads to developmental toxicity. The need of a ArfD will be discussed at an EPCO meeting.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. ARfD: 0.1 mg/kg bw with a safety factor of 100.

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2.1	Notifier to submit the position paper Gordon and Kinzell (2004) and the study Moore and Creasey (2004). (see reporting table 2(3))	The paper by Gordon and Kinzell (2004) is summarised in the new addendum under Point IIA, 5.10/01. The study by Moore and Creasey (2004) is summarised in the new addendum under Point IIA, 5.8.2/06. Note: Moore and Creasey (2004) is a study on folpet but is applicable to captan.	April 2005 Paper available and summarized in the addendum. See above	EPCO 23 (10 – 13.5.2005): Data requirement fulfilled
	Open point 2.3: MS to agree on the ADI value at an expert meeting. (see reporting table 2(4))	Awaiting expert meeting comments.	April 2005 The RMS already agreed to lower to 0.1 mg/kg b.w. the ADI based on the NOAEL for maternal and developmental toxicity of 10 mg/kg b.w. in rabbit.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. ADI and AOEL: 0.1 mg/kg, safety factor 100.
	Open point 2.4: The dermal absorption value should be discussed at an expert meeting. (see reporting table 2(6))	The notifier contends that a dermal absorption value of 3% is appropriate for captan for use in risk assessment. The notifier's arguments supporting this contention and the notifier's response to comments received from Member States on the dermal absorption studies with captan is presented the new addendum under Point IIIA 7.3. This conclusion is also supported by the RMS.	April 2005 RMS confirms the acceptability of the Notifier's comments based, in accordance with some shortcomings of the in vivo studies, on the worst case data. RMS does not consider the shortcomings so critical to repeat the study.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. Dermal absorption: 10% based on in vivo data. RMS to amend the list of endpoints. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.

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	Open point 2.5: The setting of the highest relevant NOAEL for the long-term studies should be discussed at an expert meeting. (see reporting table 2(9))	Awaiting expert meeting comments.	April 2005 The NOAEL of the three generation study (25 mg/kg b.w) is acceptable since the treatment can be assimilate to a chronic treatment, i.e. rat chronic 2-years exposure, that shows a NOAEL of 24 and 25 mg/kg b.w.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. NOAEL: 25 mg/kg bw/day, 2 year rat study RMS to amend the list of end points. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.
2.2	Notifier to submit new toxicokinetic study. (see reporting table 2(10))	[Should read reporting table 2(11)]. The study by Arndt, T. and Dohn, D. (2004) is summarised in new addendum under Point IIA 5.1/08. Thiophosgene (a captan reactive metabolite intermediate) disappears rapidly when added in excess (100 µg/mL) to human whole blood *in vitro.* The half-life was calculated to be 0.6 seconds. **Conclusion:** This study demonstrates why neither captan (with the DT_{50} of 0.97 sec. in human blood) nor thiophosgene are likely to reach sensitive target distant to the mucosal surface of the gastrointestinal tract and as part of the mechanism data it further supports the captan mode of action.	April 2005 The study is acceptable but RMS still needs some clarifications on the metabolism of Captan before the fungicide enters into the blood (i.e. in the skin, in the gut etc.). Would Captan per se in tissues different from blood react with the thiols within seconds as thiophosgene does when the parent compound is degraded?	EPCO 23 (10 – 13.5.2005): Data requirement fulfilled. The half-life of thiophosgene is 0.6 sec.

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	Open point 2.6: The RMS to provide a summary of the new toxicokinetic study in the addendum to be discussed in an expert meeting. (see reporting table 2(11))	The study by Arndt, T. and Dohn, D. (2004) is summarised in new addendum under Point IIA 5.1/08. Thiophosgene (a captan reactive metabolite intermediate) disappears rapidly when added in excess (100 µg/mL) to human whole blood *in vitro.* The half-life was calculated to be 0.6 seconds. **Conclusion:** This study demonstrates why neither captan (with the DT_{50} of 0.97 sec. in human blood) nor thiophosgene are likely to reach sensitive target distant to the mucosal surface of the gastrointestinal tract and as part of the mechanism data it further supports the captan mode of action.	April 2005 See above	EPCO 23 (10 – 13.5.2005): Open point fulfilled.
	Open point 2.7: The need of performing a 90-day oral study in rat should be discussed at an expert meeting. (see reporting table 2(13))	The notifier contends that a 90-day rat study is not required. The reasons supporting this contention are summarised in the new addendum under Point IIA 5.3.2. The reasons are as follows: 1. The mode of action (MOA) for captan for toxicity is well established. This MOA is based on the rapid chemical reaction of captan and thiophosgene with thiol (-SH) groups. 2. The basis for the waiver as set forth in the DAR is believed adequate:	April 2005 RMS fully support the Notifier's comments. It is unlikely that a 90-day study in rats will identify a new target or adverse effect that has not been already observed.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. A 90 day oral rat study is not required.

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	continued Open point 2.7: The need of performing a 90-day oral study in rat should be discussed at an expert meeting. (see reporting table 2(13))	a. Given the well established captan MOA, it is unlikely that transitory changes in clinical chemistry or hematology, seen at 90 days in the two year study would lower the NOEL already established by the rat two year study, should a new 90-day study be initiated. b. The collective data in mice, rats and dogs have not identified an organ, other than the gastrointestinal tract, that captan targets. It is unlikely that a 90-day study in rats will identify a new target or adverse effect that has not already been evaluated. 3. A 90-day oral rat is not likely to affect the endpoints or NOELs used for risk assessments. The mode of action for captan is constant over time and does not change with enzyme induction or other changes as test animals age. This conclusion is also supported by the RMS.		

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	Open point 2.8: The setting of the NOAEL(C) in the 90-day inhalatory study should be discussed at an expert meeting. (see reporting table 2(14))	The notifier contends that the NOEL in the 90-day inhalation study in rat is 0.60 µg/L. The reasons supporting this contention are summarised in the new addendum under Point IIA 5.3.3. **Conclusion:** it is clear that the irritant effects on the respiratory passages are local effects caused by captan deposition. The NOEC for toxicological effects, 0.60 µg/L is supported. This conclusion is also supported by the RMS.	April 2005 RMS tends to agree that the rat larynx is particular sensitive to irritants but the NOAEC 0.6 µg/l is sustainable since the only effect was the reduction of body weight (-8%) registered during the treatment that returned to control levels after the end of the exposure.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. NOAEC (systemic): 0.6 µg/L
	Open point 2.9: MS to discuss the highest relevant NOAEL in the reproductive toxicity studies at an expert meeting. (see reporting table 2(17))	A position paper by Neal (2004) is summarised in new addendum under Annex Point IIA 5.6.2 (5.6.2.1/04 and 5.6.2.2/02). **Conclusion:** The existing database provides adequate information regarding the reproductive and developmental toxicity of captan to permit informed and conservative risk assessment. There is no evidence that there is any unique developmental susceptibility of the developing young to captan. Further reproductive or developmental toxicity testing of captan should not be required.	April 2005 The NOAEL of 12.5 mg/kg b.w. for reproductive toxicology appears appropriate. As far as developmental toxicity RMS still support the need of new data able to analyze the possible influence of Captan to adversely effect the intestine walls and the welfare of rabbits during pregnancy.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. Developmental toxicity: NOAEL 10 mg/kg bw/day (rabbit) NOAEL 90 mg/kg bw/day (rat)

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2.3	Notifier to submit the position paper "Comments on captan Monograph Volume III" for RMS to provide a summary in an addendum. (see reporting table 2(17))	A position paper by Neal (2004) is summarised in new addendum under Annex Point IIA 5.6.2 (5.6.2.1/04 and 5.6.2.2/02). **Conclusion:** The existing database provides adequate information regarding the reproductive and developmental toxicity of captan to permit informed and conservative risk assessment. There is no evidence that there is any unique developmental susceptibility of the developing young to captan. Further reproductive or developmental toxicity testing of captan should not be required.	April 2005 See above	EPCO 23 (10 – 13.5.2005): Data requirement fulfilled.
	Open point 2.10: MS to agree on the AOEL value at an expert meeting. (see reporting table 2(18))	Awaiting expert meeting comments.	April 2005 The RMS agreed already to lower the AOEL to 0.1 mg/kg b.w. based on the NOAEL for maternal and developmental toxicity in the teratogenicity study in rabbit (10 mg/kg b.w.).	EPCO 23 (10 – 13.5.2005): Open point fulfilled. AOEL: 0.1 mg/kg bw/day
	Open point 2.11: The RMS to present new exposure calculations in an addendum, to be discussed at an expert meeting. (see reporting table 2(18))	[Should be reporting table 2(24)]. The use of two models for operator risk assessment is not a requirement. The German model is appropriate and suitable to estimate exposure with Merpan 80WDG/Malvin WG.	April 2005 RMS agrees October 2005 New calculations of operator exposure using a dermal absorption value of 10% are provided in a new addendum. The results of the evaluation show that	EPCO 23 (10 – 13.5.2005): Open point still open A new calculation on operator exposure has to be submitted. Evaluation Meeting (06.-09.02.2006):

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	continued Open point 2.11: The RMS to present new exposure calculations in an addendum, to be discussed at an expert meeting. (see reporting table 2(18))		estimated exposure is below the AOEL for all proposed uses when operators wear protective clothing (56 to 91% of the AOEL - German model)	Open point fulfilled.
	Open point 2.12: The risk for bystanders should be discussed in an expert meeting. (see reporting table 2(26))	An estimate of dermal exposure of bystanders is presented in the DAR. This shows a wide margin of safety. Furthermore, the vapour pressure of captan is low 4.2 x 10^{-6} Pa at 20^{o}C and so the inhalation risk to bystanders is considered to be negligible. Therefore, the overall risk to bystanders is considered to be negligible. This conclusion is consistent with the conclusion of the RMS.	April 2005 RMS agrees October 2005 New calculations of bystander exposure using a dermal absorption value of 10% are provided in a new addendum. New calculations show that exposure of bystanders is below the AOEL (25% of the AOEL).	EPCO 23 (10 – 13.5.2005): Open point fulfilled. A new calculation on bystander exposure has to be submitted.
	Open point 2.13: The RMS to clarify which PPE that was included in the operator exposure calculations, together with open point 2.11 (in comment 2(18) in the reporting table). (see reporting table 2(27))	The operator exposure study represents a worst-case as the mixing/loading was done with a WP formulation which would lead to higher exposure than with the WG formulations supported in the dossier. Also, the applications were made by tractors without cabs. The operators wore what are	April 2005 More information are needed from the Notifier. October 2005 New calculations of operator exposure using a dermal absorption value of 10% are provided in a new addendum. Using operator exposure modelling, estimated	EPCO 23 (10 – 13.5.2005): Open point still open A new calculation on operator exposure has to be submitted. Evaluation Meeting (06.-09.02.2006):

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	continued Open point 2.13: The RMS to clarify which PPE that was included in the operator exposure calculations, together with open point 2.11 (in comment 2(18) in the reporting table). (see reporting table 2(27))	described in the report as 'overalls'; these are not described in the report as chemical proof coveralls. A full description of the overalls is not given. The photographs indicate that the workers were not wearing heavy chemical proof garments. The notifier contends that the use of PPE in the form of protective gloves will provide sufficient protection for operators.	exposure to captan when using 'Merpan 80 WDG'/ 'Malvin' WG is below the AOEL for operators wearing gloves during mixing/loading and application - for applications to tomato - and gloves plus a chemical proof garment/sturdy footwear during application to orchard crops. (German model)	Open point fulfilled.
	Open point 2.14: The RMS to provide clarifications of the measurements of worker exposure in an addendum.The worker exposure should be discussed at an expert meeting. (see reporting table 2(30))	New calculations of worker exposure for workers with uncovered arms and legs are summarised in new addendum under Point IIIA, 7.2.3.3. **Conclusion**: The risk to all workers involved with the handling of crops treated with 'Merpan' 80 WDG/'Malvin' WDG in the absence of protective clothing is considered to be low. It is not necessary to set additional re-entry periods longer than the PHI for workers after the spray has dried or for workers to wear gloves when handling treated crops. This conclusion is consistent with the conclusion of the RMS.	April 2005 RMS agrees October 2005 New calculations of worker exposure using a dermal absorption value of 10% are provided in a new addendum, taking into account dislodgeable foliar residues. Exposure to captan of all workers involved with handling of crops treated with 'Merpan' 80 WDG/'Malvin' WDG is below the AOEL after 14 days from the application (35.5% of the AOEL with gloves, based on the German model and results of a study on dislodgeable residues; 75% of the AOEL, based on field study, workers with uncovered arms and legs),	EPCO 23 (10 – 13.5.2005): Open point still open A new calculation on worker exposure has to be submitted taking into account the new value for dermal absorption and foliar residues. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.

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			Exposure is above the AOEL after 7 days from the application (115%, German model – 107% field study).	
	Open point 2.15: Acceptability of the genotoxicity studies to be clarified by the RMS.If they are not acceptable they should be deleted fom the reference list. (see reporting table 2(33))	See notifier response to comments made by Greece on the toxicology section of the DAR summarised in the new addendum under Annex Point IIA 5.10/02. The notifier concludes that there remain no data gaps in the genotoxicity database for captan.	April 2005 The overall weight of evidence indicates that Captan is unlikely to be an in vivo mutagen. In in vitro test systems captan and/or its metabolites, particularly thiophosgene, have the ability to induce mutagenic effects. The mutagenic potency is markedly reduced in the presence of material presenting thiol groups. Neither captan nor its breakdown products are likely to reach the stem cells within the duodenal crypts due their short half-life. There is no evidence of any chromosomal aberrations in the duodenal cells following oral administration.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. Based on two recent studies (Jacoby 1985, and Kenelly, 1990), there is no evidence of genotoxicity for the technical material.
	Open point 2.16: The genotoxic effect of Captan to be clarified by the RMS and to be discussed at an expert meeting. (see reporting table 2(34))	See notifier response to comments made by Greece on the toxicology section of the DAR summarised in the new addendum under Annex Point IIA 5.10/02. The notifier concludes that captan does not pose a risk of mutagenicity *in vivo*	April 2005 See above	EPCO 23 (10 – 13.5.2005): Open point fulfilled.

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	Open point 2.17: RMS to check the publications mentioned in the comment from GR (e.g.: Reuber MD, 1989; Cabral R et al., 1991; Hasegawa R et al., 1993; Perocco P et al, 1995) regarding the carcenogicity of Captan and to summarize in an addendum. (see reporting table 2(35))	See notifier response to comments made by Greece on the toxicology section of the DAR summarised in the new addendum under Annex Point IIA 5.10/02. In addition, the notifier's summary and interpretation of the Reuber, Cabral Hasegawa studies are presented in the new addendum under Points IIA 5.5.3/01, 5.5.3/02 and 5.5.3/03. Based on the new Guidelines for Carcinogen Risk Assessment, EPA's current B2 (probably human) carcinogen classification for captan is inappropriate.	April 2005 RMS agrees with the Notifier's comments. Reuber's conclusions are based just on his personal judgement and are not shared by other scientific and/or regulatory bodies. The data published by Cabral, Hasegawa and Perocco, although scientifically valid, do not add value to the overall toxicological data on which RMS has drawn his assessment.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. Classification has been proposed to be category 3, R 40
	Open point 2.18: RMS to review the study mentioned in the comment from GR (Mills PK, 1998 and MCDuffie HH et al, 2001) regarding medical data. (see reporting table 2(36))	The notifier's summary and interpretation of the epidemiology studies is presented in the new addendum under Annex Point IIA 5.9.3 (5.9.3/02, 5.9.3/03). **Conclusion**: These epidemiology studies have suggested captan is associated with human cancer. The study conclusions are judged suspect in light of the well-established mode of action of captan, its rapid degradation in vivo, and the absence of collaborating cancers in populations of workers manufacturing captan (Palshaw, 1980, Palshaw, 1987). It should be concluded that there is	April 2005 RMS agrees with the Notifier's comments suggesting more rigorous study designs to further determine any possible correlation between Captan exposure and human cancer.	EPCO 23 (10 – 13.5.2005): Open point fulfilled.

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	continued Open point 2.18: RMS to review the study mentioned in the comment from GR (Mills PK, 1998 and MCDuffie HH et al, 2001) regarding medical data. (see reporting table 2(36))	insufficient epidemiologic evidence to link captan to human cancer.		
2.4	Notifier to submit the two rat carcinogenicity studies by Goldenthal et al., 1982 and Bruyntjes, 1984. (see reporting table 2(37))	See notifier response to comments made by Greece on the toxicology section of the DAR summarised in the new addendum under Annex Point IIA 5.10/02. This document includes background data by Bruyntjes, 1984. Note that the Goldenthal et al., 1982 report is included in the DAR referenced under original author Rajesekaran (Report R-9282/TMN-0768).	Goldenthal et al., 1982 is already summarized in the DAR referenced under the original Author Rajesekaran (report R-9282/TMN 0768 IIA 5.5.1/01). Bruyntjes 1984 is available to the RMS.	EPCO 23 (10 – 13.5.2005): See open point 2.1
M 1	Message from EPCO 24 to EPCO 23: Please clarify the toxicological relevance of the metabolites THPI, THPI epoxide, 3 OH-THPI and 5 OH-THPI .			EPCO 23 (10 – 13.5.2005): THPI is the first product of metabolism: LD_{50} > 2000 mg/kg bw/day THPAM is the second metabolite. It is an animal metabolite which would be covered by the ADI for captan.. It shows negative genotoxicity.

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	continued Message from EPCO 24 to EPCO 23: Please clarify the toxicological relevance of the metabolites THPI, THPI epoxide, 3 OH-THPI and 5 OH-THPI .			3 OH-THPI and 5 OH-THPI (animal metabolites) show up in low amounts. They are hydrophilic. Nevertheless they are said to be covered by the ADI as well. Information on THPI epoxide is not available.
	New open point 2.19 Since ~~folpet~~ captan is to be classified as toxic an analytical method for determining ~~folpet~~ captan or ~~folpet~~ captan residue(s) in body fluids or tissues (blood) must be available. The open point has been amended due to a mistake of cut and paste after the Feb. Evaluation Meeting			EPCO 23 (10 – 13.5.2005): Open point still open. RMS to identify a marker for ~~folpet~~ captan in blood as well as an analytical method for the determination. Evaluation Meeting (06.-09.02.2006): Open point still open.
	New open point 2.20: RMS to amend the list of end points. (See above)		October 2005: The list of end points has been amended.	EPCO 23 (10 – 13.5.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.

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M 2	Message from EPCO 21 to EPCO 23: It cannot be excluded that traces of thiophosgen occur in the air.			Noted Closed
M 3	Message from EPCO 21 to EPCO 22 and EPCO 23: Relevance of metabolites in groundwater THPI and THPAM should be addressed by ecotox and toxiclogy meetings. It should be noted that for this use PEC_{GW} of the metabolites (THPI and THPAM) exceed the threshold of 0.75 µg/l.			Answer from EPCO 22: The risk from the metabolites is acceptable Evaluation Meeting (06.-09.02.2006): A new data gap has been identified, Notifier to address the acute toxicity of THPAM and to address the carcinogenic properties of THPI and THPAM Data gap still open.
M 4	Message from EPCO 25 to experts of the toxicology and ecotoxicology section: From the analytical point of view the technical materials cannot be regarded as equivalent.			Evaluation Meeting (06.-09.02.2006): This is open from the toxicological point of view. Open point still open.

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M 5	Message from EPCO 25 to experts of the toxicology and ecotoxicology section: To confirm the proposed max value for Folpet of 10 g/kg as a relevant impurity.			Evaluation Meeting (06.-09.02.2006): Still open
M 6	Message from EPCO 25 to experts of the toxicology section: The respective residue in blood should be confirmed. Is it feasible to require an analytical method for the determination of captan in blood?			Evaluation Meeting (06.-09.02.2006): See open point 2.19 Closed
M 7	Message from EPCO 25 to experts of the toxicology and ecotoxicology section: The technical materials cannot be regarded as equivalent from an analytical point of view.			Evaluation Meeting (06.-09.02.2006): See M 4 Closed

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M 8	Message from EPCO 25 to experts of the toxicology section: To confirm that carbon tetrachloride has not to be regarded as a relevant impurity in the technical material of captan.			Evaluation Meeting (06.-09.02.2006): As it is classified as T, it has to be regarded as a relevant impurity. Closed.

3. Residues

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	Section 3 Data requirements: ***4*** Open points: ***14***			Section 3 Data requirements: ***2*** Open points: **-** Data gaps: **-**
	Open point 3.1: RMS to provide an addendum to be considered in expert meeting with the new MRL proposal for peaches and nectarines, new TMDI and I(N)EDI calculations, as well as new STMR calculations. (see reporting table 3(1))	The GAP for peaches/nectarines is amended – the PHI is changed from 7 days to 21 days. No other changes to the GAP have been made. The change in PHI for peaches/nectarines has no affect on the existing assessments of risk of captan to operators or the environment. No new data are submitted to support this change. The same residue trials as those summarised in Table B.7.6.3.1 of the DAR are relevant to the amended GAP as all trials included a measurement of residue levels at 20-22 days. Calculations of the MRL for a PHI of 21 days are included in new addendum under Point IIA, 6.7 Proposed maximum residue Levels (MRLs) and residue definition. Amended consumer calculations are included in Point IIA, 6.9 Estimation of the potential and actual exposure through diet and other means. **Conclusion:** Both methods of calculation indicate that a MRL of	Addendum provided. After change of the GAPs (PHI 21 days) for peaches and nectarines we agree with new proposals of MRL = 3 mg/kg and STMR = 0.78 mg/kg. New TMDI and IEDI have been calculated and included into the addendum. TMDI is less than the ADI for captan in adults (WHO and UK diets), children (UK and German diets) and infants (UK diet) and exceed ADI in toddler (UK diet). However in these subjects (toddlers), NEDI is less than the ADI (UK model). Oct. 05 New addendum provided, as required, with PHI for peaches and nectarines = 7 days, and MRL=10 mg/kg. TMDI is less than the ADI for captan in adult (WHO and UK diets), child (UK	EPCO 24 (11.05. – 13.05.2005): Information in the addendum does not address the issue. Open point still open. Evaluation Meeting (06.-09.02.2006): A new addendum has been submitted by the RMS and in addition, the issue is also reconsidered in the EFSA addendum on the basis of the residue definition established in the expert meeting. Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued Open point 3.1: RMS to provide an addendum to be considered in expert meeting with the new MRL proposal for peaches and nectarines, new TMDI and I(N)EDI calculations, as well as new STMR calculations. (see reporting table 3(1))	3.0 mg/kg is appropriate for peaches and nectarines based on a PHI of 21 days. The STMR is 0.78 mg/kg. Based on the MRL values, the TMDI is less than the ADI for captan of 0.1 mg/kg bw/day for adults (WHO and UK diets), children (UK and German diets) and infants (UK diet). Based on the STMR values, the NEDI value is less than the ADI for captan for toddlers (UK model). There is therefore a large margin of safety for all consumer groups.	and German diets) and exceed ADI in toddler and infant (UK diet). However in these subjects (toddler and infant), NEDI is less than the ADI (UK model). Open point fulfilled	
	Open point 3.2: RMS to amend the list of end points on the following points: - summary of residue data: GAPs in N and S for pome fruits should be addressed separately (in accordance with the EPCO manual) - TMDI and I(N)EDI calculations - Proposed MRLs (see reporting table 3(1))		List of end points amended.	EPCO 24 (11.05. – 13.05.2005): List of end points has been amended. Open point fulfilled.

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	Open point 3.3: RMS to prepare an addendum to be discussed in expert meeting addressing uncharacterized material in fruit wash, foliage, peel and pulp extracts of the metabolism study on apples (level and number of individual fractions…). (see reporting table 3(2))	A new table of results for the apple study together with discussion of the results is presented in the new addendum, under Annex Point IIA, 6.1. **Conclusion:** Based on the information for apple, tomato and lettuce crops, it is concluded that captan is metabolised via a common route in plants. It is therefore also concluded that unidentified residues observed in apples will be of a similar nature to those observed in tomato and lettuce and as such will be present as a multi-component residue composed of polar products most likely containing conjugates of captan metabolites. This conclusion is consistent with the conclusion of the RMS in the reporting table.	Addendum prepared (a new table of results for the apple study has been included, See point IIA 6.1 of the addendum) and open to discussion., Our opinion is that uncharacterised material (UM) represents polar products that are formed following the slow adsorption of captan into the peel and pulp. Based on the metabolism observed in tomato and lettuce these polar products are considered likely to be conjugates of captan metabolites. This is consistent with the observation that UM is low in fruit wash and foliage, increase in peel and is maximum in pulp.	EPCO 24 (11.05. – 13.05.2005): RMS provided the addendum. Open point fulfilled.
3.1	A hydrolysis study in representative hydrolytic conditions. (see reporting table 3(4))	A position paper is summarised in new addendum under Annex Point IIA, 6.5.1/01. **Conclusion:** Sufficient data already exist to predict the effect of processing hydrolysis on the nature of the residue and therefore new studies are not required.	Data discussed in the position paper do not fulfil the point. Specific studies are still required. Moreover we have been informed from the applicant that hydrolysis studies are on going and results will be available soon. Data requirement still open. Oct. 05 Data requirement still open.	EPCO 24 (11.05. – 13.05.2005): Results of ongoing hydrolysis studies still have to be awaited. Data requirement still open. Evaluation Meeting (06.-09.02.2006): Data requirement still open.

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	Open point 3.4: RMS to address in an addendum to be discussed in expert meeting the position paper of the notifier **"Captan. Position Paper on Effects on the Nature of the Residue (2004)"**. Open point relates to data requirement 3.1. (see reporting table 3(4) and 3(22))	Summarised in new addendum under Annex Point IIA, 6.5.1/01. **Conclusion:** Sufficient data already exist to predict the effect of processing hydrolysis on the nature of the residue and therefore new studies are not required.	Addendum prepared and open to discussion (see RMS comments, under the point IIA 6.5). Our opinion is that data discussed in the position paper do not fulfil the point. Specific studies are still required.	EPCO 24 (11.05. – 13.05.2005): Open point closed. See data requirement 3.1.
3.2	A whole balance study for tomato washed, peeled and canned or used for juice, plus a follow-up study in canned tomato and tomato juice. (see reporting table 3(4))	Results of one balance study and one follow-up study are summarised in new addendum under Annex Point IIA, 6.5.2/07 and 6.5.2/08. **Conclusion:** There was no concentration of captan residues in any processed tomato commodity.	Study accepted and included into the addendum (point IIA 6.5.2/07 and /08). Oct. 05 Following results of the last toxicological evaluations (see the Addendum "definition of the residue" of July 2005) the residue definition for captan was changed going back to the parent compound alone, (residue definition for captan=captan). Data requirement is therefore fulfilled	EPCO 24 (11.05. – 13.05.2005): Data requirement fulfilled. According to the new residue definition the study needs to be revisited by the RMS. (See new open point 3.15)
	Open point 3.5: RMS to evaluate in an addendum to be considered in expert meeting the studies provided by the notifier:	Results of one balance study and one follow-up study are summarised in new addendum under Annex Point IIA, 6.5.2/07 and 6.5.2/08.	Study evaluated, accepted and included into the addendum (point IIA 6.5.2/07 and /08). New TFs values included in the addendum and list of end points.	EPCO 24 (11.05. – 13.05.2005): RMS presented an addendum. In addition a room document was tabled including results of these processing studies for THPI metabolite

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	"Faessel, V. (2004). Residue study in and on tomatoes following 4 applications of the test item Malvin WG. Anadiag report R A3154.", "Faessel, V. (2004). Residue study in and on tomatoes following 4 applications of the test item Malvin WG. Anadiag report R A3156." and "Faessel, V.(2004). Validation study of the analytical method for the determination of captan and tetrahydrophthalimide (THPI) in tomato processed fractions. Anadiag report R A3153." Open point relates to data requirement 3.2. (see reporting table 3(4) and 3(28))	**Conclusion:** There was no concentration of captan residues in any processed tomato commodity.	Oct. 05 Following results of the last toxicological evaluations (see the Addendum "definition of the residue" of July 2005) the residue definition for captan was changed going back to the parent compound alone, (residue definition for captan=captan). Data requirement is therefore fulfilled	Open point fulfilled. (See new open point 3.15)

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3.3	A balance study and 3 follow-up studies for canned peaches/nectarines. (see reporting table 3(4))	Studies to investigate the effects on residue levels of captan in peaches and nectarines after processing have not been carried out. Effects of canning are not normally required for apple but two studies have been done and are included in the DAR (see Table B.7.7.2.5 on page 47). These show that no residues above the LOQ were found in canned fruit. Based on the studies in canned apple, no residues of captan are expected to be found above the LOQ in canned peaches and nectarines or canned juice. The notifier contends that the existing studies in apple should be sufficient to reduce the requirements for peaches/ nectarines from 1 balance plus 3 follow-up studies to 1 balance plus 1 follow-up study. These studies will be conducted during the 2005 season.	Our opinion is that 1 balance plus 1 follow-up study are enough if it is confirmed that the levels of the residues in processed commodities are below the LOD. According to the MDS studies will be conducted during the 2005 season. Data requirement still open. Oct. 05 Data requirement still open	EPCO 24 (11.05. – 13.05.2005): Data requirement still open. Evaluation Meeting (06.-09.02.2006): Data requirement still open.
	Open point 3.6: MSs to discuss residue definition for processed commodities and processing yields in an expert meeting. Open point relates to open point 1.16. (see reporting table 3(7)) *continued*	Studies on the toxicity and biological activity of potential captan metabolites are summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/01, 02, 03. In addition a discussion paper by Gordon (2005) is summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/04. **Conclusion**: The discussion paper	New information provided by the MDS seems to confirm that the captan metabolite THPI is of low toxicological concern, compared to the parent compound captan (see addendum). The residue definition, for Risk Assessment, should be therefore captan alone. However, heating convert captan into	EPCO 24 (11.05. – 13.05.2005): Residue definition : refer to open point 3.7 Processing yields : general discussion postponed due to the lack of time. Open point fulfilled.

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	Open point 3.6: MSs to discuss residue definition for processed commodities and processing yields in an expert meeting. Open point relates to open point 1.16. (see reporting table 3(7))	expands on the discussion of the toxicological significance of the degradates of captan and concludes in conformity with the JMPR (FAO/WHO 2000) and US-EPA, based on the DG SANCO Guideline for Metabolism and Distribution in Plants (European Commission 1997) that the metabolites present a significantly lower hazard to man than captan, evidenced by the complete lack of systemic toxicity observed in the captan long term and subchronic toxicity studies. In addition, direct comparisons of captan and THPI aquatic toxicity further reinforces the differences due primarily to its mode of action as a primary irritant. Key to resolving the differences in toxicity between captan, THPI and other systemically circulating THPI-metabolites is the exceptionally rapid degradation of captan in the presence of blood. As such, all systemic toxicity observed in captan studies is attributed to the metabolites along with secondary effects of captan's irritation of the GI tract. The definition of the residue in plants including processed commodities is therefore captan alone.	THPI . Therefore in processed commodities monitoring should include captan plus THPI, expressed as captan equivalents (converting factor for THPI to captan =). Accepting this view, residue definition in processed commodities should be captan for Risk Assessment and captan plus THPI, expressed as captan equivalents for monitoring. This position is open to discussion.	

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	Open point 3.7: MSs to discuss in an expert meeting the residue definition for animal products. Open point relates to open point 1.16. (see reporting table 3(9))	Studies on the toxicity and biological activity of potential captan metabolites are summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/01, 02, 03. In addition a discussion paper by Gordon (2005) is summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/04. **Conclusion**: The discussion paper expands on the discussion of the toxicological significance of the degradates of captan and concludes in conformity with the JMPR (FAO/WHO 2000) and US-EPA, based on the DG SANCO Guideline for Metabolism and Distribution in Plants (European Commission 1997) that the metabolites present a significantly lower hazard to man than captan, evidenced by the complete lack of systemic toxicity observed in the captan long term and subchronic toxicity studies. In addition, direct comparisons of captan and THPI aquatic toxicity further reinforces the differences due primarily to its mode of action as a primary irritant. Key to resolving the differences in toxicity between captan, THPI and other systemically circulating THPI-metabolites is the exceptionally rapid degradation of captan in the presence of blood. As such, all systemic toxicity	After captan administration to lactating goats, about 1-1.5% of the dose is retained in tissues and 2% in milk. Levels of parent captan are below the LOD since captan is rapidly converted to intermediate like THPI, THPI epoxide, 3-OH THPI and 5-OH THPI, that are subsequently incorporated into natural products . There is no evidence that they could be of toxicological concern and new information provided by the MDS seems to confirm that captan metabolites are of low toxicological concern, compared to the parent compound (see addendum). For residue definition we see three possibilities: 1) no needs for residue definition 2) sum of THPI, THPI epoxide, 3-OH THPI and 5-OH THPI (expressed as captan equivalents? And only for monitoring?) 3) the most abundant metabolite, 3-OH THPI (expressed as captan equivalents? And only for monitoring?) This position is open to discussion.	EPCO 24 (11.05. – 13.05.2005): The meeting agreed on the following residue definitions: Plant products (for monitoring and risk assessment: sum of captane and THPI expressed as captane Animal products (for monitoring and risk assessment: sum of THPI, 3-OH THPI and 5-OH THPI expressed as captane Open point fulfilled. RMS to amend the list of end points accordingly. See new open point 3.16. New open point 3.15: RMS to go back to the available data set and make new evaluation of the available data so that the MRL proposals and the risk assessment can be done on the basis of the new residue definitions. The new calculations should be summarised in an addendum. Message from EPCO 24 to EPCO 23: Please clarify the toxicological relevance of the metabolites THPI, THPI epoxide, 3 OH-THPI and 5 OH-THPI.

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	continued Open point 3.7: MSs to discuss in an expert meeting the residue definition for animal products. Open point relates to open point 1.16. (see reporting table 3(9))	observed in captan studies is attributed to the metabolites along with secondary effects of captan's irritation of the GI tract. The main animal residue is a collective of THPI-based molecules and do not confer toxicity that is considered toxicologically significant. None of these degradates or metabolites are judged candidates for inclusion in the residue expression. The definition of the residue in animal products is therefore captan alone. This conclusion is consistent with the conclusion of the RMS.	Oct. 05 Following results of the last toxicological evaluations (see the Addendum "definition of the residue" of July 2005) the residue definition for captan was changed going back to the parent compound alone, (residue definition for captan=captan). The new open point is therefore invalid.	
	New open point 3.15: RMS to go back to the available data set and make new evaluation of the available data so that the MRL proposals and the risk assessment can be done on the basis of the new residue definitions. The new calculations should be summarised in an addendum. This open point was proposed at EPCO 24.		Oct. 05 Following results of the last toxicological evaluations (see the Addendum "definition of the residue" of July 2005) the residue definition for captan was changed going back to the parent compound alone, (residue definition for captan=captan). The new open point is therefore invalid.	EPCO 24 (11.05. – 13.05.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): The required re-evaluation has been made in the addendum prepared by the EFSA Open point fulfilled.

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	Message from EPCO 24 to EPCO 23: Please clarify the toxicological relevance of the metabolites THPI, THPI epoxide, 3 OH-THPI and 5 OH-THPI.			Answer from EPCO 23: THPI is the first product of metabolism: LD50 > 2000mg/L THPAM is the second metabolite. It is an animal metabolite which will be covered by the ADI. Therefore no additional information is required. It shows negative genotoxicity. 3 OH-THPI and 5 OH-THPI (animal metabolites) show up in low amounts. They are hydrophilic. Nevertheless they are covered by the ADI as well. Information on THPI epoxide is not available.
	Open point 3.8: RMS to provide in an addendum informations in column 3 of comments 3(8) and 3(9) of the reporting table. (see reporting table 3(9))	Studies on the toxicity and biological activity of potential captan metabolites are summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/01, 02, 03. In addition a discussion paper by Gordon (2005) is summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/04. **Conclusion**: The discussion paper expands on the discussion of the toxicological significance of the degradates of captan and concludes in conformity with the JMPR (FAO/WHO 2000) and US-EPA, based on the DG SANCO Guideline for Metabolism and Distribution in Plants (European	For row crops THPI and THPAM represent only a minor part of the residue. Residues should be therefore expressed as captan alone. For processed commodities see point 3.6 For commodities of animal origin see point 3.7 New information provided by the MDS have been included into the addendum. RMS comments are reported under point IIA 6.7 (proposed residue	EPCO 24 (11.05. – 13.05.2005): RMS provided the information in an addendum. Open point fulfilled.

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	continued Open point 3.8: RMS to provide in an addendum informations in column 3 of comments 3(8) and 3(9) of the reporting table. (see reporting table 3(9))	Commission 1997) that the metabolites present a significantly lower hazard to man than captan, evidenced by the complete lack of systemic toxicity observed in the captan long term and subchronic toxicity studies. In addition, direct comparisons of captan and THPI aquatic toxicity further reinforces the differences due primarily to its mode of action as a primary irritant. Key to resolving the differences in toxicity between captan, THPI and other systemically circulating THPI-metabolites is the exceptionally rapid degradation of captan in the presence of blood. As such, all systemic toxicity observed in captan studies is attributed to the metabolites along with secondary effects of captan's irritation of the GI tract. The main animal residue is a collective of THPI-based molecules and do not confer toxicity that is considered toxicologically significant. None of these degradates or metabolites are judged candidates for inclusion in the residue expression. The definition of the residue in animal products is therefore captan alone. This conclusion is consistent with the conclusion of the RMS.	definition) of the addendum.	

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 3.9: MSs to discuss the reliability of the residue of 8.0 mg/kg in pome fruits in an expert meeting. (see reporting table 3(11))	The results of a two year EU co-ordinated programme of monitoring in all countries of the European Union plus Norway, Iceland and Lichtenstein in 2001 and 2002 for residues of captan in apples and pears are presented in the new addendum under Point IIA 6.3/24 and 6.3/25. **Conclusion:** Monitoring data show that residues of captan were non-detectable in the majority of samples of apples and pears. 99.97% of the total number of samples contained residues at or below the proposed MRL of 5 mg/kg. The monitoring results confirm that the result of 8 mg/kg from one trial in Italy is out of step with all other residue values in apples and pears in north and south EU. This conclusion is consistent with the conclusion of the RMS which states that the value of 8.0 mg/kg recorded in one supervised residue trial is an outlier.	The 8.0 mg/kg residue on apple was considered an outlier according to EU regulations (EC document 7039/VI/95 EN, Appendix I, 4.1 Elimination of outlier). New evidences provided by the MDS (point IIA, residue trials, pome fruit) support this conclusion since the 99.97% of the samples from a two year EU co-ordinated programme of monitoring contained captan residues at or below 5 mg/kg. This position is open to discussion.	EPCO 24 (11.05. – 13.05.2005): The experts are of the opinion the value 8 mg/kg can not be considered an outlier. This leads to the MRL proposal of 10 mg/kg in pome fruits. Open point fulfilled.
3.4	Clarification of the results of the McKay study on storage stability, providing stability data for captan and THPI separately . If not available new experimental data are required. (see reporting table 3(16))	Results of full study are summarised in new addendum under Point IIA 6.3/01. **Conclusion:** The critical residues data used to propose MRLs for apple and tomato was based on samples from residue trials which had been stored in the freezer prior to analysis. Apple samples were stored for up to 11 months and tomatoes were stored for	New evidences provided by the MDS seem to confirm storage stability of captan in the crops investigated. The data are summarized in the addendum (point IIA 6.3, stability of residues during storage of samples). Oct. 05	EPCO 24 (11.05. – 13.05.2005): Data requirement fulfilled. RMS to amend the list of end points. See new open point 3.16.

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3.4	*continued* Clarification of the results of the McKay study on storage stability, providing stability data for captan and THPI separately . If not available new experimental data are required. (see reporting table 3(16))	up to 5 months. Freezer storage stability data have demonstrated that residues of captan are stable when stored for at least 14 months in apple fruit and for at least 9.5 months in tomato fruit. Therefore, all the trials in apple and tomato are validated by the freezer storage data. Freezer storage stability data have demonstrated that residues of captan are stable when stored for 15 months in apple juice, 9.5 months in apple sauce (puree), 9.5 months in apple pomace (based on extrapolation from data on grape and tomato pomace), for 9/9.5 months in tomato pomace and tomato sauce (ketchup) and for 15 months in tomato juice (based on extrapolation from data on apple juice). All commodities were stored for less than the maximum period tested in all the available storage studies except for apple sauce in study 6.5.2/04 and 6.5.2/05 and apple pomace in study 6.5.2/05. No degradation is expected to have occurred during storage and the processing studies in apple and tomato are validated by the freezer storage data. The residue data for peaches/ nectarines are validated by storage data already summarised in the DAR.	New open point 3.16 invalid. List of end point amended. Data requirement fulfilled	

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	Open point 3.10: RMS to provide an addendum with summary table of the processing studies where THPI data are included to be discussed in an expert meeting. (see reporting table 3(20))	The definition of the residue in plants including processed commodities is captan alone. See response to open point 3.6, 3.7 and 3.8. Studies on the toxicity and biological activity of potential captan metabolites are summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/01, 02, 03. In addition a discussion paper by Gordon (2005) is summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/04. Therefore, THPI data from processing studies are not relevant.	Data are presently not available. They have been requested to the MDS and, if provided, will be presented and discussed during the next expert meeting.	EPCO 24 (11.05. – 13.05.2005): Relevant information was tabled at the meeting. Open point fulfilled.
	Open point 3.11: RMS to discuss on how the risk assessment specifically for processed commodities is to be carried out in an expert meeting. (see reporting table 3(20a))	The definition of the residue in plants including processed commodities is captan alone. See response to open point 3.6, 3.7 and 3.8. Studies on the toxicity and biological activity of potential captan metabolites are summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/01, 02, 03. In addition a discussion paper by Gordon (2005) is summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/04. Therefore, THPI data from processing	See replay to open point 3.6	EPCO 24 (11.05. – 13.05.2005): Discussion not needed due to the new residue definition. Open point fulfilled.

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	continued Open point 3.11: RMS to discuss on how the risk assessment specifically for processed commodities is to be carried out in an expert meeting. (see reporting table 3(20a))	studies are not relevant.		
	Open point 3.12: RMS to amend the list of end points for apple pasteurized juice and apple puree by mentioning TF < 0.05 rather than as an accurate figure. (see reporting table 3(21))		List of end points amended.	EPCO 24 (11.05. – 13.05.2005): RMS amended the list of end points. Open point fulfilled.
	Open point 3.13: RMS to include calculations of the potential exposure of animals by consumption of apple pomace in an addendum to be considered in expert meeting. (see reporting table 3(30))	Calculations of the potential exposure of animals by consumption of apple pomace are presented in new addendum under Annex Point IIA, 6.4 **Conclusion:** In metabolism studies in goats, captan was administered at a dietary concentration of 50 mg/kg for seven days and only 1-2% of the administered radioactivity was detected in animal tissues and milk; no parent captan was found in milk and tissues. The dietary concentration in the study was approximately 7 times the worst-	Calculation of the potential exposure of animals by consumption of apple pomace has been included in the addendum (point IIA 6.4). Oct. 05 Calculations considering an MRL of 10 mg/kg for apple are provided in the addendum. Open point fulfilled	EPCO 24 (11.05. – 13.05.2005): Due to the new MRL of 10 mg/kg for apple this point remains open since the current calculations base on a MRL of 5 mg/kg for apple. Open point still open. Evaluation Meeting (06.-09.02.2006): This topic is covered by the addendum prepared by EFSA

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	continued Open point 3.13: RMS to include calculations of the potential exposure of animals by consumption of apple pomace in an addendum to be considered in expert meeting. (see reporting table 3(30))	case dietary burden (based on the MRL) and 26 times the realistic dietary burden (based on the STMR) for beef cattle, and approximately 21 times the worst-case dietary burden (based on the MRL) and 81 times the realistic dietary burden (based on the STMR) for dairy cattle. Therefore, no residues in excess of the LOQ for captan in milk and bovine tissues are expected and a feeding study in ruminants is not required.		Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 3.14: RMS to include acute intake calculation in an addendum to be considered in an expert meeting. (see reporting table 3(38))	The notifier contends that an ARfD is not applicable for captan. The arguments supporting this contention are presented in the paper by Gordon and Kinzell (2004) summarised in the new addendum under Point IIA, 5.10/01, supported by Moore and Creasey (2004) summarised in the new addendum under Point IIA, 5.8.2/06. Note: Moore and Creasey (2004) is a study on folpet but is directly applicable to captan.	Acute intake calculation has been included in the addendum (Point IIA, 6.9). Using the UK model for the determination of the acute intake, the ARfD is exceeded in toddler by the 237 % for apples, 319% for pears, 118% for peaches and 158% for nectarines. Conclusions are open to discussion. Oct. 05 Calculations according to the latest formula are provided in the addendum. Using the UK and German models for the determination of the acute intake, the ARfD is exceeded in toddler and in children for apples, pears, and peaches/nectarines (respectively 357%, 485% and 226% in toddler by the UK model and 477%, 525% and 201% in children by the German model). Open point fulfilled However, the notifier has presented a position paper with alternative calculations based on different assumptions, showing the safe use of captan for all the crops. These alternative calculations are also reported in the addendum. These results are not acceptable for the	EPCO 24 (11.05. – 13.05.2005): Recalculations according to the latest formula is necessary. Open point still open. Evaluation Meeting (06.-09.02.2006): This has been made in the addendum prepared by EFSA Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
			current EFSA rules	
	New open point 3.16: RMS to revise the list of end points according the amendments proposed by EPCO 24.		Oct. 05 Following results of the last toxicological evaluations (see the Addendum “definition of the residue” of July 2005) the residue definition for captan was changed going back to the parent compound alone, (residue definition for captan=captan). The new open point is therefore invalid.	EPCO 24 (11.05. – 13.05.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.

4. **Environmental fate and behaviour**

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Section 4 Data requirements: ***19*** Open points: ***18***			Section 4 Data requirements: ***1*** Open points: ***1*** Data gaps: ***1***
	Open point 4.1: RMS to update list of end points with respect to PEC gw. (see reporting table 4(2))	The new report: *Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater scenarios* has been made available to the RMS.	list of end point updated Oct. 05 list of endpoints amended.	EPCO 21 (11. – 14.04.2005): Open point fulfilled. The experts agreed to set a new open point (see new open point 4.21): RMS to amend list of endpoints and include names of FOCUS scenarios.
	Open point 4.2: RMS to amend the list of end points. For PEC soil method of calculation it is sufficient to indicate that first order kinetic was assumed. (see reporting table 4(5)9		list of end point updated	EPCO 21 (11. – 14.04.2005): Open point fulfilled. The experts agreed to set a new open point 4.19: RMS to clarify the inconsistency in the list of endpoints between sections PECsoil and route of degradation concerning the DT50 of metabolite THPAM

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	New open point: 4.19: RMS to clarify the inconsistency in the list of endpoints between sections PECsoil and route of degradation concerning the DT50 of metabolite THPAM. This open point was proposed at EPCO 21.		Oct. 05 Inconsistency clarified, list of endpoints amended.	EPCO 21 (11. – 14.04.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.
	Open point 4.3: RMS to amend the list of end points to include individual values of DT_{50} with the mean. (see reporting table 4(7))		list of end point updated Oct. 05 list of endpoints amended.	EPCO 21 (11. – 14.04.2005): Open point fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points, to include the individual values as the THPAM degradation is pH-dependent and also to remove the means.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 4.4: RMS to amend list of end points to include individual values for sorption Koc together with the mean and to clearly indicate the pH dependence on the adsorption of THPAM. (see reporting table 4(8))		list of end point updated Oct. 05 list of endpoints amended.	EPCO 21 (11. – 14.04.2005): Open point fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points to add individual Koc values and to remove the mean K_{oc}.
	Open point 4.5: PEC sed for THPI should be included in the list of end points. (see reporting table 4(9))	The new report: *Terry, A. (2005). Predicted Environmental Concentrations of THPI and THPAM in surface water and sediment arising from spray drift, in the European Union*, has been made available to the RMS.	list of end point updated	EPCO 21 (11. – 14.04.2005): Open point fulfilled.
	Open point 4.6: RMS to report main hydrolysis products in the end points list. (see reporting table 4(13))		list of end point updated Oct. 05 list of endpoints amended.	EPCO 21 (11. – 14.04.2005): Open point fulfilled. The experts agreed to set a new open point (see new open point 4.21): RMS to include percentages of formation of the main hydrolysis products in the list of endpoints.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 4.7: RMS to report the max. amounts of metabolites in water and in sediment and DT_{50} if available. (see reporting table 4(14))		Reported Oct. 05 list of endpoints amended.	EPCO 21 (11. – 14.04.2005): Open point fulfilled. The experts agreed to set a new open point (see new open point 4.21): RMS to amend the list of end points and to include available DT50 of the metabolites for the water phase and the total system.
	Open point 4.8: RMS to include input parameters of the FOCUS PEC gw calculations in the end points list. (see reporting table 4(15))	The new report: *Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater scenarios* has been made available to the RMS. This contains the input parameters for use in FOCUS PEC gw modelling.	list of end point updated	EPCO 21 (11. – 14.04.2005): Open point fulfilled.
4.1	Two new laboratory aerobic soil degradation studies. These studies should cover the ranges of pH 4.5 to 5 and pH 8. Metabolites THCY and THPAI should be addressed as well with separate studies if necessary. (see reporting table 4(16))	See new report: '*Terry, A. and Price, O. (2005). Fate of captan in soil under aerobic conditions: A Review*. Results in the field dissipation studies clearly establish that captan degrades very rapidly in soils of all pH values. Additional laboratory studies are, therefore, not required. THCY only occurs under anaerobic conditions, which are not relevant for the use of captan. THPAI is a minor soil metabolite reaching only 3.19% of	agrees that the available data are sufficient to characterise the fate and behaviour of captan (and its metabolites) in soil. Additional data are not necessary. Oct. 05 list of endpoints amended, but anaerobic DT50 values not calculable (note that anaerobic conditions not relevant for captan GAPs).	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to include in the list of end points the percentage of metabolites formed under aerobic conditions as well as the results of the anaerobic soil degradation study (formation of metabolites, DT50).

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
4.1	*continued* Two new laboratory aerobic soil degradation studies. These studies should cover the ranges of pH 4.5 to 5 and pH 8. Metabolites THCY and THPAI should be addressed as well with separate studies if necessary. (see reporting table 4(16))	applied under aerobic conditions. Further laboratory studies on THCY and THPAI are not required.		
4.2	Adequate kinetic analysis of degradation data should be provided for the soil degradation studies (kinetic model employed, goodness of fitting). (see reporting table 4(16))	Re-calculation of DT50 values has been conducted and reported (together with goodness of fit) in new report: '*Terry, A. and Price, O. (2005). Fate of captan in soil under aerobic conditions: A Review*.	See comment 4.3	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled.
4.3	Relevance of field USA study with respect to EU conditions should be assessed. (see reporting table 4(16))	The relevance of the USA field studies has been examined and reported in new report: '*Terry, A. and Price, O. (2005). Fate of captan in soil under aerobic conditions: A Review*. 5 of the 6 studies were found to be conducted under climatic conditions with relevance to the EU.	The new report submitted show the field dissipation studies conducted in the USA were very useful for confirming the fate of captan in soil. It should be noted that the undertaking of field studies is not triggered by the laboratory degradation studies for captan nor for the major soil metabolites (DT_{50} <60 days). Hence, field studies are not strictly necessary for the risk assessment process.	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
4.3	*continued* Relevance of field USA study with respect to EU conditions should be assessed. (see reporting table 4(16))		However, the Notifier has re-calculated the DT_{50} values for captan and THPI and analysed for correspondence of climatic conditions at the field locations with locations in the EU. Five of the six field studies were conducted under conditions similar to those at locations in the EU, with one corresponding to a location in Northern Europe (the study conducted at Waterloo, New York corresponding to conditions in Helsinki, Finland). The Notifier has proposed that the captan DT_{50} derived from this site (7.04 days) be selected for use in PEC_{soil} calculation. The RMS considers this approach to be conservative and appropriate.	
4.4	DT_{50} values estimated in the laboratory studies for the metabolites THPI and THPAM using first order kinetics should be provided for modelling purposes. (see reporting table 4(21))	Re-calculation of DT50 values has been conducted and reported (together with goodness of fit) in new report: '*Terry, A. and Price, O. (2005). Fate of captan in soil under aerobic conditions: A Review*.	See comment 4.3	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. See also data requirement 4.2

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4.5	Notifier to provide clarification on deviations of the anaerobic degradation studies(Lay (1992) and Pack et al. (1988b)). (see reporting table 4(28))	Captan is only used in the spring and summer and not in the autumn and winter. In addition, captan and its major soil metabolites degrade with laboratory DT50 values of between 0.4 and 14 days. Therefore, it is very unlikely that significant amounts of these substances will be present in soil during times when anaerobic conditions might be experienced (autumn/winter) following use according to the GAP. Therefore, the anaerobic degradation studies are not required for risk assessment purposes.	we agree	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. See also open point 4.9.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 4.9: RMS to assess if the anaerobic degradation studies (Lay (1992) and Pack et al. (1988b) are acceptable and essential for the risk assessement. If anaerobic studies are finally considered not acceptable and not essential this information should be removed from the end points list. (see reporting table 4(28) and 4(29)	Captan is only used in the spring and summer and not in the autumn and winter. In addition, captan and its major soil metabolites degrade with laboratory DT50 values of between 0.4 and 14 days. Therefore, it is very unlikely that significant amounts of these substances will be present in soil during times when anaerobic conditions might be experienced (autumn/winter) following use according to the GAP. Therefore, the anaerobic degradation studies are not required for risk assessment purposes.	see point 4.5 not Oct. 05 list of endpoints amended.	EPCO 21 (11. – 14.04.2005): Open point fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points and include data on anaerobic degradation. See also data requirement 4.5
4.6	Literature data and references to support Captan Koc must be provided and assessed. (see reporting table 4(41))	Reference: Wauchope, R.D., Butler, T.M, Hornsby, A.G., Augustijn-Beckers, P.W.M. and Burt, J.P. (1992). 'The SCS/ARC/CES pesticide properties database for environmental decision making' Rev Environ. Contam. & Toxicol., vol 123 pp. 1 – 157, has been made available to the RMS for assessment.	The literature was provided and assessed. The selected value is acceptable	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. Mean Koc = 110.66 mL / g from literature data (see D.R 4.15) The experts agreed to set a new open point 4.20: RMS to amend the list of end points with regard to K_{OC} values for captan. The selected values from open literature should not comprise data from personal communications.

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	New open point 4.20: RMS to amend the list of end points with regard to K_{OC} values for captan. The selected values from open literature should not comprise data from personal communications. This open point results from data requirement 4.6 and was proposed at EPCO 21.		Oct. 05 list of endpoints amended.	EPCO 21 (11. – 14.04.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point still open for formal reasons, because the original literature data have still not been independently assessed as originally requested in data requirement 4.6. What was provided and assessed was only a review paper summarising the available published papers.
	Open point 4.10: RMS to consider relevance of leaching studies with respect to soil degradation. Also to consider if a reliable Koc may be obtained from column leaching studies. (see reporting table 4(46))	A new evaluation of the hydrolysis, soil degradation and field dissipation studies for captan and its major soil metabolites has been conducted and is reported in the new report: '*Terry, A. and Price, O. (2005). Fate of captan in soil under aerobic conditions: A Review*. The fate and behaviour of captan in soil is clear and has been derived from studies designed to investigate the fate in soil of captan, including the generation of representative DT50 values. The aged column leaching study was designed to investigate the leaching potential of captan degradation products rather than the rate of degradation of captan; and the incubation of captan in soil would have been carried out in a way that would	The Notifier has submitted a new appropriate report . See the NOT comment	EPCO 21 (11. – 14.04.2005): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	continued Open point 4.10: RMS to consider relevance of leaching studies with respect to soil degradation. Also to consider if a reliable Koc may be obtained from column leaching studies. (see reporting table 4(46))	have allowed the best opportunity to arrive at a mixture of all captan soil metabolites so that their leaching characteristics could be examined. Given the results of the other studies designed to measure captan degradation it is more reasonable to assume that the DT50 derived from the aged column leaching study is atypical. It would not be appropriate to include this DT50 for risk assessment purposes. It is clear that as soon as the aged soil was added onto the column and leaching started that the captan present in the soil degraded very rapidly. It is therefore very unlikely that a column leaching study with captan would allow any conclusions to be drawn with respect to captan's intrinsic adsorption/desorption to soil.		

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	Open point 4.11: RMS to clarify on the information available on the degradation of anaerobic metabolite THCY under aerobic conditions. (see reporting table 4(30) and 4(48))	Captan is only used in the spring and summer and not in the autumn and winter. In addition, captan and its major soil metabolites degrade with laboratory DT50 values of between 0.4 and 14 days. Therefore, it is very unlikely that significant amounts of these substances will be present in soil during times when anaerobic conditions might be experienced (autumn/winter) following use according to the GAP. Therefore, the aerobic fate of the anaerobic metabolite THCY is not relevant.	Agree Oct. 05 list of endpoints amended.	EPCO 21 (11. – 14.04.2005): Open point fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points. Aerobic data (Pack 1979) for anaerobic metabolite THCY should be included in the list of endpoints.
	Open point 4.12: RMS to clarify which DT_{50} are relevant ofr the risk assessment of metabolite THPI. (see reporting table 4(49))	A new evaluation of the hydrolysis, soil degradation and field dissipation studies for captan and its major soil metabolites has been conducted and is reported in the new report: '*Terry, A. and Price, O. (2005). Fate of captan in soil under aerobic conditions: A Review*. This includes clarification of the DT50 values relevant for the risk assessment of THPI.	See comment 4.3	EPCO 21 (11. – 14.04.2005): Open point fulfilled.

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4.7	Report Verharr, H.J.M. (1999) "Relevance and leaching behaviour of THPI and THPAM, two degradation products of captan" must be provided and assessed by the RMS in an addendum. (see reporting table 4(50))	This has been provided to the RMS. However, since the availability of the new report: '*Terry, A. and Price, O. (2005). Fate of captan in soil under aerobic conditions: A Review*, the *Verharr* report is no longer relevant for the risk assessment process.	agree	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled.
4.8	New PEC soil with worst case field DT_{50} should be calculated in the lack of more reliable data (see data requirements 4.1, 4.2 and 4.3 (in comment 4(16) of the reporting table)). (see reporting table 4(55))	A new report: *Terry, A. (2005). Predicted environmental concentrations of captan and its major degradation products in soil in the European Union*, has been made available to the RMS.	The Notifier has submitted a new report in which appropriate PEC_{soil} values have been calculated according to the revised DT_{50} values.	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled.
4.9	New initial PEC sw, taking into account multiple applications must be provided for metabolites THPI and THPAM. (see reporting table 4(60))	A new report: *Terry, A. (2005). Predicted Environmental Concentrations of THPI and THPAM in surface water and sediment arising from spray drift, in the European Union*, has been provided to the RMS.	The Notifier has submitted a new report in which appropriate $PEC_{sw\ sed}$ values of THPI and THPAM have been calculated Oct. 05 list of endpoints amended	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to include an explanation with regard to the derivation of the DT50 values for the metabolites in water used for PEC_{SW} calculations in the list of endpoints.

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4.10	Notifier to calculate the hydrolysis rate from the ring labelled captan (Lee, K.S. 1989b.) (see reporting table 4(62))	The requested values were, in fact, reported in the study but, by oversight, were not included in the DAR. The calculated hydrolysis DT_{50} values were determined to be 11.7 hours, 4.7 hours and 8.1 minutes at pH values of 5, 7 and 9 respectively.		EPCO 21 (11. – 14.04.2005): Data requirement fulfilled.
4.11	Hydrolysis of metabolites THPI, THPC and THPAM should be provided according EEC guidelines. Metabolites should be reported. (see reporting table 4(64))	The hydrolysis studies conducted with THPI and THPAM were reasonable and sufficient to derive the rate of hydrolysis of these two metabolites at 25°C, as the rate constants for the hydrolyses had been determined at three temperatures allowing appropriate extrapolation to 25°C. Only THPI, THPAM and THPC were detected above 10% in the parent hydrolysis study. Therefore, although it is agreed that the rate of degradation of these metabolites should be provided, it is not considered necessary that the nature of their transformation products be determined. The rate of transformation of THPC can be calculated from the parent study using a multicompartment modelling package (new report: *Terry, A. (2005). Kinetic analysis of the degradation of THPC generated in hydrolysis studies on captan at pH9*). This demonstrates that THPC is a very transient intermediate with a calculated DT50 of 15.7 minutes	we agree	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled.

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4.11	*continued* Hydrolysis of metabolites THPI, THPC and THPAM should be provided according EEC guidelines. Metabolites should be reported. (see reporting table 4(64))	under conditions where it was most stable (high pH). Further studies with THPC would not be justified		
4.12	Nofitier to provide readily biodegradability test. (see reporting table 4(66))	Given the very rapid hydrolysis of captan at all pH values it is very likely that it would hydrolyse very rapidly in a ready biodegradability study. Therefore, there is no new information to be gained from conducting a ready biodegradability study with captan.	Agree	EPCO 21 (11. – 14.04.2005): Data requirement not fulfilled Data requirement removed. The active substance should be regarded as not readily biodegradable.
4.13	Notifier to provide calculation of DT_{50} value of the metabolite THPI in the water sediment system. (see reporting table 4(69))	This value has been calculated and is reported in the new report *Terry, A. (2005). Predicted Environmental Concentrations of THPI and THPAM in surface water and sediment arising from spray drift, in the European Union*.	The Notifier has submitted a new report in which appropriate values have been calculated	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled.

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	Open point ~~4.12~~ 4.18: Due to the lack of water sediment study at alkaline pH, a worst case assessment may be performed for alkaline conditions using results of hydrolysis study to make the risk assessment for surface water contamination by metabolite THPC. (see reporting table 4(70)) (Numbering of open point has been corrected. Reference in addendum vol3 B8 has also been amended accordingly)	The water/sediment studies were conducted at ALKALINE pH. Given that THPC was formed/detected at neutral to alkaline pH values in the hydrolysis studies it follows that IF THPC was a significant transformation product in natural water systems then it would have been detected in the water/sediment studies. It is, though, not surprising that THPC does not feature in the water/sediment studies because it was a very transient intermediate even at pH9 (calculated DT50 maximum of 15.7 minutes; new report: *Terry, A. (2005). Kinetic analysis of the degradation of THPC generated in hydrolysis studies on captan at pH9*) under sterile conditions. Therefore, THPC is not relevant for the risk assessment process.	agree	EPCO 21 (11. – 14.04.2005): Open point fulfilled.
4.14	PEC sed for metabolites THPI and THPAI must be provided. (see reporting table 4(78))	A new report: *Terry, A. (2005). Predicted Environmental Concentrations of THPI and THPAM in surface water and sediment arising from spray drift, in the European Union*, has been provided to the RMS.	The Notifier has submitted a new report in which appropriate PEC values have been calculated Oct. 05 RMS : Calculations provided by Notifier (see addendum, September 2005) and list of endpoints amended.	EPCO 21 (11. – 14.04.2005): Data requirement still open. PEC values for THPAI to be provided and PEC sediment to be recalculated with density of 1.3 g/mL. Evaluation Meeting (06.-09.02.2006): Data requirement fulfilled. Endpoints have been updated accordingly

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	Open point 4.13: RMS to assess relevance of ground water metabolite THPAM if enough data available or identify data gaps. (see reporting table 4(79))	New PEC groundwater calculations (new report: *Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater* scenarios) show that safe uses are indicated for captan in the EU. A study on pesticidal (fungicidal) activity of THPI and THPAM shows them to be non-relevant in this context.	Agree	EPCO 21 (11. – 14.04.2005): Open point covered by data requirement 4.15.
4.15	Notifier to provide new PEC GW modelling consistent with GAPs and reliable input parameters. Metabolites should be assessed according SANCO/221/2000-rev 10. (see reporting table 4(80))	The new report: *Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater scenarios* has been made available to the RMS. This contains the input parameters for use in FOCUS PEC gw modelling. For many scenarios PECgw values for captan and metabolites are <0.1 µg/L. Hence, 'safe uses' in the context of Annex 1 listing have been established. In addition, a study on pesticidal (fungicidal) activity of THPI and THPAM shows them to be non-relevant in this context.	Oct. 05 list of endpoints amended.	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. Relevance of metabolites in groundwater THPI and THPAM should be addressed by ecotox and toxiclogy meetings. It should be noted that for this use PEC_{GW} of the metabolites (THPI and THPAM) exceed the threshold of 0.75 µg/l.. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points and include correlation K_{OC} versus pH for metabolite THPAM.

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	Message from EPCO 21 to EPCO 22 and EPCO 23: Relevance of metabolites in groundwater THPI and THPAM should be addressed by ecotox and toxiclogy meetings. It should be noted that for this use PEC_{GW} of the metabolites (THPI and THPAM) exceed the threshold of 0.75 µg/l.			Answer from EPCO 22: The risk from the metabolites is acceptable.
	Open point 4.14: RMS to prepare new addendum with new information of potential groundwater contamination. (see reporting table 4(80))	The new report: *Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater scenarios* has been made available to the RMS.	The Notifier has submitted a new report in which appropriate values have been calculated	EPCO 21 (11. – 14.04.2005): Open point fulfilled. See open point 4.13

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	Open point 4.15: RMS to revise the residue definition in ground water. Monitoring analytical methods will need to be provided for the new metabolites if they will be added to the residue defintion. (see reporting table 4(81))	The PEC_{GW} calculations indicate that there are many use scenarios where captan, THPI and THPAM do not exceed 0.1 μg/L. Hence, 'safe uses' in the context of Annex 1 listing have been established. In those scenarios where THPI and THPAM do exceed 0.1 μg/L, the concentrations are not predicted to reach 10 μg/L. A study on pesticidal (fungicidal) activity of THPI and THPAM shows them to be non-relevant in this context. As such, it is proposed that the residue in groundwater should be considered to be captan only (although based on modelling captan is very unlikely to be found in groundwater).	The new report: *Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater scenarios* has been made available to the RMS. The PEC_{GW} calculations indicate that there are some use scenarios THPI and THPAM exceed 0.1 μg/L Where THPI and THPAM do exceed 0.1 μg/L, the concentrations are not predicted to reach 10 μg/L. A study on pesticidal (fungicidal) activity of THPI and THPAM shows them to be non-relevant in this context. Oct. 05 Not included in list of endpoints as THPI and THPAM have been determined to be non-relevant on the basis of lack of pesticidal activity.	EPCO 21 (11. – 14.04.2005): Open point still open. The experts agreed to set a new open point (see open point 4.21): RMS to include metabolites THPI and THPAM in the residue definition for groundwater in the list of endpoints. Evaluation Meeting (06.-09.02.2006): Open point still open as ecotoxicology and mammalian toxicology data gaps have been identified that need to be closed before a monitoring residue definition in groundwater can be finalised.

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4.16	PEC FOCUS sw taking into account run off and drainage must be provided. Input parameters should be clearly justified. (see reporting table 4(82))	It is not considered necessary to conduct FOCUS surface water evaluations for Annex 1 listing as when the dossier was submitted this was not a requirement. In addition, an assessment of risk to surface waters has been included in the DAR for run-off and for captan for spray drift. A new report: *Terry, A. (2005). Predicted Environmental Concentrations of THPI and THPAM in surface water and sediment arising from spray drift, in the European Union* has been submitted giving PECs for THPI and THPAM. Drainage is not an exposure route of relevance for captan as products are only used late spring/summer and soil DT50 values for captan and its metabolites are between 0.4 and 14 days, only. In any case, the growing of pome fruit, peaches/ nectarines, and tomatoes would not be expected on artificially drained soil.	Agree Oct. 05 RMS (September 2005): The Notifier has provided PECSW values for northern European use scenarios (see addendum, September 2005) and list of endpoints amended. Notifier has also provided an analysis based on FOCUS SW methodology (see addendum, September 2005) which demonstrated that runoff and drainage are not significant exposure routes for captan use in Northern Europe.	EPCO 21 (11. – 14.04.2005): Data requirement still open. For northern European use scenarios entry routes other than spray drift need to be addressed. The experts agreed to set a new open point (see open point 4.21): RMS to include PEC_{SW} for northern European use scenarios in the list of endpoints. Evaluation Meeting (06.-09.02.2006): Data requirement still open. Data are available but have not been independently assessed.

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4.17	Relevance of depleted thiophosgen in air should be assessed. An analytical method for monitoring thiophosgene may be needed if it is finally included in the residue definition in air. (see reporting table 4(87))	The amount of trichloromethyl –^{14}C captan derived radioactivity volatilised from the soil surface amounted to 0.4% per day averaged over the 9 day study. As a worst-case, on the first day the amount volatilised comprised < 1%. This would lead to negligible concentrations of thiophosgene in air, even assuming that all the material lost was thiophosgene, and therefore this metabolite need not be considered further.	agree	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. Message from EPCO 21 to EPCO 23 (tox section): It cannot be excluded that traces of thiophosgene occur in the air.
	Message from EPCO 21 to EPCO 23 (tox section): It cannot be excluded that traces of thiophosgene occur in the air.			
4.18	Rate of degradation in air must be provided. (see reporting table 4(88))	A new report: *Curl, M.G. (2004).The Estimation of Photochemical Oxidative Degradation of Captan*, has been made available to the RMS.	The Notifier has submitted a new report in which appropriate values have been calculated Oct. 05 list of endpoints amended.	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to add in the list of endpoints that the calculations are based on the average concentrations of hydroxyl radicals and ozone for a 12 h day.

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4.19	Report with the monitoring data should be provided and assessed in an addendum by RMS. (see reporting table 4(90))	A translation of this report has been provided to the RMS.		EPCO 21 (11. – 14.04.2005): Data requirement fulfilled.
	Open point 4.16: The request of a lysimeter study to be discussed in an expert meeting. (see reporting table 4(92))	A new FOCUS PELMO modelling exercise has been conducted (Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater scenarios) taking into account the pH variability of K_{OC} for THPAM (there is no pH sensitivity for captan and THPI K_{OC} values). This modelling demonstrates that significant safe usage for captan is predicted to exist in the EU (scenarios where PECgw <0.1 µg/l). As such, a lysimeter study is not needed for Annex 1 listing.	agree	EPCO 21 (11. – 14.04.2005): Open point fulfilled.

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	Open point 4.17: DT_{90} in water < 3 days needs to be confirmed in an expert meeting and to communicate to the experts of the phys-chem section. (see reporting table 4(93) and 1(65))	The rate of hydrolysis of captan was found to be extremely rapid in water at all pH values. The longest DT50 was at pH 5 (18.8 hours) which corresponds to a DT90 of 62 hours (2.6 days). Therefore, DT90 in water <3 days.	agree	EPCO 21 (11. – 14.04.2005): DT_{90} in water below three days is confirmed! Information was coummunicated to the experts of the phys-chem section. Open point fulfilled.
4.20	Notifier to assess soil photolysis metabolite THCY with regard to occurrence under field conditions and possibility of leaching into groundwater. This data gap was identified at EPCO 21.		Oct. 05 Notifier has provided arguments as to why THCY should not be considered as a photolysis metabolite. RMS accepts this (see addendum, September 2005).	EPCO 21 (11. – 14.04.2005): Data gap identified. Evaluation Meeting (06.-09.02.2006): Data gap still open.
	New open point 4.21: RMS to revise the list of end points according to the amendments proposed by EPCO 21.		Oct. 05 List of endpoints amended.	EPCO 21 (11. – 14.04.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.

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	Message EPCO 22 to EPCO 21: Argumentation of the Notifier on open point 5.17 is forwarded to EPCO 21.			EPCO 21 (11. – 14.04.2005): EPCO 21 is happy with the PEC soil values provided in the new list of end points.

5. Ecotoxicology

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	Section 5 Data requirements: ***2*** Open points: ***19***			Section 5 Data requirements: ***1*** Open points: ***4*** Data gaps: ***2***
	Open point 5.1: RMS to amend the list of endpoints regarding the toxicity values for bees. (see reporting table 5(1))		List of end points amended Oct. 05 Higher-than symbol has been deleted from list of endpoints.	EPCO 22 (11.04.-15.04.2005): Open point still open. RMS to amend the higher than symbol before the trigger value for bees in the list of endpoints. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.
	Open point 5.2: RMS to amend the list of endpoints regarding NTA (indicating exact effect percentages and study type). (see reporting table 5(2))		List of end points amended	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

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	Open point 5.3: RMS to amend the list of endpoints regarding the acute toxicity to earthworms. (see reporting table 5(4))		List of end points amended (values are reported both in original and corrected by dividing endpoint by 2)	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.4: RMS to amend the list of endpoints regarding the data on toxicity to aquatic organisms. (see reporting table 5(5))		List of end points amended (lowest endpoint for each aquatic group and metabolites were included)	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.5: RMS to amend the list of endpoints regarding the LC_{50} and NOEC for birds. (see reporting table 5(7))		List of end points amended Oct. 05 NOEL for bobwhite quail recalculated based on correct food intake of 17 g/day. List of endpoints amended. No effect on risk assessment as not the lowest endpoint.	EPCO 22 (11.04.-15.04.2005): Open point still open. RMS should verify the recalculation to daily dose of the NOEC for bobwhite quail. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 5.6: RMS is proposed to prepare an addendum with a revised risk assessment for birds and mammals according to SANCO/4145/2000. (see reporting table 5(10))	A risk assessment according to SANCO/4145/2000 has been provided to the RMS (*Ref: Norman and Wyness, 2003*). Addition comments from Member States have also been addressed (*ref: Norman, 2005, EU Review of captan: Notifier responses to various comments on ecotoxicology raised in the official Reporting Table*)	Endpoints for birds risk assessment were: >2000 mg/kg/bw (acute), > 800 mg /kg/bw/day (short term), 74.4 mg/kg/bw (long term). For mammals toxicity endpoints were: >2000 mg/kg bw/day (acute), 250 mg /kg bw/day (long term). Tier 1 risk assessment Acute and short term TERs were acceptable while the long term TERs for insectivorous birds (all uses) and small herbivorous mammals in South EU (pome, peaches/nectarines) were less than 5 indicating further refinement. Tier 1 short term TER for medium herbivorous bird was>5 but this scenario is unrealistic since the foliage of tomato plants is not attractive to birds. Tier 2 risk assessment. The following assumptions were used: for insectivorous birds RUD on insects was 5.1 mg/kg.; PT= 0.61 (based on blue tits behaviour in orchards) . For mammals the ecological relevant endpoint was 250 mg/kg bw (based on a rat multigeneration study); the PT value was set at 0.5 assuming that a field vole would get half of the diet with the grass growing under the trees which is reasonable and still conservative since the grass under the trees is often managed and its growth is restricted by shading.	EPCO 22 (11.04.-15.04.2005): Open point closed. New open point 5.20 set. Data gap 5.3 identified. Still to be discussed: MS experts have two weeks after the meeting to react on the long-term risk assessment. Especially comments on 100 mg a.s /kg bw are welcome. Post meeting EFSA Note: 8 participants to the meeting reacted after the meeting. The RMS remains with their original proposal for a NOEC of 250 mg as/kg bw. One expert proposed a NOEL of 40 mg as/kg bw. The other 6 experts reconfirmed the NOEC of 100 mg as/kg bw. New open point 5.21 set. Data gap 5.4 identified.

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	continued Open point 5.6: RMS is proposed to prepare an addendum with a revised risk assessment for birds and mammals according to SANCO/4145/2000. (see reporting table 5(10))		Under these assumptions all the calculated TERs are above the triggers. Captan is of low toxicity to birds and mammals and its degradation rate is rapid. TERs long term values are moreover based on no effect of the highest dose tested in reproduction studies, the risk to birds and mammals is considered acceptable.	
	New open point 5.20: RMS to recalculate the long term risk to birds with the default RUD value. See open point 5.6 This open point was proposed at EPCO 22.		Oct. 05 Notifier submitted recalculated TERs using default RUD. TERs range from 1.4 to 3.2, i.e. they are <5. Higher tier risk assessment has been submitted (Ref: Gerlach, 2005) based on published ecology information. Risk assessment evaluated in Addendum to DAR (Sept 2005) . Choice of key species (yellow wagtail for tomato; great tit for orchards) and refinements considered to be reasonable. Refined TERs range from 7.09 to 10.6, i.e. >5. Taking refined assessment together with fact that no effects in avian reproduction studies at highest treatment level of 1000 ppm, risk is considered to be acceptable.	EPCO 22 (11.04.-15.04.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point still open.

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5.3	Notifier to present an argumentation on the residue decline in insects. See open point 5.6. This data gap was identified at EPCO 22.		Oct. 05 Notifier has stated (ref: Norman, 2005) that no insect residues data available, as captan is of low toxicity to birds (acute, short term and repro.) . Based on generally, fast degradation in the environment (in soil and water, by hydrolysis) notifier predicts residues of captan on insects would decline relatively quickly. RMS agrees	EPCO 22 (11.04.-15.04.2005): Data gap identified. Evaluation Meeting (06.-09.02.2006): Data gap still open.
	New open point 5.21: Open point pending on the outcome of the relevance of insectivorous mammals in southern European orchards a risk has to be calculated. See open point 5.6 This open point was proposed at EPCO 22.		Oct. 05 Notifier states (ref: Norman, 2005) that this is a generic issue not only related to captan, and is outside current guidance (SANCO 4145/2000). Notifier provided long term TER based on shrew (as used in standard cereals scenario) which was >5. RMS concludes low risk.	EPCO 22 (11.04.-15.04.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point fulfilled,
5.4	Notifier to submit an argumentation on the PT assumption of 0.5 for the use in orchards. See open point 5.6. This data gap was identified at EPCO 22.		Oct. 05 RMS (September 2005): Notifier has submitted a statement (ref: Norman, 2005). Based on more attractive food sources outside treated area it is proposed that PT of 0.5 is justified, especially over long term. Notifier also states that in south EU orchards there is no ground vegetation in most cases	EPCO 22 (11.04.-15.04.2005): Data gap identified. Evaluation Meeting (06.-09.02.2006): Data gap still open.

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5.4	*continued* Notifier to submit an argumentation on the PT assumption of 0.5 for the use in orchards. See open point 5.6. This data gap was identified at EPCO 22.		(due to competition for water). RMS agrees PT of 0.5 is reasonable for north EU pome fruit, and that signficant exposure for south EU uses is unlikely. Hence, low long term risk to mammals for south EU uses. At EPCO 22, there was discussion on long term endpoint for mammals. Choice of endpoint needs to be finalised (either 250 or 100 mg/kg bw/d). Depending on endpoint ,TER for north EU pome fruit is either 7.7 or 3.1. TER of 7.7 indicates low risk. If TER is 3.1, due to conservative long term endpoint, RUD and FIR risk is considered to be acceptable.	
	Open point 5.7: MS to discuss the acceptability of the acute toxicity study to mallards in an expert meeting. (see reporting table 5(11))	The Notifier supports the statement from the RMS in the Reporting Table (5(11): Sept 04). This issue is not important for the risk assessment. Captan is clearly of low acute toxicity, as also shown in the study on bobwhite quail (LD50 >2000 mg/kg bw).	See RMS response in reporting table (5.11)	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

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	Open point 5.8: Pending on the outcome of the discussion on the PECsw and water sediment study in the section on Fate and behaviour, a revision of the aquatic risk assessment may be necessary. (see reporting table 5(21))	With respect to the sediment water fate study, a revision of the aquatic risk assessment is not required (please see Notifer comment on Open Point 4.12). PECsw values following multiple applications have been provided for THPAM and THPI (*ref: Terry, A. (2005). Predicted Environmental Concentrations of THPI and THPAM in surface water and sediment arising from spray drift, in the European Union*.). These can be used in the aquatic risk assessment.	See new risk assessment (addendum)	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.9: MS to discuss the aquatic risk assessment in an expert meeting taking into account the written comments from DE (29-10-2004). (see reporting table 5(22))	Responses to comments from DE have been provided (*ref: Norman, 2005, EU Review of captan: Notifier responses to various comments on ecotoxicology raised in the official Reporting Table*). It should be noted that two new static acute toxicity studies have been submitted on rainbow trout (Jenkins, 2004a) and stickleback (Jenkins, 2004b) which included chemical analysis of the test media. LC50 values in terms of mean measured initial concentrations were similar to those based on nominal concentrations for previous studies on the same species, using the same study design. Hence, this confirms the validity of the previous static acute toxicity studies on fish (6 species).	See new risk assessment (addendum)	EPCO 22 (11.04.-15.04.2005): See also open point 5.10 Open point closed.

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	Open point 5.10: RMS to prepare an addendum with a revised risk assessment to fish (based on the LC_{50} of 98 µg/L). (see reporting table 5(24))	Notifier agrees with use of the LC50 of 98 µg a.s./L for brown trout as the basis of the risk assessment. Six species of fish were tested, and the range of sensitivity is narrow. Hence, uncertainty over inter-species variation in sensitivity has been minimised (this approach was agreed at HARAP). Therefore, as agreed by RMS in their comment (Sept 04) and as supported by some other Member States (NL, UK) a TER trigger of 10 is appropriate.	See new risk assessment (addendum)	EPCO 22 (11.04.-15.04.2005): Open point closed. Open point for EFSA: To include the results of the opinion of the Scientific Panel in the conclusion. New open point 5.22 set.
	New open point 5.22: RMS to conduct the long-term risk assessment for aquatic organisms with proposal made by EFSA. See open point 5.10. This open point was proposed at EPCO 22.		Oct. 05 This has been undertaken (in Addendum, Sept 2005). TER >10: at 10 m (North EU pome fruit), at 15 m (S. EU pome fruit, nectarine/peach), and at 1 m (tomato).	EPCO 22 (11.04.-15.04.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point still open for formal reasons.

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	Open point 5.11: RMS to prepare an addendum to revise the endpoints for aquatic organisms (based on measured concentrations if appropriate) and revise the aquatic risk assessment if necessary. (see reporting table 5(29))	Validity of previous static acute tests on fish has been confirmed by two new acute studies with analysis of test media (please see comment on Open Point 5.9). Hence, risk assessment only requires revision in terms of choice of acute toxicity endpoint for fish (LC50 for brown trout).	The addendum include a new risk assessment based on the static acute LC50 for the most sensitive fish species (brown trout) of 98 µg a.s./l. Two new acute toxicity test on fish have been performed to confirm the results of previous tests were the concentrations of the a.s. during the test were not measured. The measured concentrations are in agreement with the nominal concentrations used in the previous test supported by measurement of the applied stock solution.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
5.1	Notifier to submit the composition of the tested formulations to proof their comparability to the lead formulations. (see reporting table 5(31))	Some ecotoxicology studies used an 83%w/w WP formulation. Formulation details have been supplied to the RMS in MCW confidential DOC J. The formulation is comparable to the 80 %w/w WG lead formulations. Where equivalent studies on the WG are not available, the WP results are relevant.	Agreed	EPCO 22 (11.04.-15.04.2005): Data requirement fulfilled. New open point 5.23: RMS to add the information to the confidential section of the DAR to be discussed at EPCO 25.

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	New open point 5.23: RMS to add the information to the confidential section of the DAR to be discussed at EPCO 25. See data requirement 5.1. This open point was proposed at EPCO 22.		Oct. 05 Information will be added to confidential section of DAR as requested.	EPCO 22 (11.04.-15.04.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point still open.
	Open point 5.12: RMS to prepare an addendum regarding the risk of the metabolite THPAI to sediment dwelling organisms (THPAI was not tested on aquatic invertebrates) to be discussed in an expert meeting. (see reporting table 5(32))	A full response has been provided by the Notifier (*ref: Norman, 2005, EU Review of captan: Notifier responses to various comments on ecotoxicology raised in the official Reporting Table*). In the sediment water fate study THPAI was only greater than 10% applied radioactivity in sediment (= 11.3%) on one sampling occasion. In addition, the sample extraction method was found to result in breakdown of THPAM to THPAI. Hence, the one detection at >10% was probably an artefact of the method. The focus of the assessment should be on acute risk to fish from captan itself.	RMS agrees with the notifier argumentation (see reporting table 5.32) that the low toxicity of THPI for invertebrates can be indirectly arguedby the results of the chronic semistatic toxicity study on Daphnia were the rapid hydrolysis of captan in water leads to the THPAI formation during the test. Moreover the structure of THPAI is similar to THPAM which has an EC50 of 220 mg/l in a 48 h test with Daphnia magna.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

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	Open point 5.13: RMS to prepare an addendum to revise the risk assessment for NTA (see reporting table 5(38))	A new risk assessment has been provided (*ref: Norman, 2004*) which is supported by two new extended laboratory studies on *Aphidius rhopalosiphi* and *Coccinella septempuntata*. Overall, a low risk is demonstrated.	The notifier has presented 2 new aged residue test studies on Aphidius rhopalosiphi and Coccinella septempunctata.. Studies were acceptable. Merpan 80 WDG applied at 6.75 kg s.a./ha on bean plants had no significant effect on survival and fecundity of Aphidius rhopalosiphi . Differences from control were less than Escort 2 trigger (50%). Following exposure to freshly dried or aged (14 days) bean leaves treated with Merpan 80WDG up to 6.75 kg s.a./ha Mortality and reproduction rate of Coccinella semipunctata was reduced less than 50 % from the controls.	EPCO 22 (11.04.-15.04.2005): Open point closed.
	Open point 5.14: MS to discuss the acceptability of the laboratory toxicity test with *T. pyri* in an expert meeting. (see reporting table 5(39))	Response has been provided by the Notifier (*ref: Norman, 2005*). In ESCORT 2 tier 1 risk assessment (glass plate tests), reproduction results are not relevant. Also, *T. pyri* is not the most sensitive species tested (this is *A. rhopalosiphi*). Field studies on *T. pyri* also show minimal effects.	Agreed	EPCO 22 (11.04.-15.04.2005): Open point closed.

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	Open point 5.15: RMS to amend the list of endpoints regarding the list of representative uses (spray interval should be included). (see reporting table 5(41))		Oct. 05 List of endpoints will be amended.	EPCO 22 (11.04.-15.04.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.
	Open point 5.16: Pending on the discussion of the PECs in the section on Fate and behaviour, a revision of the risk to earthworms may be necessary. (see reporting table 5(46))	Revised PECsoil values have been provided (*Terry, A. (2005). Predicted environmental concentrations of captan and its major degradation products in soil in the European Union*). These can be used in the risk assessment for earthworms. In addition, a justification on why the EPPO (2002) correction factor of 2 is not relevant for earthworm endpoints for captan has been submitted (*ref: Norman, 2005*). A low risk to earthworms can be demonstrated for all uses.		EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.17: RMS to prepare an addendum to revise the risk assessment for earthworms. (see reporting table 5(47))	Please refer to comment on Open Point 5.16.	A new risk assessment has been provided by the notifier (see addendum) based on PEC soil values calculated after the last application (70% foliar interception) . For North EU pome fruit TERs are above the trigger indicating an acceptable risk. For peaches and nectarines and South EU pome fruit the acute TERs values are higher than the trigger indicating a low risk while	EPCO 22 (11.04.-15.04.2005): Argumentation of the Notifier on open point 5.17 is forwarded to EPCO 21. Open point still open. Waiting for the answer from EPCO 21. Answer from EPCO 21:

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	continued Open point 5.17: RMS to prepare an addendum to revise the risk assessment for earthworms. (see reporting table 5(47))		this is not true for the long term risk which requires a refinement. Notifier propose not to use e correction factor of 2 as indicated by the Guidance document based on the rapid hydrolysis of captan during the test (DT50 and DT90 < 1day) to give degradation products which have not a strong affinity for organic matter. RMS thinks this reasoning is acceptable. This brings the long term TERs to acceptable levels.	EPCO 21 is happy with the PEC soil values provided in the new list of end points. Evaluation Meeting (06.-09.02.2006): Open point still open.
5.2	Notifier to address the risk to other non-target fauna and flora. (see reporting table 5(54))	No data are available. Captan is not a herbicide, and there are no indications of phytotoxicity from its actual use. Hence, additional data are not needed.	Oct. 05 RMS (September 2005): Notifier has provided a study on effects on non-target plants (Kay, 2000). There were no effects in the study (at 3.6 – 7.2 times the field rate). Study is evaluated in DAR Addendum (Sept 2005) and is acceptable. There is low risk to non-target plants	EPCO 22 (11.04.-15.04.2005): Data requirement still open. Evaluation Meeting (06.-09.02.2006): Data requirement still open.
	Open point 5.18: Pending on the discussion of the PECgw values in the section on Fate and behaviour, data on pesticidal activity of the major ground water metabolites may be necessary (see reporting table 5(54))	A new groundwater modelling report has been provided (*Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater scenarios*). Some scenarios give PECgw values >0.1 µg/l for THPI and THPAM. However, clear 'safe use' scenarios with PECgw <0.1	Two studies have been submitted on the fungicidal activity of THPI and THPAM . THPAM showed no effect on Botrytis cinerea (grey mold) or Venturia inaequalis (apple scab) for conidial germination or mycelial growth. THPI showed no effect on Venturia for either endpoints. THPI at 100 mg/l decreased by 35% the mycelial growth of Botrytis cinerea inomparison with a	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

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	continued Open point 5.18: Pending on the discussion of the PECgw values in the section on Fate and behaviour, data on pesticidal activity of the major ground water metabolites may be necessary (see reporting table 5(54))	µg/l have been demonstrated. Therefore, Annex 1 listing can be recommended. In addition, a study on the pesticidal (fungicidal) activity of THPI and THPAM has now been submitted. This study shows the metabolites to be non-relevant in this context.	100% reduction for captan at 25 mg/l. I t can be concluded that the activity of the metabolites is less than 50% of the parent molecule and therefore not relevant.	
	Open point 5.19: MS to discuss the need for further data to address the risk to sewage treatment in an expert meeting. (see reporting table 5(56))	Captan is rapidly hydrolysed. In addition, its use as an agricultural fungicide would not lead to contamination of the domestic drainage system. Hence, it is very unlikely to reach sewage treatment plants. Therefore, data are not needed.		EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

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	Message from EPCO 21 to EPCO 22 and EPCO 23: Relevance of metabolites in groundwater THPI and THPAM should be addressed by ecotox and toxiclogy meetings. It should be noted that for this use PEC_{GW} of the metabolites (THPI and THPAM) exceed the threshold of 0.75 µg/l.			EPCO 22 (11.04.-15.04.2005): The risk from the metabolites is acceptable.
	Message from EPCO 25 to experts of the toxicology and ecotoxicology section: From the analytical point of view the technical materials cannot be regarded as equivalent.			Evaluation Meeting (06.-09.02.2006): A disclamer will be added to the conclusion that the ecotoxicological risk assessment was based on the assumption that the technical materials used in the tests are equivalent.
	Message from EPCO 25 to experts of the toxicology and ecotoxicology section: To confirm the proposed max value for Folpet of 10 g/kg as a relevant impurity.			Evaluation Meeting (06.-09.02.2006): addressed

List of representative uses evaluated

Summary of representative uses evaluated (active substance)*

Crop	Member state or country	Product name	F, G or I	Pests or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
					Type	Conc. of a.s.	method kind	growth stage/ timing	number [b] (max.)	kg a.s./hL (max.)	water L/ha	kg a.s./ha (max.)		
Pome fruit	North EU	'Merpan' 80 WDG / 'Malvin' WG	F[a]	Scab and *Nectria*	WG	800 g/kg	Airblast foliar spray; upwards/ sideways	From BBCH 53 / April	9 - 10	0.125	1000	1.25	14	
	South EU	'Merpan' 80 WDG / 'Malvin' WG	F	Scab and *Nectria*	WG	800 g/kg	Airblast foliar spray; upwards/ sideways	From BBCH 69 / April	9 + 3 [c]	0.125 0.24	1000 1000	1.25 2.4	14	
Tomatoes	South EU	'Merpan' 80 WDG / 'Malvin' WG	F	Various diseases	WG	800 g/kg	Foliar spray; down-wards	From BBCH 60 to 87	4	0.15	1200	1.8	14	
Peaches/ nectarines	South EU	'Merpan' 80 WDG / 'Malvin' WG	F	Various diseases	WG	800 g/kg	Airblast foliar spray; upwards/ sideways	From BBCH 69: petal fall	4	0.25	1000	2.5	7	

[a] F = field.
[b] Applications at a minimum of 7 days for all crops.
[c] Nine applications at 1.25 kg a.s./ha (scab control) followed by three applications at 2.4 kg a.s/ha (*Nectria* control).

* Uses for which the risk assessment can not be concluded are marked grey.