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

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(1)	General comment	Aug 04 EFSA: Methods which do not meet the requirements should not be listed in the corresponding chapter "references relied on", because it is not possible to rely on these unacceptable methods.	Sept04 RMS: Noted	Addressed
1(2)	Vol. 1, Appendix 3, listing of endpoints, Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured:	Aug 04 ES: The [redacted] is stated as relevant impurity, which [redacted] please a clarification is needed	Sept04 RMS: Confirmation will be provided.	Open point RMS to clarifiy the discrimination between captan [redacted] See also comments 1(4), 1(24) and 1(73). Evaluation Meeting (14.-15.12.2004): Open point confirmed. In addition, notifiers stated that they will provide a position paper regarding [redacted] Open point still open.

Rapporteur: IT

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(3)	Vol 1, Level 1 pag 7. 1.3.9 Specific ation of purity of the ac tive substance (A nne x IIA 1.9)	Aug 04 ES: RMS stated in the DAR that "*Details of the specification of the active substance are confidential to Makhteshim-Agan and Tomen France SAS and are presented in the Annex C.*". According the Directive 91/414/EEC (Article 14) The purity of the active substance is not confidential . Therefore the purity of the active substance must be included in the non-confidential part of the DAR.	Sept04 RMS: The specification for purity is the FAO specification (910 g/kg) and it is quoted by both applicants. Makhteshim 92% Tomen 91%	Addressed RMS has amended the list of endpoints See also comments 1(10), 1(75) and 1(85).
1(4)	Vol 1, Level 1 pag 7. 1.3.9 Specific ation of purity of the ac tive substance (A nne x IIA 1.9)	Aug 04 ES: In the level 2 of the DAR point 2.1.2 RMS stated that *"Captan is a contact fungicide with phthalimide structure consisting of cis- and trans- isomers"*, [redacted] impurity in the list of endpoints (see comment 1 above). According the Directive 94/37/CE point 1.9, purity of the active substance must be established based on the content of active isomers. This must be clarify in the DAR and in the list of endpoints ES: As [redacted] has been declared as impurity, it is assumed that [redacted] inactive as phytosanitary.	Sept 04 RMS: Confirmation will be provided.	Open point RMS to clarify the biological activity of the two captan isomers (*cis* and *trans*) See also comments 1(2), 1(24) and 1(73). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(5)	Vol. 1, Appendix 3, listing of endpoints, Minimum purity of the active substance…	Aug 04 ES: The purity of the active substance should be expressed in g/Kg	Sept04 RMS: Text modified	Addressed RMS has amended the list of endpoints
1(6)	Vol. 1, Appendix 3, listing of endpoints, Melting point	Aug 04 ES: Vol. 3, B.2.1.1, two studies are reported for the melting point of a test material of similar purity with result of 172ºC and 173-175ºC respectively. On list of end points it should be better to report 172ºC instead of 173-175ºC.	Sept04 RMS: See point 12	See comment 1(12)
1(7)	Vol. 1, Appendix 3, listing of endpoints, Relayive density	Aug 04 ES: Vol. 3, B.2.1.1, two studies are reported for the relative density of a test material of similar purity at 20ºC and 22ºC with result of 1.71 and 1.65 respectively. On list of end points it should be better to report the result at 20ºC (1.71) and the temperature should be indicated.	Sept04 RMS: See point n. 14	See comment 1(14)
1(8)	Vol. 1, Appendix 3, listing of endpoints, Vapour pressure	Aug 04 ES: On listing of endpoints two vapour pressure values at two different temperatures are reported but the purity of test substance is not indicated.	Sept04 RMS: Purity of the test substance has been enclosed in the EP 4.2×10^{-6} Pa (20°C) (purity 99.8%) 2.01×10^{-4} Pa (50°C) (purity 98.95%)	Addressed RMS has amended the list of endpoints

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1(9)	Vol. 1, p. 57, List of endpoints, FAO specification	Aug 04 EFSA: For clarification, the given FAO specification should be read as 910 g/kg ± 30 g/kg.	Sept04 RMS: Text modified .	Addressed RMS has amended the list of endpoints
1(10)	Vol. 1, p. 57, List of endpoints, minimum purity	Aug 04 EFSA: It should be clarified whether the given minimum purity applies to both sources or only to the Makhteshim source. In the latter case, why is no value for the Tomen source mentioned? Furthermore, the reason for the deviation from the FAO specification should be clarified (e.g. by request of the notifier).	Sept04 RMS: 1. If this endpoint is supposed to refer to the minimum specification (the minimum allowed), then the value should be the minimum derived from both manufacturers' own specifications. If the value is supposed to be the lowest value obtained in the 5-batch analysis, then the information is confidential. 2. Neither company deviates from the FAO specifications. The given minimum purity applied to the Makhteshim source Tomen reports (Annex C): minimum purity 91%	Partly addressed RMS has amended the list of endpoints regarding the minimum purity of both technical materials. Open point RMS to clarify for transparency and better comprehensibility the reason/background for the given minimum purities which are higher than the FAO value. See also comments 1(3), 1(75) and 1(85). Evaluation Meeting (14.-15.12.2004): RMS to clarify for transparency and better

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	continued			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) Open point still open.
1(10)	Vol. 1, p. 57, List of endpoints, minimum purity			
1(11)	Vol. 1, p. 57, List of endpoints, Identity of relevant impurities	Aug 04 EFSA: Clarification is needed regarding the given relevant impurities. Provided that the given compounds must considered as relevant, a maximum limit should be set and validated analytical methods for the determination of these impurities in the formulation(s) must be provided. Furthermore, the maximum limits given in the FAO specification should be mentioned.	Sept 0? RMS: Maximum limits of impurities have been declared (vol.4; Composition statements). [redacted] PMM: [redacted] Folpet: [redacted] CCl_4: [redacted] Limits on impurities in the FAO specification are: Perchloromethylmercaptan (R005406) maximum level of 10 g/kg, and loss on drying, maximum level 15.0 g/kg.	Open point 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 also comment 1(28). For clarification, a maximum limit (based on toxigological and/or ecotoxicological assessment) must be set for relevant impurities. These data

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1(11)	*continued* Vol. 1, p. 57, List of endpoints, Identity of relevant impurities		We do not agree to include all these data in the EP list	can not be regarded as confidential (Article 14, 91/414/EEC) and should be given in the list of endpoints because of theirs importance. Furthermore, it would be not possible to assess the analytical methods for the determination of the relevant impurities in the formulation without these maximum values. Evaluation Meeting (14.-15.12.2004): Open point confirmed. At least the maximum content of the relevant impurity given in the FAO specification should be given. The meeting has the impression that all impurities (significant/relevant) are listed rather than the relevant, only. Open point still open.

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1(12)	Vol. 1, p. 57, List of endpoints, melting point	Aug 04 EFSA: Clarification is needed why the result of the study of Wollerton and Husband (1995b) is not mentioned.	Sept04 RMS: When similar results are obtained, as in the case of the two studies, only one is sufficient to describe the physical-chemical property. In any case, the value 172°C from the Wollerton and Husband (1995b) study has been added in the List of endpoints.	Addressed RMS has amended the list of endpoints. For clarification, it is correct that one valide study would be sufficient to address the Annex point, but if more than one study has been submitted all study has to be assessed (as done in Volume 3) and consequently also mentioned in the list of endpoints.
1(13)	Vol. 1, p. 57, List of endpoints, boiling point/temperature of decomposition in relation to Vol. 3, p. 6, B.2.1.2 and B.2.1.3.	Aug 04 EFSA: The given argumentation for not determine the boiling point is not acceptable. According to the Directive 94/37/EC, the boiling point (or if relevant the temperature of decomposition or sublimation) must be determined up to a temperature of 360 °C.	Sept04 RMS: We agree that, strictly, decomposition temperature should be presented. However since the melting point is 172-175°C the decomposition temperature must be higher than this. It is therefore questionable whether determination of this parameter will reveal any useful data.	Data requirement Data regarding the boiling point or temperature of decomposition must be provided according to Directive 94/37/EC. Open point RMS should indicate in the list of endpoints that data are required (e.g. as open point). Evaluation Meeting (14.-

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(13)	*continued* Vol. 1, p. 57, List of endpoints, boiling point/temperature of decomposition in relation to Vol. 3, p. 6, B.2.1.2 and B.2.1.3.			15.12.2004): Data requirement: The notifier (Makhteshim) will submit the requested data by mid of March 2005. Data requirement still open. Open point: Open point confirmed. Open point still open.
1(14)	Vol. 1, p. 58, List of endpoints, relative density	Aug 04 EFSA: Clarification is needed why the result of the study of Wollerton and Husband (1995b) is not mentioned.	Sept04 RMS: The result of the study (presented in Vol.3), has been enclosed in the List of endpoints	Addressed RMS has amended the list of endpoints. See also comment 1(12).
1(15)	Vol. 1, p. 58, List of endpoints, solubility in water	Aug 04 EFSA: Clarification is needed why the results for the pH buffered solutions (5 – 9) are not mentioned. Furthermore, it is unclear why the results of Schlesinger (1987a) are not mentioned.	Sept04 RMS: The requested results (presented in Vol. 3) have been enclosed in the List of endpoints 4.9 mg/L in purified water; 4.8 mg/L at pH 5; 5.2 mg/L at pH 7 (Tomen)	Addressed RMS has amended the list of endpoints. See also comment 1(12).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(15)	*continued* Vol. 1, p. 58, List of endpoints, solubility in water		3.77 mg/L at 25°C; 2.67 mg/L at 15°C (Makhteshim)	
1(16)	Vol. 1, p. 58, List of endpoints, partition coefficient	Aug 04 EFSA: Clarification is needed why the result of the study of Schlesinger (1987a) is not mentioned.	Sept04 RMS: The required results (presented in Vol. 3) have been enclosed in the List of endpoints 2.57 at 25°C (pH 7)	Addressed RMS has amended the list of endpoints. See also comment 1(12).
1(17)	Vol. 1, p. 60, Summary of intended uses	Aug 04 EFSA: For transparency and better comprehensibility, instead of the list of uses by supported data, the list of representative uses evaluated, as mentioned in EPCO Manual E4, should be used.	Sept04 RMS: The table on page 60 is the representative uses supported by the dossier .	Addressed RMS has amended the list of endpoints.
1(18)	Vol. 1, p. 61, List of endpoints, classification and labelling in relation to Vol. 3, p. 51, B.4	Aug 04 EFSA: The hazards classification T and N should be mentioned and not only the risk phrases.	Sept04 RMS: Noted	Open point RMS to amend the list of endpoints regarding the hazard classification and labelling symbol "T". Evaluation Meeting (14.-15.12.2004):

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1(18)	*continued* Vol. 1, p. 61, List of endpoints, classification and labelling in relation to Vol. 3, p. 51, B.4			Open point confirmed. Open point still open.
1(19)	Vol. 1, level 2, 2.2.1	Aug 04 NL: See comments on vol. C pertaining to methods of analysis of impurities; there are several data gaps.	Sept04 RMS: As indicated by the notifiers, the requirements for new methods are addressed in a position paper submitted in September 2004 in the addendum to dossier. Data have to be evaluated	See NL comments on Volume 4.
1(20)	Vol. 1, level 2, 2.2.3	Aug 04 NL: Plant and plant products: these methods need confirmation by a 2nd method, ILV and additional validation since replication during validation was insufficient. Moreover, methods using packed columns should not be mentioned here. Soil: methods using packed columns should not be mentioned here.	Sept04 RMS: As indicated by the notifiers, the requirements for new methods are addressed in a position paper. Two new reports (4.2.1/07 Burden, A.N. 2004; 4.2.1/08 Faessel, V. 2004a) have been submitted in September 2004 in the addendum to dossier. Data have to be evaluated. Level 2, 2.2.3. has been modified: methods using packed columns have been omitted. The same has been done for soil	See comment 1(55).
1(21)	Vol. 1, level 3, 3.2	Aug 04 NL: Captan should not be included.	Sept04 RMS: Noted	This is rather an issue of risk management than risk assessment.

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1(22)	Vol. 1, level 3, 3.3	Aug 04 NL: There are data gaps concerning analytical methods as listed in level 4.	Sept04 RMS: See point 20	This is rather an issue of risk management than risk assessment.
1(23)	Vol. 1, level 4, 4.2	Aug 04 NL: Makhetshim to address certain issues (folpet content in [redacted] validation for certain impurities). Tomen to address certain issues (loss on drying higher than FAO limit; 5-batch analysis; validation for certain impurities). Both notifiers: temperature of decomposition of a.s..	Sept04 RMS: A revised 5-batch analysis will be provided in support of the Tomen material, and the impurity profile is discussed in and newly submitted document: 'Overview of the analysis and certification of captan technical material'. Howard K., 2004. document ar20404. Data have to be evaluated. Temperature of decomposition: see point 13	Data requirement (Tomen source) A new batch analysis must be provided. Data requirement (Makhteshim source) A new specification or a justification for the set limit must be provided. (This should be regarded as a technical data requirement, being aware that the study is already available). For temperature of decomposition see 1(13) Evaluation Meeting (14.-15.12.2004): Data requirement (Tomen source):

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(23)	*continued* Vol. 1, level 4, 4.2			The notifier (Calliope) stated at the meeting that a new batch analysis was conducted and the results will be submitted by mid of January 2005. Data requirement still open. Data requirement (Makhteshim source): The notifier (Makhteshim) has already submitted a new batch analysis to the RMS. Data requirement still open.
1(24)	General comment to Volume 3	Aug 04 EFSA: Clarification is needed, regarding the identity of the used pure material. Taken into account the information given in Volume 4 it is not clear whether the pure material [redacted]	Sept04 RMS: Confirmation will be provided.	Open point RMS to clarify the identity of the used pure material (incl. [redacted] See also comments 1(2), 1(4) and 1(73) Evaluation Meeting (14.-15.12.2004):

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1(24)	*continued* General comment to Volume 3			Open point confirmed. Notifers stated that they will provide a position paper regarding the [redacted] Open point still open.
1(25)	Vol 3, B.2.1, Physical and chemical properties of the active substance	Aug 04 UK: It is desirable in the DAR for the RMS to indicate wherever a) non-GLP reports are considered acceptable and to provide clear statement to confirm where reasoned cases/justifications are considered acceptable.	Sept04 RMS: Noted	Addressed RMS consider in a revised DAR or corrigendum
1(26)	Vol 3, B.2.1, Physical and chemical properties of the active substance	Aug 04 UK: Where cases have been made for classification purposes, the RMS should indicate where these are considered acceptable or otherwise.	Sept04 RMS: Noted	Addressed RMS consider in a revised DAR or corrigendum
1(27)	Vol. 3, B.2.1.1 & B.2.1.3, Boiling point and temperature of decomposition	Aug 04 UK: Boiling point or temperature of decomposition required. (Two of the three tests are required). Typically, we see melting point and decomposition or boiling point and	Sept04 RMS: See point 13	See data requirement in comment 1(13)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(27)	*continued* Vol. 3, B.2.1.1 & B.2.1.3, Boiling point and temperature of decomposition	decomposition. Thus we would suggest decomposition temperature is requested. Decomposition should be observed up to 360°C.		
1(28)	Vol. 3, B.2.1.10, Spectra of the impurities…	Aug 04 ES: On page 9 is stated "None of the impurities present in the active substance as manufactured is considered to be of toxicological or environmental significance", nevertheless folpet is a pesticide considered very toxic for aquatic organisms and therefore spectra for this compound should be reported.	Sept04 RMS: We agree. Data have been submitted in the Folpet dossier by the same Notifier	Data requirement Spectra of relevant impurities have to be provided according to Directive 94/37/EC. See also comment 1(11). Evaluation Meeting (14.-15.12.2004): The notifier stated that the spectra of the relevant impurities are available in a short time period. Data requirement still open.
1(29)	Vol 3, B.2.1.10, UV etc spectra (impurities)	Aug 04 UK: The DAR states that none of the impurities present are of concern. However, [redacted]	Sept04 RMS: We agree. Data have been submitted in the Folpet dossier by the same notifier	See data requirement in comment 1(28).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(29)	*continued* Vol 3, B.2.1.10, UV etc spectra (impurities)	[redacted] is also included in the technical material. Folpet is an active substance in it's own right. It is considered that spectral data and fundamental physical chemical properties (water solubility, log k_{ow}) should be provided for these additional compounds.)		
1(30)	Vol. 3, B.2.1	Aug 04 NL: (a) The purity of the technical a.s. used was below the FAO specification of 910 g/kg. A justification should be provided why the test results performed with technical a.s. of low purity ar valid. (b) The impurity profile in the technical product from the two notifiers was different. Therefore each notifier should provide tests for its own technical a.s..	Sept04 RMS: a) The test can be considered acceptable because the FAO specification is 910 g/kg ± 30 g/kg (See point 9). 90.3% purity is within this range. b) The impurity profiles presented by both notifiers do not reveal differences that will significantly affect those physical and chemical properties that are determined on technical materials.	Open point a) RMS to clarify the given justification in respect to the given minimum purities of 920 g/kg and 910 g/kg, respectively. b) RMS to clarify whether this justification is based on practical experiences or on a theoretical assessment. See also open point in comment 1(32) Evaluation Meeting (14.-15.12.2004): a) Confirmed. RMS to clarify for transparency and better

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1(30)	*continued* Vol. 3, B.2.1			comprehensibility the given justification in respect to the given minimum purities of 920 g/kg and 910 g/kg, respectively. For clarification, the minimum of the FAO specification is not applicable in this issue, because in the DAR an higher minimum purity is given [see also 1(10)] b) Confirmed. 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. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(31)	Vol. 3, B.2.1.3	Aug 04 NL: The temperature of decomposition must also be determined.	Sept04 RMS: See points 13	See data requirement in comment 1(13)
1(32)	Vol. 3, p. 15, B.2.1.20 Flammability and auto-flammability	Aug 04 EFSA: It should be clarified whether the given results belongs to the technical material of both notifiers or only to one of them. Taken into account that it seems to be that the technical materials can not be regarded as equivalent (from an analytical point of view), it should be discussed whether additional studies should be required or not.	Sept04 RMS: The results belong to the technical material of one notifier (Tomen). In any case the flammability and relative self-ignition temperature tests are not sophisticated or sensitive. Neither are the results presented borderline in any way. It is highly unlikely that different results for these tests would be obtained from the two different technical materials.	Open point The need to conduct the studies regarding the flammability and auto-flammability with both technical materials should be discussed in an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
1(33)	Vol. 3, p. 16, B.2.2 Physical, chemical and technical properties of the ppp	Aug 04 EFSA: The statement that the formulation Captan 80 WDG is identical to "Merpan 80WDG" should be clarified. According to the given information it seems to be that at least the content of captan is different.	Sept04 RMS: We agree. The captan content is slightly different. Please Notifier to comment.	Data requirement Notifier to clarify whether the formulations "Captan 80 WDG" and "Merpan 80WDG" are identical or not. Evaluation Meeting (14.-

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(33)	*continued* Vol. 3, p. 16, B.2.2 Physical, chemical and technical properties of the ppp			15.12.2004): The notifier (Makhteshim) will submit the requested data by mid of March 2005. Data requirement still open.
1(34)	Vol. 3, p. 21f, B.2.2 Physical, chemical and technical properties of the ppp	Aug 04 EFSA: The statement that the formulation Captan 80 WDG is identical to "Malvin WG" and "Malvin 83" should be clarified. According to the given information it seems to be that at least the content of captan is different.	Sept04 RMS: We agree. The captan content is slightly different Captan 80 WDG and Malvin WG are two trade names for the same formulation. Malvin 83 is a very similar formulation to Malvin WG, using the same basic co-formulation chemical groups, but containing a slightly increased amount of captan.	Data requirement Notifier to clarify whether the formulations "Captan 80 WDG" and "Malvin 83" are identical or not. Evaluation Meeting (14.-15.12.2004): The notifier (Calliope) will submit a statement by mid of January 2005. Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(35)	Vol. 3, p. 17, B.2.2.10 pH value	Aug 04 EFSA: Just for clarification, is it explainable why the pH values of a 1% aqueous dispersion of the same formulation differ in two measurements in more than two decimal powers?	Sept04 RMS: A main difference exists between the two experiments: in one case (result pH 9.73) the suspension was allowed to settle for 1 min and then the pH of the supernatant measured at 25°C; in the second one (result pH 7.16-7.29) the suspension was allowed to settle overnight before pH determination. The hydrolysis study indicated that hydrolysis was very rapid at high pH and the main hydrolysis products are neutral materials which are likely to reduce the pH. This is a likely explanation for the apparent discrepancy.	Addressed RMS to consider in a revised DAR or corrigendum See also open point in comment 1(37).
1(36)	Vol. 3, B.2.2.10, Merpan 80 WDG	Aug 04 NL: What is the explanation for the very different pH values found in the two experiments?	Sept 04 RMS: See point 35	See open points in comments 1(35) and 1(37)
1(37)	Vol 3, B.2.2.10a, pH for Captan 80 WDG	Aug 04 UK: The pH determinations to be explained as values for the same test are more than 2 pH units different. Which is correct? The pH measure in the 1996 study is 9.73 which suggests (based on Annex II studies - B.2.1.15), that hydrolysis occurs too quickly to measure. The hydrolysis rate at	Sept 04 RMS: we agree.	Open point The need for a measurement of the pH value of the in use concentration should be dissucced in an expert meeting.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(37)	*continued* Vol 3, B.2.2.10a, pH for Captan 80 WDG	25ºC and pH 7 is still only 2.61 hours – the implications for the stability of the spray solution should be explained. We suggest pH of in use concentrations should be reported UK: The pH measure in the 1996 study is 9.73 which suggests (based on Annex II studies - B.2.1.15), that hydrolysis occurs too quickly to measure. The hydrolysis rate at 25ºC and pH 7 is still only 2.61 hours – the implications for the stability of the spray solution should be explained. We suggest pH of in use concentrations should be reported.		See also open point in comment 1(35) Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
1(38)	Vol. 3, B.2.2.14, Merpan 80 WDG	Aug 04 NL: Is the value given the bulk or the tap density?	Sept 04 RMS: Both terms are the same. However according to MT159 bulk density may be refined to measure two parameters; pour (or fill) density and tap density. In this case the tap density is quoted.	Addressed RMS to consider in a revised DAR or corrigendum
1(39)	Vol. 3, B.2.2.15, Merpan 80 WDG	Aug 04 NL: Was the physical stability examined in the accelerated storage stability test?	Sept04 RMS: Yes - Changes in physical properties such as phase separation or clumping were examined. No changes observed	Addressed RMS to consider in a revised DAR or corrigendum Evaluation Meeting (14.-15.12.2004):

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(39)	*continued* Vol. 3, B.2.2.15, Merpan 80 WDG			Has been changed in a new open point due to the fact that MS (NL) do not agree that the point was completely addressed. RMS to clarify whether the physical stability (in terms of physical/technical properties) was examined **after** the accelarated storage. (See also comment 1(40)). New open point set.
1(40)	Vol. 3, B.2.2.15, Merpan 80 WDG	Aug 04 NL: Was the physical stability examined in the shelf life study?	Sept04 RMS: Yes - The appearance of the test substance and of the packaging have been examined. No changes observed	Addressed RMS to consider in a revised DAR or corrigendum Evaluation Meeting (14.-15.12.2004): See comment 1(39).

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1(41)	Vol 3, B.2.2.16a, Wettability for Captan 80 WDG	Aug 04 UK: wettability was very quick, however, the values suggest that swirling was included so we suggest the product label should include the phrase that 'Agitation must be used during mixing and loading and until spraying complete'.	Sept04 RMS: Clarification of the existing data must be provided, or the proposed label phrase will be accepted.	Data requirement Notifer to clarify the test conditions to determine the wettability for "Captan 80 WDG" Evaluation Meeting (14.-15.12.2004): The notifier (Makhteshim) will submit a clarification regarding the test conditions (with or without stirring) by mid of March 2005. Data requirement still open.
1(42)	Vol 3, B.2.2.18a, Suspensibility for Captan 80WDG	Aug 04 UK: Suspensibility for Captan 80WDG after storage was outside minimum acceptable level. Pre storage was also very low. We suggest asprayability study is required as suspensibility data do not suggest that the product is uniform in the spray tank.	Sept04 RMS: In the Bonhoff study, the suspensibility was within FAO guidance. Suggested label advice 'Agitation must be used during mixing and loading and until spraying complete'	Open point The need for a sprayability study should be discussed in an expert meeting. The proposed labelling is rather an issue of risk management than of risk assessment.

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1(42)	*continued* Vol 3, B.2.2.18a, Suspensibility for Captan 80WDG			Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
1(43)	Vol. 3, B.2.2.18, Merpan 80 WDG	Aug 04 NL: Prior to and after ambient storage testing for 24 months, suspensibility was <60%. Should this not be addressed by the notifier?	Sept04 RMS: See point 42	See open point in comment 1(42)
1(44)	Vol. 3, B.2.2, Malvin WG	Aug 04 NL: A justification should be provided why the test results performed with the "similar" formulation Captan 80 WG are valid for Malvin WG.	Sept04 RMS: Captan 80 WDG and Malvin WG are two trade names for the same formulation. See point 34	See data requirement in comment 1(34)
1(45)	Vol. 3, B.2.2.15, Malvin WG	Aug 04 NL: Was the physical stability fully examined in the accelerated storage stability test (flowability only is not sufficient)?	Sept04 RMS: No. The physical and chemical properties were determined over two years at ambient conditions	Addressed RMS to consider in a revised DAR or corrigendum
1(46)	Vol. 3, B.2.2.15, Malvin WG	Aug 04 NL: The wettability of Captan 80 WDG was not acceptable (3 minutes and 40 seconds). Does this not trigger further testing?	Sept04 RMS: The 'swirling' test was performed which gave a result of 5 seconds. This information is presented in Vol. 3.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(47)	Vol 3, B.2.2.25, friability and attrition for Captan 80WDG	Aug 04 UK: We suggest MT 184 rather than 171 be used to assess the attrition characteristics of the preparation. MT 171 is a measure of dust content not kinetic interaction between granules and subsequent determination of dust.	Sept04 RMS: MT184 is a new version of the suspensibility test and is not a substitute for MT 171. MT 178 (the test I believe the UK are referring to) was not widely available when this work was completed. This Annex point is intended to show the increase in dust content caused by attrition during transport and handling. In this case 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.	Open point The need for further investigation regarding the friability and attrition for "Captan 80 WDG" should be discussed in an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
1(48)	Vol 3, B.2.2.10, pH of 1% aqueous suspension for Malvin WG	Aug 04 UK: The pH of 1% aqueous suspension was determined on different occasions to be 8.45, 8.12, 8.5 and 8.6, comments above (5) re alkaline stability of active substance apply here. Evidence that active is stable in the spray tank until applied must be presented. We suggest pH of in use concentrations should also be reported.	Sept04 RMS: Clarification of the existing data, or new data should be provided.	Data requirement Notifier to clarify the stability of the active substance in the spray tank until application See also 1(35) and 1(37) for pH determination Evaluation Meeting (14.-15.12.2004):

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(48)	*continued* Vol 3, B.2.2.10, pH of 1% aqueous suspension for Malvin WG			The notifier (Calliope) stated that it is not possible to indicate when the data will be available. Therefore a new study will be conducted. As soon as the date of availability is known, the notifier will inform the RMS. Data requirement still open.
1(49)	Vol 3, B.2.2.16b, wettability for Malvin WG	Aug 04 UK: Results without swirling are outside acceptable limits. With swirling, the results are acceptable. The product label must therefore include the phrase that 'Agitation must be used during mixing and loading and until spraying complete'.	Sept04 RMS: Clarification of the existing data should be provided, or the proposed label phrase will be accepted.	Open point: EFSA to highlight the concern of metabolites in its conclusion. Evaluation Meeting (14.-15.12.2004): This open point has been reworded, due to a mistake in writing: EFSA to highlight the concern of wettability of the formulation in its conclusion. Open point still open.

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1(50)	Vol. 3, B.3.3.2, Procedures for destruction or decontamination	Aug 04 ES: On page 46 it is stated "Captan does not contain halogens in its structural formula…". It ca be considered to write "the halogen content is less than 60%"	Sept04 RMS: We do not agree. "Captan does not contain halogens…." is a true statement and should be maintained.	Addressed
1(51)	Vol. 3, B.3.4.6, Procedures for destruction or decontamination of the plant protection product	Aug 04 ES: On page 50 it is stated "Captan does not contain halogens in its structural formula…". It can be considered to write "the halogen content is less than 60%"	Sept04 RMS: See point 50	Addressed
1(52)	Vol. 3, B.5.1.2, Methods for determination of impurities	Aug 04 ES: Confirmatory methods for impurities folpet, perchloromethylmercaptan, carbon tetrachloride, and [redacted] are necessary since the primary methods are not highly specific.	Sept04 RMS: We agree	Data requirement Data to confirm the identity of the impurities revealed by chemical analysis must be provided for folpet, perchloromethylmercaptan [redacted] to address the requirement of the Directive on the specificity of the method(s). Evaluation Meeting (14.-15.12.2004):

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(52)	*continued* Vol. 3, B.5.1.2, Methods for determination of impurities			The notifier (Makhteshim) stated that this information is included in the already submitted new batch analysis. Data requirement still open.
1(53)	Vol. 3, B.5.1.2	Aug 04 NL: See comments on vol. C pertaining to methods of analysis of impurities; there are several data gaps.	Sept04 RMS: we agree	See NL comments on Volume 4.
1(54)	Vol. 3, p. 53f, B.5.1.3 Methods for the determination of active ingredient in plant formulation	Aug 04 EFSA: In addition to the fact that it seems to be that the necessity of setting maximum level for impurities is not finally concluded, an analytical method for the determination of folpet in the formulation seems to be indispensable, because the classification of folpet as relevant in the sense of a relevant impurity should be doubtless.	Sept04 RMS: Methods are only required for impurities in the formulated product if those impurities are likely to be formed by its manufacturing process or during storage (See Commission Directive 96/46/EC).	Open point 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. For clarification, due to the fact that folpet – among other

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1(54)	*continued* Vol. 3, p. 53f, B.5.1.3 Methods for the determination of active ingredient in plant formulation			compound – is proposed as a relevant impurity (e.g. list of endpoints), analytical methods for the determination of these relevant impurities in the formulation must be provided (see 5.1.2 of Annex II of Directive 96/46/EC) Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
1(55)	Vol. 3, p. 55ff, B.5.2 Analytical methods (residue)	Aug 04 EFSA: Depending on the outcome of the discussion concerning the residue definitions for food of plant and animal origin, further analytical methods could be required (see comments residue section).	Sept04 RMS: Two new reports (4.2.1/07 Burden, A.N. 2004; 4.2.1/08 Faessel, V. 2004a). have been submitted in September 2004 in the addendum to dossier. Data have to be evaluated.	Open point 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)] and the evaluation of the recently submitted methods. See also comments 1(20),

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1(55)	*continued* Vol. 3, p. 55ff, B.5.2 Analytical methods (residue)			1(56), 1(58), 1(60), 1(61), 1(62), 1(63) and 1(64). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
1(56)	Vol. 3, p. 55ff, B.5.2 Analytical methods (residue)	Aug 04 EFSA: It should be stated more precisely, which method is regarded as the proposed enforcement method to ensure for which method an ILV and/or confirmatory method must be provided.	Sept 04 RMS: The method of Schlesinger H.M., (1992; IIA, 4.2.1/02) further validated by Gallais C. (2002; IIA, 4.2.1/06) needs further improvement (ILV and confirmatory assay) Note that new reports have been presented in 2004 (See point 55)	See open point in comment 1(55)
1(57)	Vol. 3, p. 61ff, B.5.2 Analytical methods (residue) soil, water, air	Aug 04 EFSA: It should be stated more precisely, which method is regarded as the proposed enforcement method to ensure for which method a confirmatory method must be provided. For example, it seems to be that for soil the method of Wegner (2003) is the only one that fulfils the requirement of Directive 94/46/EC and SANCO/825/00.	Sept 04 RMS: The only suitable method is that of Wegner (2003).	Partially addressed For water and air data requirements were set in the DAR [for water see 1(65)]. Data requirement A validated analytical method for the determination of

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1(57)	*continued* Vol. 3, p. 61ff, B.5.2 Analytical methods (residue) soil, water, air			residues in air. [This data requirement was already mentioned in the DAR, Vol. 1, Level 4] Evaluation Meeting (14.-15.12.2004): Data requirement: The notifier has already provided a position paper covering this issue. Data requirement still open.
1(58)	Vol. 3, B.5.2.1	Aug 04 NL: The DFG method is not acceptable as it used a packed column (moreover no separate validation report provided, no confirmation by 2nd method, no ILV). Validation for the GC/ECD method by Schlesinger was incomplete (n=3 instead of n=5 at claimed LOQ, no confirmation by 2nd method, no ILV). The GC/ECD method by Iwata is not acceptable as it used a packed column (moreover n=3	Sept 04 RMS: All these notes were already reported in Vol. 3, B.5.2.1, none of the presented methods have been fully validated. See point 55	See open point in comment 1(55).

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1(58)	*continued* Vol. 3, B.5.2.1	instead of n=5 at claimed LOQ, no confirmation by 2nd method, no ILV). Validation for the GC/ECD method by Gallats was also incomplete (no confirmation by 2nd method, no ILV); the study by Schlesinger cannot be considered as an ILV since the sample work-up was different. Therefore there is no fully validated method in plants.		
1(59)	**General Remark**	Aug 04 DE: The substances captan and folpet (and captafol), belong to the same chemical class (Phthalimid fungicides). They possess the same toxicological profile and based on the WHO assessment (1995, 2000) the same ADI. The current residue definition for plants in the EU is "sum of captan and folpet". Therefore these substances should be discussed together in all sections of the DAR.	Sept04 RMS: We agree	Complying with the relevant legislation a DAR has to be produced for each active substance notified.
1(60)	Vol. 3, B.5.2.1, Analytical methods (residue) for plant material	Aug 04 DE: Data Requirement: For determination of captan in commodities with high water content a confirmatory method is missing and should be provided.	Sept 04 RMS: We agree (already outlined in vol. 3) and in Vol. 1 – Level 4, 4.5 See also point 55	See open point in comment 1(55).

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1(61)	Vol. 3, B.5.2.1, Analytical methods (residue) for plant material	Aug 04 DE: Data Requirement: For determination of captan in commodities with high water content an independent laboratory validation is missing and should be provided.	Sept 04 RMS: We agree – See also point 55	See open point in comment 1(55).
1(62)	Vol. 1, 4.5, and Vol 3, B.5.2.1, methods of analysis in plants, plant products	Aug 04 NOT: The DAR volume 1 concludes the following: Four analytical methods are available for non-oily crops. One of them (Iwata ,1989) is not acceptable; the others have been validated for apples and tomatoes (but not for processed fractions) and require for final acceptance a suitable confirmatory assay. Each of the deficiencies and data gaps identified by the RMS has been addressed (see Column 3) and in conclusion, no additional data are considered necessary.	Aug 04 NOT:Overall validation data available for crop methods: IIA, 4.2.1/01: This method has been adequately validated for all crops in the critical GAP (apple, tomato and nectarine). The use of a packed gas chromatography column does not indicate that there are problems with specificity. The report provides two sets of chromatographic conditions for captan with two different selective detectors (ECD and NPD). Therefore, any apparent positive residues can be confirmed using the alternative conditions. No specific validation has been carried out for processed fractions. However, based on the good validation data obtained for the different raw agricultural commodities, it is considered that this method will be applicable to processed	See open point in comment 1(55).

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1(62)	*continued* Vol. 1, 4.5, and Vol 3, B.5.2.1, methods of analysis in plants, plant products		fractions. IIA, 4.2.1/02: The method has been adequately validated for two relevant crops (apple and tomato). In addition, comprehensive validation data are available for a range of apple processed fractions (juice, puree, dry pomace, wet pomace, sauce). It is accepted that the validation of processed fractions does not completely meet the current requirements of SANCO/825/00 with respect to the size of sample sets. Current guidance for validation of analytical methods recommends that five replicate recovery values are determined at two concentrations. In this case sample sets are reduced, but a significant amount of acceptable data has been generated to demonstrate the validity of the method. The method was validated before the current guidance was available, the study design is based on sound analytical principles and is not atypical of validation work carried out at that time. The validation data presented clearly demonstrate that the method is both accurate and precise, and it is considered that any minor deviations in the size of the sample sets compared to the current guidance is not significant. There is no scientific basis on which to reject the results	

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1(62)	*continued* Vol. 1, 4.5, and Vol 3, B.5.2.1, methods of analysis in plants, plant products		of this method validation study and a pragmatic evaluation will confirm 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 purposes. Based on the good validation data obtained for apple and tomato raw agricultural commodities, and a wide range of apple processed fractions, it is considered that this method will be applicable to tomato processed fractions and peaches/nectarines. No additional validation work is considered to be necessary. IIA, 4.2.1/03: The method has been adequately validated for apples. It is accepted, as stated by the report author, that alternative confirmatory conditions are required for unexpected positive results. However, it is not accepted that these conditions must be based on a mass selective detector. See comments below for further considerations of the confirmatory procedures. IIA, 4.2.1/06: The method has been adequately validated for tomato. See	

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1(62)	*continued* Vol. 1, 4.5, and Vol 3, B.5.2.1, methods of analysis in plants, plant products		comments below for further considerations of the confirmatory procedures. Confirmatory procedure: Firstly, it should be noted that the reports described under IIA, 4.2.1/01 and IIA, 4.2.1/06 do contain additional chromatographic conditions for confirmatory purposes. For the other crop methods, it is considered that residues may be confirmed using the many other chromatographic conditions presented for captan residue determination (other crops, soil, water, air etc.). These methods are based on packed or capillary GC with electron capture, nitrogen specific or mass selective detection using a range of stationary phases of varying polarity, and the various conditions will be sufficient for use in confirmation of captan residues. Therefore, it is considered unnecessary to conduct further work on confirmation when there are numerous existing chromatographic conditions available. Summaries of all the analytical methods, the validation data, a summary of the various chromatographic methods available for	

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1(62)	*continued* Vol. 1, 4.5, and Vol 3, B.5.2.1, methods of analysis in plants, plant products		determination of captan and the response to the data requirements/deficiencies are presented in the following position paper: **"Captan. Position Paper on Residue Analytical Methods (April 2004)".** This will be included in the addendum to be submitted to the RMS. Sept 04 RMS: when available the new data will be evaluated-see point 55	
1(63)	Vol. 3, B.5.2.2	Aug 04 NL: It should be clearly stated that the GC/ECD method by Mende is not sufficiently validated, rather than stating that the method "can be considered acceptable in principle", since n=2 instead of n=5 at claimed LOQ, no confirmation by 2nd method, linearity and specificity not reported, no ILV). Therefore there is no fully validated method in animal matrices.	Sept 04 RMS:Noted	See open point in comment 1(55).
1(64)	Vol. 1, 4.5, and Vol 3, B.5.2.2, methods of analysis in animal tissues and milk	Aug 04 NOT: The DAR volume 1 concludes that independent laboratory validation and a confirmatory assay are required.	Aug 04 NOT: The report of Tilkes described under Annex Point IIA, 4.2.1/05 was included to demonstrate that the standard multi-residue	See open point in comment 1(55).

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1(64)	*continued* Vol. 1, 4.5, and Vol 3, B.5.2.2, methods of analysis in animal tissues and milk	NOT: 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.	method DFG S19 is not directly applicable to determination of captan residues in animal products. It is accepted that this method has not been adequately validated. It is considered that the analytical method described by Mende under Annex Point IIA, 4.2.1/04 has been adequately validated in all respects except that an independent laboratory validation has not been conducted. The comments above regarding confirmation for crop residue methods also apply to animal tissue methods - it is considered that residues may be confirmed using the many other chromatographic conditions presented for captan residue determination (crops, soil, water, air etc.). These methods are based on packed or capillary GC with electron capture, nitrogen specific or mass selective detection using a range of stationary phases of varying polarity, and the various conditions will be sufficient for use in confirmation of captan residues. Therefore, it is considered unnecessary to conduct further work on confirmation when there are numerous existing chromatographic conditions available.	

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1(64)	*continued* Vol. 1, 4.5, and Vol 3, B.5.2.2, methods of analysis in animal tissues and milk		It is considered appropriate to retract the original claim in the dossier that the method is suitable for monitoring purposes. However, further validation work is not required for the following reason. The metabolism studies in the goat demonstrated that significant captan residues did not occur in edible animal tissues following administration of a worst-case dietary concentration. Consequently, MRLs for animal tissues, milk and eggs are not applicable. Therefore, an analytical method for monitoring purposes is not required under these circumstances (as defined by Commission Directive 96/46/EC) and the validity of the methods presented need not be evaluated. The methods presented for determination of captan in animal tissues and milk should be considered as supporting information for the methods dossier and any deficiencies in their validation are irrelevant. Summaries of all the analytical methods and the validation data for determination of captan and the response to the data requirements/deficiencies are presented in	

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	continued		the following position paper: **"Captan. Position Paper on Residue Analytical Methods (April 2004)".**	
1(64)	Vol. 1, 4.5, and Vol 3, B.5.2.2, methods of analysis in animal tissues and milk		This will be included in the addendum to be submitted to the RMS. Sept 04 RMS: when available the new data will be evaluated-see point 55	
1(65)	Vol. 1, 4.5, and Vol 3, B.5.3.2, methods of analysis in water	Aug 04 NOT: The DAR volume 1 concludes that a fully validated method with a suitable LOQ value for analysis of captan in water is required. 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.	Aug 04 NOT:It is accepted that the two methods for captan have not been shown to be sufficiently sensitive with respect to the EU drinking water limit of 0.1 µg/L. However it should be noted that these methods are provided as supporting information and are not proposed as monitoring methods. In fact, monitoring methods are not required for captan. According to the current guidance for residue monitoring methods, SANCO/825/00, a monitoring method for water is not required for an active substance with a DT_{90} in water of less than three days. It has been calculated from the hydrolysis	Open point DT_{90} values must be confirmed by the fate and behaviour section. Provided that the values will be confirmed, an analytical method is not required. => Discussion in expert meeting (fate and behaviour) See also comment 1(67) Evaluation Meeting (14.-15.12.2004):

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1(65)	*continued* Vol. 1, 4.5, and Vol 3, B.5.3.2, methods of analysis in water		data that the DT_{90} for captan is in the range 8 minutes to 1.3 days depending on pH. The DT_{90} values are newly calculated data which have not been previously submitted. 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. Summaries of all the analytical methods and the validation data for determination of captan and the response to the data requirements/deficiencies are presented in the following position paper: **"Captan. Position Paper on Residue Analytical Methods (April 2004)".** This will be included in the addendum to be submitted to the RMS.	Open point confirmed. Depending on the outcome of the fate and behaviour meeting, it could be that no analytical method for the determination of residues of captan in water is required. Open point still open.

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1(65)	*continued* Vol. 1, 4.5, and Vol 3, B.5.3.2, methods of analysis in water		Sept 04 RMS: when available the new data will be evaluated-see point 55	
1(66)				
1(67)	Vol. 3, B.5.3.2, Analytical methods (residues) for water	Aug 04 DE: Data Requirement: For determination of the metabolite THPI in drinking and surface water a confirmatory method is missing and should be provided. Additional confirmatory methods are only not necessary, if the highly specific properties of the GC-MS technique were used and at least 3 fragment ions were monitored.	Sept 04 RMS: The method presented for determination of THPI in drinking and surface water is based on GC/MS monitoring of one fragment ion only. Therefore, we agree that the method alone cannot be considered to be self-confirmatory.	See open point in comment 1(65)
1(68)	Vol. 3, B.5.4.1 Analytical methods for body fluids and tissues(Annex IIA 4.2.5; Annex IIIA 5.2)	Aug 04 DE: Data Requirement: For determination of captan in human body tissues a confirmatory method is missing and should be provided.	Sept 04 RMS: We agree – Already outlined in vol. 1, Level 4, 4.5. See also point 71	Data requirement A validated analytical method for the determination of residue in blood. See also comment 1(71) Evaluation Meeting (14.-

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(68)	*continued* Vol. 3, B.5.4.1 Analytical methods for body fluids and tissues(Annex IIA 4.2.5; Annex IIIA 5.2)			15.12.2004): The notifier (Makhteshim) will submit the requested data by mid of April 2005. Data requirement still open.
1(69)	Vol. 3, B.5.4.1 Analytical methods for body fluids and tissues(Annex IIA 4.2.5; Annex IIIA 5.2)	Aug 04 DE: Data Requirement: For determination of captan in human body fluids a sufficiently validated method is missing and should be provided.	Sept 04 RMS: See point 68	See data requirement in comment 1(68)
1(70)	Vol. 3, B.5.4.1 Analytical methods for body fluids and tissues(Annex IIA 4.2.5; Annex IIIA 5.2)	Aug 04 DE: Data Requirement: For determination of captan in human body fluids a confirmatory method is missing and should be provided.	Sept 04 RMS: See point 68	See data requirement in comment 1(68)
1(71)	Vol. 3, p. 65, B.5.4 Analytical methods (residue) for body fluids and tissues	Aug 04 EFSA: It should be noted, that neither the Directive nor the guidance document SANCO/825/00 requires analytical	Sept 04 RMS: Noted – We agree A validated method for human body fluids	See data requirement in comment 1(68)

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1(71)	*continued* Vol. 3, p. 65, B.5.4 Analytical methods (residue) for body fluids and tissues	methods for the determination of residues in human tissues. The issue of this requirement is to determine substances which are of acute toxicological relevance humans or animals. The validation of tissues is in general covered by food of animal origin, but milk is not regarded as body fluid. Due to the fact that the metabolism is normally different, blood was selected as the commodity which has to be validated. However, it is not compulsory to validate the method with human blood. Therefore, the set data requirement should be reworded.	and tissues con A method for human body fluids and tissues.	
1(72)	Vol. 3, B.5.5	Aug 04 NL: The conclusions need amendments: methods for certain impurities must be improved or provided; the methods for plants need more validation than ILV only (see above comments on B.5.2.2); methods using packed columns are not acceptable (pertains to certain methods in plant and soil). It should also be clearly stated that methods for determination of residues in human body fluids and tissues are required since captan is classified as toxic.	Sept 04 RMS: Noted. See also point 55 We agree that a method for body fluids and tissues is required.	Addressed RMS to consider in a revised DAR or corrigendum See also above mentioned data requirements and open points

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1(73)	General comment to Volume 4	EFSA: Clarification is needed regarding the discrimination between captan and [redacted] Captan is the international harmonised name for N-(trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide (IUPAC). [redacted] The consequence of the given discrimination would be that the compound named in volume 4 as captan is not captan, [redacted]	Sept 04 RMS: We agrre. A comparison of active substances should be provided	Open point RMS to evaluate the comparability of the two technical materials. Regarding the identity/discrimination of captan [redacted] see 1(2), 1(4), 1(24) and 1(73). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(73)	*continued* General comment to Volume 4	(code) not less than xxx g/kg The advantages would be that still the name captan can be used and sufficient information would be available concerning the kind of (technical) material which was the basis of the assessment. In addition, an assessment concerning the equivalence of the two technical materials is missing. Furthermore, it should be clarified whether an assessment by the RMS was conducted or not. It seems to be that Volume 4 contains just the two original J-documents of the dossiers.		
1(74)	Vol. 4, p. 6, 1.8 Method of manufacture	Aug 04 EFSA: Data concerning the identity of the starting material (source, purity) are missing.	Sept 04 RMS: We agree	Data requirement Data regarding the purity and source (commercially available or not) of the starting material must be provided according to Directive 94/37/EC.. Evaluation Meeting (14.-15.12.2004): The notifier Makhteshim will submit the requested data by

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(74)	*continued* Vol. 4, p. 6, 1.8 Method of manufacture			mid of March 2005. The notifier Calliope will submit the requested data by mid of January 2005. Data requirement still open.
1(75)	Vol. 4, p. 11, Composition statement	Aug 04 EFSA: The specified limits for [redacted] and [redacted] are not reliable according to the submitted batch analyses. A new specification or a justification is required.	Sept 04 RMS: A revised 5-batch analysis will be provided in support of the Tomen material, and the impurity profile is discussed in and newly submitted document: 'Overview of the analysis and certification of captan technical material'. Howard K., 2004. document ar20404. Data have to be evaluated	Data requirement New batch analysis must be provided (This should be regarded as a technical data requirement, being aware that the study is already available). Evaluation Meeting (14.-15.12.2004): Data requirement confirmed. Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(76)	Vol. 4, p. 8 and 27, 1.10 Identity of isomers, impurities and additives	Aug 04 EFSA: Clarification is needed regarding the pattern of impurities. Taken both synthesis pathways into account, the different pattern is not reliable.	Sept 04 RMS: We agree	Open point RMS to reflect on the different impurity pattern in the evaluation of the comparability of the two technical materials. See also open point in comment 1(73) Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
1(77)	Vol. 4, p. 12 and 41, 4. Analytical methods in relation to Volume 3, p. 53ff, B.5.1 Analytical methods for formulation analysis.	Aug 04 EFSA: The applicability or non-applicability of CIPAC method(s) was not mentioned.	Sept 04 RMS: We suggest to include the following: In addition, the existing CIPAC methods for captan in technical material, wettable powders and dustable powders would be expected to be appropriate for determination of captan in water dispersible granule preparations.	Open point RMS to indicate in the list of endpoints that a CIPAC method is available for the determination of captan in the technical material. Open point RMS to clarify the basis of the assumption that the CIPAC

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(77)	*continued* ol. 4, p. 12 and 41, 4. Analytical methods in relation to Volume 3, p. 53ff, B.5.1 Analytical methods for formulation analysis.			method for WP and DP formulations is also applicable for WG formulations. Evaluation Meeting (14.-15.12.2004): Both open points confirmed. Open points still open.
1(78)	Vol. C, 1.11, Makhteshim	Aug 04 NL: The content of the impurity folpet in one of 5 batches [redacted] exceeded the maximum specification of [redacted]	Sept 04 RMS: Noted. Notifier please comment	Addressed For clarification it should be noted that the technical material, which is not in line with the set limits can not be used for formulations.
1(79)	Vol. C, 4.1.2, Makhteshim	Aug 04 NL: On which principle is the commercial moisture meter method to determine water based? Is there any validation data for this method?	Sept 04 RMS: This commercial moisture meter uses the Karl Fischer technique (widely accepted and used) as described in CIPAC MT30.1	Addressed RMS to consider in a revised DAR or corrigendum

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1(80)	Vol. C, 4.1.3.1, Makhteshim	Aug 04 NL: Specificity should be adequately addressed for all impurities.	Sept 04 RMS: We agree	Data requirement 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). Evaluation Meeting (14.-15.12.2004): The notifier (Makhteshim) stated that this information is included in the already submitted new batch analysis. Data requirement still open.
1(81)	Vol. C, 4.1.3.2, Makhteshim	Aug 04 NL: There is no information on linearity for the [redacted]	Sept 04 RMS: We agree	See open points in comments 1(2), 1(4), 1(24) and 1(73)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(82)	Vol. C, 4.1.3.3, Makhteshim	Aug 04 NL: 4.1.2/02: the fortification levels in terms of % w/w are needed to assess whether the relevant range was validated.	Sept 04 RMS: We agree. It is assumed that this comment is related to 4.1.2/01 because there is no reference 4.1.2/02.	Data requirement Notifier to clarify the investigated fortification levels in the method for the determination of folpet and the impurities. Evaluation Meeting (14.-15.12.2004): The notifier (Makhteshim) will submit the requested data by mid of March 2005. Data requirement still open.
1(83)	Vol. C, 4.1.3.4, Makhteshim	Aug 04 NL: 4.1.2/02: what is the (fortification) level at which RSD for carbon tetrachloride was determined?	Sept 04 RMS: This information is presented in the study report. RSD was determined for carbon tetrachloride at a level of 0.05g in a 0.5 to 1.3g technical sample.	Addressed RMS to consider in a revised DAR or corrigendum
1(84)	Vol. C, 4.1.3.5, Makhteshim	Aug 04 NL: Validation was incomplete: linearity and specificity for certain impurities not addressed.	Sept 04 RMS: See points 80 and 81	See comments 1(80) and 1(81)

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1(85)	Vol. C, 1.9 & 1.10, Tomen	Aug 04 NL: 1.9/01& 1.10/01: the conclusion is not correct, since the FAO specification is minimum 910 g/kg and the 5 batches had a captan content of 883-917 g/kg, some batches had a content <910 g/kg.	Sept 04 RMS: Vol. C does not exist. Comment made with reference to Doc J. The FAO specification states that the captan content shall be declared (not less than 910 g/kg) and, when determined, the content obtained shall not differ from that declared by more than ± 30 g. 88.3% is within this range. See also point 75 (revised Tomen 5-batch analysis).	See open points and data requirements in comments 1(3), 1(10) and 1(75)
1(86)	Vol. C, 1.10, Tomen	Aug 04 NL: 1.10/01: the conclusion states that the loss on drying agreed with the FAO specification (maximum 15 g/kg), but was this parameter determined in the batch analysis? If it was determined as acetonitrile insolubles, these were >15 g/kg (18.3-38.2 g/kg).	Sept 04 RMS: Vol. C does not exist.. Comment made with reference to Doc J. The FAO specification, 'loss on drying' is normally taken to mean water content. In this case the water content was measured. It should be noted that no other components in Tomen captan technical are volatile and so the water content is expected to equate to the 'loss on drying' . Acetonitrile insolubles is irrelevant to this issue. See also point 75 (revised Tomen 5-batch analysis).	See data requirement in comment 1(75)

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1(87)	Vol. C, 1.10, Tomen	Aug 04 NL: 1.10/02: Is table 1.10-2 correct? Only the captan content differs from that in the previous table. The content of the impurities is identical to that of the previous analysis, which seems unlikely. Were captan and impurities analysed, or captan only? If the latter is correct, the data for impurities should not be included in Table 1.10-2 as they were determined in other batches than captan. The analytical closure of 106.69 is too high. If the impurities were not analysed again, no analytical closure should be given. Since there have been modifications to the production process ("process optimisation"), leading to an increased captan content, not only captan but also the impurities should be reanalysed. Hence Tomen should provide a complete 5-batch analysis.	Sept 04 RMS: Vol. C does not exist. .. Comment made with reference to Doc J. See point 75	See data requirement in comment 1(75)
1(88)	Vol. C, 1.11, Tomen	Aug 04 NL: 1.11/01: the conclusion is not correct, since the FAO specification is minimum 910 g/kg and the 5 batches had a captan content of 883-917 g/kg, some batches had a content <910 g/kg.	Sept 04 RMS: Vol. C does not exist. Comment made with reference to Doc J. The FAO specification states that the captan content shall be declared (not less than 910 g/kg) and, when determined, the content	See comment 1(85)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(88)	*continued* Vol. C, 1.11, Tomen		obtained shall not differ from that declared by more than ± 30 g. 88.3% is within this range. See also point 75 (revised Tomen 5-batch analysis).	
1(89)	Vol. C, 1.11, Tomen	Aug 04 NL: 1.11/01: the conclusion states that the loss on drying agreed with the FAO specification (maximum 15 g/kg), but was this parameter determined in the batch analysis? If it was determined as acetonitrile insolubles, these were >15 g/kg (18.3-38.2 g/kg).	Sept 04 RMS: See point 86	See data requirement in comment 1(75)
1(90)	Vol. C, 1.11, Tomen	Aug 04 NL: Composition statement: the maximum level of [redacted] is higher than the FAO specification [redacted]	Sept 04 RMS: Vol. C does not exist. Comment made with reference to Doc J.. The level of [redacted] is not specified in FAO Specification 40/TC/S (1990). See also point 75 (revised Tomen 5-batch analysis).	Addressed, unless NL can clarify where the mention value comes from.
1(91)	Vol. C, 4.1.2, Tomen	Aug 04 NL: On which principle is the commercial moisture meter method to determine water based? Is there any validation data for this method?	Sept 04 RMS: see point 79	See comment 1(79)

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1(92)	Vol. C, 4.1.3.1, Tomen	Aug 04 NL: Specificity should be adequately addressed for all impurities.	Sept 04 RMS: See point 75 (revised Tomen 5-batch analysis).	See data requirement in comment 1(75)
1(93)	Vol. C, 4.1.3.2, Tomen	Aug 04 NL: There is no information on linearity of most impurities.	Sept 04 RMS: See point 75 (revised Tomen 5-batch analysis).	See data requirement in comment 1(75)
1(94)	Vol. C, 4.1.3.3, Tomen	Aug 04 NL: 4.1.2/02: the fortification levels in terms of % w/w are needed to assess whether the relevant range was validated. Recovery data should be provided for all impurities from the specification.	Sept 04 RMS: see point 82	See data requirement in comment 1(82)
1(95)	Vol. C, 4.1.3.3, Tomen	Aug 04 NL: Recovery data should be provided for all impurities from the specification.	Sept 04 RMS: See point 75 (revised Tomen 5-batch analysis).	See data requirement in comment 1(75)
1(96)	Vol. C, 4.1.3.4, Tomen	Aug 04 NL: Repeatability data should be provided for all impurities from the specification.	Sept 04 RMS: See point 75 (revised Tomen 5-batch analysis).	See data requirement in comment 1(75)

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1(97)	Vol. C, 4.1.3.5, Tomen	Aug 04 NL: Validation was incomplete: specificity, linearity, recovery and repeatability for certain impurities not addressed.	Sept 04 RMS: See point 75 (revised Tomen 5-batch analysis).	See data requirement in comment 1(75)
1(98)	New open point			Evaluation Meeting (14.-15.12.2004): 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. New open point set.
1(99)	Late incoming German comment			Evaluation Meeting (14.-15.12.2004): The German comment regarding the number of applications was noted but the meeting agreed that this will not be taken into account in the list of representative uses,

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1(99)	*continued* Late incoming German comment			because the risk assessment will not be changed (worst case is covered).

2. Mammalian toxicology

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(1)	Vol. 1, 2.1.4, Classification and labelling	Aug 04 DE: In accordance to the 28th Time Council Directive 67/548/EC, captan has to be classified and labelled for toxicological properties as follows: T; R23-40-41-43. The risk phrase R40 is necessary because of the clear neoplastic effect in mice and must be amended, therefore. The need for classification and labelling with R40 is also acknowledged in the DAR but only in Vol. 3 under B.6.11 with regard to the formulations	Sept 04 RMS on a basis of a pure hazard characterization we can agree with R 40 labelling of captan. However, at the light of risk assessment for man the toxicology expert of RMS still believes that captan does not require R40 in view of the fact that: i) Captan is not considered genotoxic and ii) mice tumours are species specific and appear only above a dose that causes chronic toxicity. . Robust chemical/physical data, mechanistic data supporting a threshold MOA, and bioassays in rats, mice and dogs allow a judgment of no cancer risk to man with a high degree of certainty; accordingly, the risk phrase, R-40, is not required nor appropriate. Captan acts through a non-genotoxic threshold based mechanism. This MOA requires high oral doses that sustain a duodenal-specific proliferative response. Captan is not carcinogenic in rats or dogs; the gastrointestinal tumors (primarily in the	Open point The MS to discuss the classification and labelling with regard to cancerogenic properties at an expert meeting. See also comments 2(15), 2(16), 2(19) and 2(21). Evaluation Meeting (14.-15.12.2004): Open point rephrased: MS to discuss the canceriogenic properties in an expert meeting. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(1)	*continued* Vol. 1, 2.1.4, Classification and labelling		duodenum) that appear in mice may well be species specific. See also point 21.	
2(2)	Vol. 1, 2.3.1	Aug 04 NOT: The first paragraph at the top of page 21 of Volume 1 of the DAR includes a statement and there is no reference to this statement in Volume 3. The statement in the first paragraph on page 21 states: "Dermal application in rats produced skin irritation which was pronounced at higher dose levels and which was reversible when dosing was discontinued. Males showed a more severe reaction than females and body weights in the males were reduced although there were no differences in food consumption. There were macroscopic and microscopic changes in the skin of animals at 10 and 30 mg/kg/day". This statement is not included in Volume 3 of the DAR or the dossier. No reference to such effects can be found. Therefore, we request that this statement is removed.	Sept 04 We agree to delete the statement	Addressed RMS to consider in a revised DAR or corrigendum.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(3)	Vol. 1, 2.3.3	Aug 04 NOT: An ARfD of 0.1 mg/kg bw is proposed. An ARfD is not required for captan for the following reasons: 1) There is minimal irritation seen in the gastrointestinal tract after one day exposures to captan at doses above 500 mg/kg. 2) Gastrointestinal irritation following repeated captan oral exposure is rapidly reversed upon cessation of treatment. 3) Captan is not present in the systemic circulation and is not a systemic toxin. 4) Captan will not induce adverse effects when residues are ingested continuously, even at the theoretical maximum residue values. 5) Captan's oral toxicity is greater than 5 g/kg. Full and detailed comments on all aspects of the ARfD for captan are presented in a position paper: **"Gordon, E and Kinzell, J. (2004). Captan. A summary basis for why an acute reference dose (aRfD) is not needed", report R-17080**.	Sept 04 RMS: An ARfD of 0.1 mg/kg bw is agreable	Open point The setting of ARfD to be discussed at an expert meeting. Data requirement Notifier to submitt the position paper Gordon and Kinzell (2004) and the study Moore and Creasey (2004). See also comments 2(10), 2(18) and 2(20). Evaluation Meeting (14.-15.12.2004): Data requirement: A position paper and the study have already been submitted to the RMS. Data requirement still open. Open point confirmed.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(3)	*continued* Vol. 1, 2.3.3	This position paper is supported by a new previously unsubmitted acute intestinal irritation study, namely **"Moore, G.E. and Creasey, D. (2004). Intestinal irritation in CD-1 mice after a 24-hour exposure to folpet. [redacted] unpublished report number[redacted] (Company file: R-16283)"** This study concludes that folpet (a closely related compound to captan) administered by oral gavage at 900 mg/kg/bw or in the diet for 24 hours at 5000 ppm (as well as 500 ppm, 200 ppm, and 50 ppm) caused only minimal ("borderline") irritation of the proximal duodenum. The initial finding of apparent irritation in the first study was shown to be due to artefacts upon thorough (eight step serial section) examination of the expanded second study. It was concluded that folpet was borderline for producing irritancy at 5000 ppm. The common mechanism of toxicity for captan and folpet legitimize these data for the evaluation of captan. The position paper and the new study will be included in the addendum to be submitted to the RMS.		Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	continued			
2(3)	Vol. 1, 2.3.3	We propose that, based on an evaluation of the toxicology database for captan, an ARfD for captan is not needed.		
2(4)	Vol. 1, 2.3.2, ADI	Aug 04 DE: Proposal: The ADI should be lowered to 0.1 mg/kg bw and based on the NOEL for maternal and developmental toxicity in the teratogenicity study in rabbits supported by the outcome of the one-generation study in rats. Otherwise, it would be higher than the proposed ARfD. The ADI cannot be higher than the ARfD according to the principles for the derivation of the ARfD (JMPR, 2002). The ADI of 0.1 mg/kg bw is in accordance with the WHO-evaluation (1995, 2000).	Sept 04 RMS:We agree to lower to 0.1 mg/kg bw the ADI based on the NOEL for maternal and developmental toxicity in the teratogenicity study in rabbits	Open point MS to agree on the ADI value at an expert meeting. See also comments 2(10) and 2(18). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(5)	Vol. 1, 2.3.4, AOEL	Aug 04 DE: Proposal: It is proposed to derive the systemic AOEL from the NOEL for maternal and developmental toxicity in the teratogenicity study in rabbits since this is a study of shorter duration that may better reflect the operator exposure. This calculation would result in a lower numeric value of 0.1 mg/kg bw/day. An AOEL of 0.1 mg/kg bw/day is also mentioned in Volume 1 under "Overall Conclusions" subsequent to point 2.6.7 and in the "List of endpoints", chapter 3. Thus, there is a contradiction in the DAR.		See open point in comment 2(18).
2(6)	Vol. 1, 2.3.6, Impact on human and animal health and Vol.3, B.6.14, Exposure data	Aug 04 DE: On the basis of the proposed dermal absorption rate of 9 % and a systemic AOEL of 0.1 mg/kg bw/day [see (4) and (23)] a new risk assessment should be carried out. Remark: Erroneously in the end point sheet an operator exposure assessment on the basis of the UK POEM is given. This model is not used in the monograph (B.6.14: "...Therefore, calculations of	Sept 04 RMS: see comment 22 RMS: remark noted	Open point The dermal absorption value should be discussed at an expert meeting. See also comments 2(22) and 2(23). Regarding setting of AOEL, see open point 2(18) and

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(6)	*continued* Vol. 1, 2.3.6, Impact on human and animal health and Vol.3, B.6.14, Exposure data	operator exposure are presented using the German BBA model only."))..		comment 2(5). Addressed (editorial) The RMS to revise the DAR and delete sentence relating to UK-POEM. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
2(7)	Vol. 1, Level 4, Further information and demand point 4.6	Aug 04 DE: The requirement of new teratogenicity studies in rats and rabbits are not supported. Three acceptable studies in rabbits and one study in rats are presented and developmental toxicity is not of concern.	Sept 04 RMS: We agree	See open point in comment 2(17) and comment 2(18).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(8)	Vol. 1, appendix 3, list of end points, ADME studies	Aug 04 NL: ADME studies: Please present the extent of absorption.	Sept 04 RMS: End Point List has been amended (81%)	Addressed List of endpoint has been amended.
2(9)	Vol. 1, appendix 3, list of end points, long-term toxicity	Aug 04 NL: A lowest relevant NOAEL for long-term toxicity in rat of 24 mg/kg bw/d (carcinogenicity study rat) should be presented (instead of the NOAEL from the three generation study).	Sept 04 RMS: The NOAEL of the three generation studies is acceptable since the treatment is equal to a chronic exposure.	Open point The setting of the highest relevant NOAEL for the long-term studies should be discussed at an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
2(10)	Vol. 1, appendix 3, list of end points, summary	Aug 04 NL: Please mention the studies and applied safety factors, used to derive the ADI, AOEL and ARfD.	Sept 04 RMS: ADI and ArfD are based on the NOEL for maternal and developmental toxicity in the teratogenicity study in rabbits (10 mg/kg b.w.) with a safety factor of 100. The EP list has been amended	See open points 2(3), 2(4), 2(6) and 2(18).

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2(11)	Vol. 3, B.6.1	Aug 04 NOT: A study to measure the half life of captan in whole blood is included in the DAR (see page 24 of volume 3). A new study is available which reports the half-life of thiophosgene (a captan reactive metabolite intermeiate) in human blood. A method to measure the presence of thiophosgene in human blood was developed. Blood was fortified with thiophosgene, quenched with an acidic acetone solution and the remaining thiophosgene was derivatized to the cyclic compound (R)-2-thioxo-4-thiazolidinecarboxylic acid using L-cysteine and analyzed by HPLC-UV. Pre-quenched blood fortified with 10, 30 and 100 µg/mL thiophosgene resulted in an average recovery of 42% ± 8.6%. The method was employed to measure the half-life of an exaggerated concentration of thiophosgene (100 µg/mL) in human blood. Thiophosgene was added to 10 human blood samples (at 37˚C) and allowed to react for times ranging from 1.9 seconds to 31.1 seconds. The reactions were then arrested and the remaining thiophosgene was	Sept 04 RMS: noted	Open point The RMS to provide a summary of the new toxicokinetic study in the addendum. Evaluation Meeting (14.-15.12.2004): New data requirement set : Notifier to submit new toxicokinetic study. The notifier already has provided a new human degradation study in blood to the RMS. Data requirement still open. Open point confirmed. To be discussed in an expert meeting. Open point still open.

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2(11)	*continued* Vol. 3, B.6.1	determined. The thiophosgene % recovered data was normalized to account for a threshold level of about 1% found in samples reacted for at least 7 seconds believed to be attributed to saturation of the relevant blood nucleophiles by the exaggerated rate of thiophosgene employed. An exponential equation (of the form $y = a + b*\exp^{(-k*x)}$) was used to fit the normalized % thiophosgene recovered vs. reaction time data with a correlation coefficient of > 0.99 when the data point of 100% recovery at time zero is assumed. The half-life of thiophosgene in human blood was found to be 0.6 seconds. 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. The new study is listed below: **"Arndt, T and Dohn, D. (2004). Measurement of the Half-Life of Thiophosgene in Human Blood. PTRL West unpublished report number 1146W-**		

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2(11)	*continued* Vol. 3, B.6.1	**1"** This new study and our evaluation of this study (in Tier 2 format) will be included in the addendum to be submitted to the RMS.		
2(12)	Vol. 3, B.6.3.2 Oral 90-day study rat	Aug 04 NL: There is no 90-day oral toxicity study rat available. It is discussed in the monograph that this is acceptable, since clinical chemistry and haematology at 3 months are available from the 2-year rat study. However, possible (adverse) changes in organs after 90 days of exposure can have disappeared after 2 years of exposure due to adaptation or can be 'overlooked' because the interindividual differences in older animals are much higher. It should be considered to require a 90-day study rat.	Sept 04 RMS: We agree that a new 90-day oral toxicity study in rat is not necessary: i) existence 2 years exposure ii) the UE recommend not to carry animal experiments if not strictly necessary	Open point The need of performing a 90-day oral study in rat should be discussed at an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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2(13)	Vol. 3, B.6.3.2 Oral 90-day study dog	Aug 04 NL: A NOAEL of 60 mg/kg bw/d should be considered, based on (besides emesis and soft stool) decreased plasma total protein and albumin concentrations and increased relative liver weights (with no significant differences in group mean body weight) at 300 mg/kg bw/d. At 300 mg/kg bw, relative liver weights were increased by 15%, which is considered to be toxicologically relevant, especially with a concomitant decrease in albumin concentration which is synthesized in the liver.	Sept 04 RMS: We agree to lower the NOAEL to 60 mg/kg b.w. EP have been modified	Addressed List of endpoint has been amended.
2(14)	Vol. 3, B.6.3.3, other routes, 90-day inhalation rat	Aug 04 NL: A NOEC of <0.13 µg/L should be considered, based on hyperplasia in the larynx. The study authors claim that the rat larynx is extremely sensitive to particulates, and since the hyperplasia at 0.13 and 0.60 µg/L was not accompanied by other effects, there is no toxicological significance in the context of human exposure. However, it is not generally accepted that the rat larynx is extremely sensitive to particulates and there are no data included to support this statement.	Sept 04 RMS:We still support the 0.60 value considering the reactivity of the substance	Open point The setting of the NOAEL(C) in the 90-day inhalatory study should be discussed at an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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	continued	Therefore, the observed hyperplasia in the larynx in the two lowest dose groups should be considered toxicologically relevant.		
2(14)	Vol. 3, B.6.3.3, other routes, 90-day inhalation rat			
2(15)	Vol. 3, B.6.4.3, summary of genotoxicity studies	Aug 04 NL: It is clear that captan is genotoxic *in vitro.* However, it is not clear whether captan is genotoxic *in vivo* or not. Is all the literature data with regard to genotoxicity *in vivo* discussed in the monograph? NL proposes to discuss the possible genotoxicity *in vivo* in an expert meeting.	Sept 04 RMS: All published studies on the *in vivo* genotoxicity/mutagenicity of captan, in addition to the unpublished reports provided by the applicant, have been evaluated in this Monograph. Even though captan is genotoxic *in vitro*, the weight of the negative experimental evidence provided by *in vivo* studies, together with information on half-life of captan in biological fluids (< 1 sec. in thiol-rich medium), strongly supports the view that captan is not genotoxic *in vivo*. Of course, as a null hypothesis cannot be proven, a formal demonstration of absence of mutagenicity cannot be obtained, for captan as well as for any other chemical. The genotoxic potential of captan *in vivo* has been already evaluated by other expert committees, largely based on the same experimental evidence considered in this Monograph. Both the JMPR (1995) and the UK Pesticides Safety Directorate (1998) concluded that captan is not genotoxic *in*	See open point in comment 2(1) and comments 2(16), 2(19) and 2(21).

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2(15)	*continued* Vol. 3, B.6.4.3, summary of genotoxicity studies		*vivo*. Therefore, another expert meeting on the same item is regarded as unnecessary.	
2(16)	Vol. 3, B.6.5.3 Summary of long-term toxicity and carcinogenicity	Aug 04 DK: In the life-span study with rats (Til *et al* 1983) DK considers the tumour formation to be highly relevant for carcinogen potential to man. DK: There was tumour formation that was both ordinary occurrence but also unusual occurrence for this species. The usual findings were fibroadenomas in mammary glands (females), polyp in uterus and pituitary gland adenoma (both sex). But there was also a significant increased incident of sacomas in uterus and in a few males laiomysacromas in the small interstine. Also there were incidences of lymfosarcomas in a few animals.	Sept 04 RMS: we agree with the statement of the study director: "Neoplasms observed most frequently were fibroadenomas of the mammary gland and polyps of the uterus in females and adenomas of the pituitary in males and females. A few tumour types, not common in the strain of rats used, were found in a small number of animals in one group only, i.e., sarcoma of the uterus in the top-dose group and leiomyosarcomas of the small intestine in males of the mid-dose group. There was, however, no statistically significant difference in incidence of any tumour type between test groups and controls, and no relationship between dose and tumour incidences was seen.	See open point in comment 2(1) and comments 2(15) , 2(19) and 2(21).

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2(17)	Vol. 1, 4.6, and Vol 3, B.6.6 reproductive toxicity	Aug 04 NOT: The DAR volume 1 concludes that new teratogenic studies in rat and rabbit are required with histopathological examination of the gastro-intestinal tract of the mothers. We respectfully request consideration of the following changes to the Reproductive Toxicity section of the captan monograph. **Reproductive toxicity studies** The NOAEL for pup body weight in the 3-generation reproductive toxicity study and one-generation reproductive toxicity studies is revised to 25 mg/kg bw/day, supported by evaluation of the study methodology for data collection and analyses, and the lack of effects in the one-generation study at that dose level. This dose level is equivalent to the parental NOEL, demonstrating a lack of unique susceptibility of the young to captan toxicity. Using 12.5 mg/kg bw/day as the NOEL for pup toxicity (and the basis for the captan ADI) provides a very conservative additional margin of safety for risk extrapolation. **Developmental studies** We concur with the RMS reviewer that the axial abnormalities observed at maternally	Sept 04 RMS: REPRODUCTIVE TOXICITY STUDIES: The NOEL of 12.5 mg/kg bw/day appears more appropriate than 25 mg/kg bw/day considering that in the three generation study the mean pup weight in 25 mg/kg bw/day group resulted CONSTANTLY lower than the pup weight of controls and considering that this constant decrease in pup weight was confirmed (even if never the statistical significance was reached) by the one generation study. **DEVELOPMENTAL STUDIES**: The data from the rabbit study performed by Tinston support a developmental NOAEL of 10 mg/kg bw/day as at 30 mg/kg bw/day the incidence of major skeletal defects as well as abnormalities probably related to the maternal imbalance on nutrient absorption was increased. The NOEL of 25 mg/Kg bw/day for the Palmer et al. study was set on the basis of effects on uterine, litter and foetal weight as well as on decrease of crown-rump lenght.	Open point MS to discuss the highest relevant NOAEL in the reproductive toxicity studies at an expert meeting. Data requirement Notifier to submit the position paper “Comments on captan Monograph Volume III” for RMS to provide a summary in an addendum. See also comments 2(7) and (18). Evaluation Meeting (14.-15.12.2004): Data requirement: The position paper already has been submitted to the RMS. Data requirement still open. Open point:

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2(17)	*continued* Vol. 1, 4.6, and Vol 3, B.6.6 reproductive toxicity	toxic dose levels in several captan developmental toxicity studies may be related to the maternotoxic effect elicited by captan on the gastrointestinal tract. In addition to the noted irritant action of captan on the gastrointestinal mucosae, high bolus gavage doses of captan are likely to adversely affect the intestinal flora, leading to nutrient malabsorption or deficiencies. The data from the rabbit studies support a developmental NOAEL of 30 mg/kg bw/day for the Tinston study and a developmental NOEL of 60 mg/kg bw/day for the Palmer et al. study, respectively. A weight-of-the evidence evaluation of the rabbit developmental toxicity studies concludes the malformations seen in the Tinston rabbit study are not related to treatment with captan, based on the nature of the findings in the Tinston study and the absence of treatment-related malformations in either the Rubin or Palmer *et al* studies. Further, distribution of captan to the foetus is considered unlikely because of the very short half-life of captan in aqueous media, and the primary metabolite THPI produced no malformations in two supplementary teratogenicity evaluations in rabbits.		Open point confirmed. Open point still open.

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2(17)	*continued* Vol. 1, 4.6, and Vol 3, B.6.6 reproductive toxicity	**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. **Response to the Requirement for Further Reproductive or Developmental Toxicity Studies of Captan** The existing database provides adequate information regarding the reproductive and developmental toxicity of captan to permit informed and conservative risk assessment. For reproductive toxicity evaluation, we concur with the RMS reviewer that in cases where the studies are not congruent with existing guidelines, the absence of any evidence of reproductive toxicity in a study producing overt toxicity to the parental animals suggests no additional useful information would be obtained from further		

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2(17)	*continued* Vol. 1, 4.6, and Vol 3, B.6.6 reproductive toxicity	studies. For developmental toxicity evaluation, we respectfully disagree with the reviewer that additional useful information would be obtained through replication of the rat and rabbit developmental toxicity studies, and that animals and resource expenditure in such an effort is therefore not justifiable. The basis for our conclusion is that: • Existing studies comply with Guidelines in effect at the time the studies were performed, and provide information on the most critical elements in current Testing Guidelines. • NOELs are available for all endpoints of concern, • Captan does not show unique evidence of developmental susceptibility, and a weight-of-the evidence evaluation does not support a concern for teratogenicity. The one remaining question is that the postulated mechanism for maternotoxicity resulting in the axial respecifications observed in several developmental studies		

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2(17)	*continued* Vol. 1, 4.6, and Vol 3, B.6.6 reproductive toxicity	of captan at maternally toxic dose levels has not been clearly demonstrated in the existing data. If this mechanism were confined to nutritional deficiencies resulting from gastrointestinal irritation, it could possibly be demonstrated through histopathological evaluation of the maternal gastrointestinal tract. However, it seems likely that the bacteriostatic action of captan when administered in high gavage doses also plays a significant role in subsequent maternal nutrient deficiencies, contributing to the axial respecifications observed in some studies of captan. Such a mechanism would not be possible to demonstrate in a conventional developmental toxicity study, and it is difficult to conceive of a study design to adequately test this mechanism. Direct evidence of bacteriostatic action of captan is available in the published literature. Indirect evidence may be inferred by contrasting the rat developmental toxicity study, in which axial respecifications were seen after high dose gavage administration, with the developmental phase in the 3-generation study, in which no treatment related anomalies were evident after dietary administration (even at maternally toxic doses).		

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2(17)	*continued* Vol. 1, 4.6, and Vol 3, B.6.6 reproductive toxicity	Based on these factors, we believe no useful information would be gained from further developmental toxicity studies of captan. Full and detailed comments on all aspects on the reproductive toxicity and teratogenicity of captan are presented in a position paper "**Comments on Captan Monograph Volume III"**. The position paper will be included in the addendum to be submitted to the RMS. Based on several factors (see column 3), we believe no useful information would be gained from further developmental toxicity studies conducted with captan.		
2(18)	Vol. 3, B.6.10, Summary of mammalian toxicology and proposed ADI, AOEL and ArfD	Aug 04 UK: We would propose the ADI, AOEL (LT+ST) and ARfD to be 0.1 mg/kg bw/day. All derived from the rabbit teratology study NOAEL for developmental effect (10 mg/kg bw/day +SF of 100) (Tinston, D.J. 1991). Developmental effects however are not	Sept 04 RMS: see points 3, 4, 10. We agree to lower the AOEL to 0.1 mg/kg bw, based on the NOEL for maternal and developmental toxicity in the teratogenicity study in rabbits	Open point MS to agree on the AOEL value at an expert meeting. See also comments 2(5) and 2(10).

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2(18)	*continued* Vol. 3, B.6.10, Summary of mammalian toxicology and proposed ADI, AOEL and ARfD	serious enough to warrant further investigation, and might be expected given the level of maternal toxicity seen. RMS bases ADI and AOEL on a NOAEL (12.5 mg/kg bw/day) from the 1 gen rat study based on reduced pup weight at 25 mg/kg bw/day. However the reduction is only just discernible in this study, and in the 3 gen rat study at 25 mg/kgbw. It is not of a magnitude that can be considered adverse (hence UK propose NOAELs of 25 mg/kg bw/day for these studies).		Open point The RMS to present new exposure calculations in an addendum, to be discussed at an expert meeting. See also comments 2(5) and 2(10). Regarding setting of ADI and ARfD, see open points 2(3) and 2(4). Regarding setting of NOAEL for the reproductive toxicity studies see open point 2(17). Evaluation Meeting (14.-15.12.2004): Both open points confirmed. Open points still open.

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2(19)	Vol. 3, B.6.10, Summary of mammalian toxicology and proposed ADI, AOEL and ArfD	Aug 04 UK: In the overall summaries, RMS discounted duodenal tumours from the risk assessment saying they were not related to treatment (based on a re-evaluation of archived material). We have previously considered the same data, and concluded that the mechanism was non-genotoxic and driven by captan mediated inflammation. We propose that the duodenal tumours and the relevance to man be considered expert committee/panel at European level.	Sept 04 RMS: We do not support the proposal since we believe that the evidences based on the studies on the mechanism of action already had clearified that the tumours are not relevant to man	See open point 2(1) and comments 2(15), 2(16) and 2(21).
2(20)	Vol. 3, B.6.10, Summary and proposed ADI, AOEL, **ARfD**	Aug 04 NL: It is not described how the ARfD was derived. It seems that acute effects are not expected after a single dose, so it should be discussed whether it is necessary to derive an ARfD for captan.	Sept 04 RMS: Noted	See open point in comment 2(3) and comments 2(10) and 2(18)

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2(21)	Vol. 3, B.6.10, Summary and proposed ADI, AOEL, ARfD; **mode of oncogenic activity in the mouse**	Aug 04 NL: It is not clear whether the saturation of detoxification or possible genotoxicity is the mechanism of tumour formation in the duodenum in the mouse. Saturation of detoxification does not explain the species difference: no tumours are formed in the rat. NL proposes to discuss this in an expert meeting.	Sept 04 RMS: An expert committee/panel at European level is considered an appropriate forum to discuss these issues.	See open point in comment 2(1) and comments 2(15), 2(16) and 2(19).
2(22)	Vol. 3, B.6.12 Dermal absorption, study a), the *in vivo* study	Aug 04 NL: This study has several shortcomings. The treated skin area is not specified. Measurements were performed after 1, 2, 4, or 8 h of exposure and not again after e.g. 24 h. It cannot be concluded whether captan remaining in the skin (dermal depot) may be absorbed after 8 h. Recovery is not measured or not presented (should be 100 ± 10%). Presentation of the study is too minimal; not enough detail is described to evaluate the results. No conclusions can be drawn based on this study. A new *in vivo* study according to the Guidance Doc. should be considered.	Sept 04 RMS: The *in vivo* rat study by Adir (1982), shows a maximum 10% absorption. Integrating these data with the *in vitro* studies gives an estimate of 3% dermal penetration. Under the conditions of the *in vivo* study, rats absorbed a maximum of 6.4 - 9.0 % of the applied doses (0.5 mg/rat and 5.0 mg/rat) of captan within 2-4 hrs of its application. The absorbed radioactivity did not increase between 4 and 8 hours of dosing, indicating that penetration had reached a plateau, and suggesting that no further significant absorption may occur between 8 and 24 hours.	See open point in comment 2(6) and comment 2(23).

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2(22)	*continued* Vol. 3, B.6.12 Dermal absorption, study a), the *in vivo* study		The treated skin area was of 4 squared inches (16% of the rat surface area) and was kept unoccluded to simulate exposure through the uncovered skin of applicators and harvesters. Recovery is in the range 93.0% to 101.0% of applied radioactivity. The values for absorption are not based on radioactivity per unit area, but are expressed as percentage penetration of applied radioactivity, independent of area. The two dose levels were an order of magnitude apart (0.5 mg/rat and 5.0 mg/rat), and the similarity in the average values for percentage dermal penetration of radioactivity (6.4 and 9.0 % of each dose level applied) indicate that the process was approximately linear and was not saturated. The 5 mg/rat dose level was calculated to represent twice the estimated exposure of a worker mixing and loading the formulation at an orchard site, based on a human exposure study. Therefore, the value of 10% is considered conservative. Comparison of rat and human *in vitro* data shows that the rat is a poor model for dermal	

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2(22)	*continued* Vol. 3, B.6.12 Dermal absorption, study a), the *in vivo* study		penetration in man (100:1 ratio in dermal penetration between rat and human for the technical material). Repeating an *in vivo* study would not improve the assessment of dermal penetration in humans: any advantage in obtaining an arguably more accurate value for rats would be outweighed by the margin of error in estimating the species differences between rats and humans. A new *in vivo* study would be a needless repetition of experiments on vertebrate animals, and contrary to EU Dir. 86/609/EEC. The ratio in dermal penetration between rat and human skin *in vitro* varies from 100-fold (technical material) to 10, 5, and 3 times for varying concentrations of spray dilutions. The selected rat:human ratio of 3 represents a worst-case, and can be considered protective.	

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2(23)	Vol. 3, B.6.12, Dermal absorption	Aug 04 DE: With regard to the deficiencies in the in vivo study in rats, a dermal absorption rate of 9 % is proposed as a worst-case assumption.	Sept 04 RMS: see previous point	See open point in comment 2(6) and comment 2(22).
2(24)	Vol. 3, B.6.14.1.1, text below Table B.6.14.1.1.1: use of the UK predictive operator exposure model (POEM)	Aug 04 UK: The statement that 'the German model based on geometric mean values is considered appropriate for EC regulatory use' appears in PSD's guidance document for the German Model not the guidance document for the UK POEM as stated here. The current version of the UK POEM (with exposure data for mixing and loading solid formulations) is an appropriate model to use (in addition to the German model) in this DAR.	Oct 04 RMS: We agree	Addressed RMS to consider in a revised DAR or corrigendum.
2(25)	Vol. 3, B.6.14.1.2, text below Table B.6.14.1.3.1	Aug 04 UK: Based on the results of the operator monitoring study, it is considered necessary for operators to wear coveralls in addition to protective gloves when handling and applying the product.	Oct 04 RMS: It is agreed. Moreover, risk estimates of operator exposure should be refined, taking into account the new AOEL of 0.1 mg/kg bw (assuming 3% dermal penetration).	See open points in comments 2(18) and 2(27).

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2(26)	Vol. 3, B.6.14..2, bystander exposure	Aug 04 UK: The bystander exposure estimate, based on published drift data, does not take into account inhalation exposure. It may be more appropriate to base this risk assessment on simulated bystander exposure studies which are available for orchard and field crops.	Oct 04: RMS: see 2 (22) Captan has a low vapour pressure (lower than 4.0×10^{-6} Pa at 20 C°), therefore inhalation risk is negligible.	Open point The risk for bystanders should be discussed in an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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2(27)	Vol. 3, B.6.14..3.1, estimation of worker exposure, 2nd paragraph	Aug 04 UK: The only PPE considered in the operator exposure estimate for orchard crops was gloves during mixing and loading, not respiratory protective equipment as stated here.	Oct 04: RMS: We agree	Open point The RMS to clarify which PPE that was included in the operator exposure calculations, together with open point 2(18). See also comment 2(25). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
2(28)	Vol. 3, B.6.14..3.1, estimation of worker exposure	Aug 04 UK: No detailed information has been provided about the study in which dislodgeable residues of captan were measured on peach foliage. More details are required to demonstrate that these data are valid and to justify their use in the worker exposure calculation (for example, to demonstrate that the decline of foliar residues measured in the Californian study is representative of that likely to occur under typical European conditions.	Oct 04: RMS: the measured residue value of 10.5 µg captan cm2 (equivalent to the value of 2.3 µg captan x kg a.s. applied used in the risk assessment for workers) was measured 7 days after the application on 31 march 1992. On the day of application the air temperature was 14°C and irrigation was applied to the crop 3 days after application. In the EU, captan is applied to orchard crops from the end of flowering onwards (peaches, pome fruit in South	Addressed

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2(28)	*continued* Vol. 3, B.6.14..3.1, estimation of worker exposure		EU) or from inflorescence emergence onwards (pome fruit in North EU). The weather conditions recorded in California in March-April when the trial was conducted are similar to those that would occur from Spring onwards in the EU	
2(29)	Vol. 3, B.6.14..3.1, estimation of worker exposure	Aug 04 UK: Although the worker exposure estimate indicates that the risk to harvest workers will be acceptable when protective gloves are worn, it is not considered appropriate to assume that harvest workers will wear protective equipment other than that used routinely during all harvesting tasks. In practice, harvest workers are unlikely to know what products have been applied to the crop or what precautions should be taken as a result.	Oct 04: RMS: On the basis of the worker exposure study, the exposure of workers without PPE does not exceed the new AOEL of 0.1 mg/kg bw.	See also open points in comments 2(18) and 2(30).

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2(30)	Vol. 3, B.6.14..3.2, measurement of worker exposure	Aug 04 UK: It is not clear how the values in Table B.6.14.3.2.2 relate to those in Table B.6.14.3.2.3 Specifically, it is not clear whether the values in Table B.6.14.3.2.2 relate to individual patch samples or whether they have been corrected for the surface area of the associated body part. Also, it is unclear whether the values in Table B.6.14.3.2.3 are based on the inner or outer samples (or a combination).	Oct 04: RMS: The values in Table B.6.14.3.2.3 are derived by multiplying the values measured on the patches by body surface area. The totals are derived from the addition of exposure of uncovered body parts (face, back of neck, chest, and hands) plus covered body parts (head, trunk, arms, legs and feet).	Open point 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 also open point 2(18) and comment 2(29) and 2(31). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
2(31)	Vol. 3, B.6.14..3.3, overall assessment of worker exposure	Aug 04 UK: It is unclear whether the values presented in Table B.6.14.3.3.1 (and the following risk assessment) are based on measurements from the inner or outer patches (or a combination). If the risk assessment is based on the inner patch measurements, these reflect the clothing worn in the study ('polyester-cotton shirts	Oct 04: RMS: The values in Table B.6.14.3.3.1 are derived from the addition of exposure of uncovered body parts (face, back of neck, chest, and hands) plus covered body parts (head, trunk, arms, legs and feet). Forearms and legs account for a relatively small part of the total exposure, therefore the	See open points 2(18) and 2(30) and comment 2(29).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(31)	*continued* Vol. 3, B.6.14..3.3, overall assessment of worker exposure	and jeans'). In many situations it is likely that harvest workers may wear clothing which leaves the arms and legs uncovered and, in such situations, a risk assessment assuming a complete layer of clothing may not be appropriate.	exposure is unlikely to exceed the AOEL. The notifier should recalculate exposure from the original data, using the new AOEL of 0.1 mg/kg, and assuming uncovered arms and legs	
~~2(32)~~	~~Vol. 3, B.6.12 Dermal absorption, study a), the *in vivo* study~~	~~Aug 04~~ ~~NL: This study has several shortcomings. The treated skin area is not specified. Measurements were performed after 1, 2, 4, or 8 h of exposure and not again after e.g. 24 h. It cannot be concluded whether captan remaining in the skin (dermal depot) may be absorbed after 8 h. Recovery is not measured or not presented (should be 100 ± 10%). Presentation of the study is too minimal; not enough detail is described to evaluate the results. No conclusions can be drawn based on this study. A new *in vivo* study according to the Guidance Doc. should be considered.~~	~~Sept 04~~ ~~RMS: see points 22~~	Duplicate (see 2(22))

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(33)	New open point Based on written comments from GR (03-11-2004)			Evaluation Meeting (14.-15.12.2004): Acceptability of the genotoxicity studies to be clarified by the RMS. If they are not acceptable they should be deleted fom the reference list. New open point set.
2(34)	New open point Based on written comments from GR (03-11-2004)			Evaluation Meeting (14.-15.12.2004): The genotoxic effect of Captan to be clarified by the RMS and to be discussed at an Expert Meeting. New open point set.

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2(35)	New open point Based on written comments from GR (03-11-2004)			Evaluation Meeting (14.-15.12.2004): 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. New open point set.
2(36)	New open point Based on written comments from GR (03-11-2004)			Evaluation Meeting (14.-15.12.2004): RMS to review the study mentioned in the comment from GR (Mills PK, 1998 and MCDuffie HH et al, 2001) regarding medical data. New open point set.

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2(37)	New data requirement Based on written comments from GR (03-11-2004)			Evaluation Meeting (14.-15.12.2004): Notifier to submit the two rat carcinogenicity studies by Goldenthal et al., 1982 and Bruyntjes, 1984. The notifier plan to submit the studies to the RMS during mid March 2005. RMS to evaluate and present summary in an addendum. New data requirement set

3. Residues

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(1)	Vol. 1, Appendix 3 (listing of end points), chapter 4 (residues), summary of critical residues data (… MRL, STMR), page 69	Aug 04 AT: Concerning peaches and nectarines: The MRL-value of "5 mg/kg" seems to be under-estimated, if you take the trial results into consideration (e.g. "1x 5,6" and "1x 4.9" mg/kg). According to R_{ber} - and R_{max} - calculation (EC-document 7039/VI/95 EN) a MRL of "10 mg/kg" would be proposed, unless there is an additional justification. Concerning apples and pears: In our opinion the data of North-EU and South-EU should be treated separately. The STMR-value (peaches/nectarines) should be "3.6 mg/kg" and not "3.7 mg/kg", if the given trial results are correct. The STMR-value (tomatoes) should be "0.22 mg/kg" and not "0.28 mg/kg", if the shown datas are correct. The amounts of applied active substance are strong different between North and South Europe (approximately two times higher) and the values of determined parent	Sept 04 RMS: As reported in Vol 3, page 76, we are aware that according to Rmax, MRL is 10 mg/kg. We proposed 5 mg/kg because 10 mg/kg is excessive if compared to the existing EU-MRL of 2 mg/kg, and because all the measured values but one are below 5 mg/kg. We feel 5 mg/kg more appropriate to protect consumer (higher MRL do not affect NEDI and risk assessment but might increase improperly exposure of the consumer). However, since all the experts who presented comments agree on an MRL of 10 mg, we accept this position and we will amend DAR accordingly. **Peaches and nectarines: MRL =10 mg/kg** 3.6 and 0.28 mg/kg are correct. STMR was calculated as the residue value in position (0.5 (n+1)). Apple and pear: after exclusion of the outlier, mean and median for north and south are similar. We think that there is no means in considering the data separately	Open point 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. (Note: for STMR calculations the rule is to calculate the average of the 2 median values of an even number of data points) 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

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(1)	*continued* Vol. 1, Appendix 3 (listing of end points), chapter 4 (residues), summary of critical residues data (… MRL, STMR), page 69	compounds are considered similar. (Maybe caused by different speed of metabolic pathway and therefore different determined metabolites).		Note 1 : For pome fruits, considering comment 3(11), it is propose to carry out intake calculations considering a MRL of 10 mg/kg as worst case scenario. Note 2: It must be kept in mind that the ADI value is still under discussion (see comment 2(4)) <u>Evaluation Meeting (14.-15.12.2004):</u> Open point confirmed. Open point still open.
3(2)	Vol 3, B.7.1, metabolism, distribution and expression of residues in plants	<u>Aug 04</u> UK: we note that the level of uncharacterised material in apple peel and pulp increases with increasing time period after application. Whilst the proposed metabolic pathway suggests that the residues are incorporated into natural products this can only be conjecture as the metabolism study doesn't offer any data confirming this,	<u>Sept 04</u> RMS: Uncharacterised material (UM) represents presumably 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	Open Point 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

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(2)	*continued* Vol 3, B.7.1, metabolism, distribution and expression of residues in plants	although the levels of identified metabolites are largely consistent over time with only the uncharacterised material increasing. However, we consider that a more robust case needs to be made to address the high levels of uncharacterised material in apple pulp and peel	low in fruit wash and foliage, increase in peel and is maximum in pulp. Moreover, considering the data as a percent of the TRR in the whole fruit, the UM in pulp extract is 0.3% (dat 0), 1.6% (dat 20) , 5.3% (dat 50) and 13.5% (dat 80) of the TRR.	fractions…) Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
3(3)	Vol. 1, level 2, 3 and 4	Aug 04 EFSA: referring to comments about Vol. 3, section B. 7, reserves are made concerning (i) the safety of the consumer (an ARfD is proposed but acute intake calculations are not provided), (ii) the residue definition for certain processed plant products and for animal products, and (iii) the proposed MRL in peaches and nectarines.	Sept 04 RMS: i) see point 38 ii) see point 7 and 8 iii) see point 1	i) see point 38 ii) see points 7 and 8 iii) see point 1
3(4)	Vol. 1, level 4, 4.7, Residue data	Aug 04 EFSA: We agree with the proposal of the rapporteur to require: (i) An hydrolysis study in representative hydrolytic conditions, (ii) 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 and (iii) A	Sept 04 RMS: We agree	Data requirements (i) A hydrolysis study in representative hydrolytic conditions, (ii) A whole balance study for tomato washed, peeled and canned or used for juice, plus a follow-up study in canned tomato and

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(4)	*continued* Vol. 1, level 4, 4.7, Residue data	balance study and 3 follow-up studies for canned peaches/nectarines		tomato juice and (iii) A balance study and 3 follow-up studies for canned peaches/nectarines Evaluation Meeting (14.-15.12.2004): (i) The notifier has already produced a position paper which has not been considered by the RMS so far. 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)"** (ii) Data already provided but not evaluated by the RMS RMS to evaluate in an addendum to be considered in expert meeting the studies provided by the notifier: "**Faessel, V. (2004). Residue study in and on tomatoes following 4 applications of**

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(4)	*continued* Vol. 1, level 4, 4.7, Residue data			**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."** (iii) The notifier intends not to conduct the requested study and will provide a statement on this issue. Data requirements still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(5)	Vol. 3, B.7.2, Metabolism in livestock	Aug 04 EFSA: As general remark, the exposure rate of animals should also be expressed in mg/kg bw/d.	Sept 04 RMS: Noted	Addressed RMS to provide a corrigendum/addendum or to consider a revised DAR if data from the dossier allow to calculate the exposure rate in mg/kg/bw
3(6)	Vol. 3, Figure B.7.2.1.1, Proposed metabolic pathway of captan in domestic animals, page 25	Aug 04 AT: A formal remark to figure B.7.2.1.1: Second line, right structure, abbreviation "4,5-diOH **HHPI**" is not congruent with the designation in Vol. 1, level 2; figure 2 (captan proposed metabolic pathway in domestic animals), page 15, structure left, upon: "4,5-diOH **THPI**"	Sept 04 RMS: 4,5-diOH HHPI is correct	Addressed. RMS to provide a corrigendum/addendum or to consider in a revised DAR
3(7)	Vol. 3, B.7.3, Residue definition	Aug 04 EFSA: Plant products: The residue definition is in line with the results of metabolism studies and is relevant for raw commodities. However for certain processed products THPI is the indicator compound while captan is below the LOQ. The need of a specific residue definition for processed commodities should be addressed.	Sept 04 RMS: We agree that since heating convert captan to THPI, THPI is a better indicator of captan in processed products were heating is required and residue definition should be captan plus THPI, expressed as captan equivalents (if no other metabolites of concern are identified following hydrolysis studies). However definition of residue in processed	Open point. MSs to discuss residue definition for processed commodities and processing yields in an expert meeting Evaluation Meeting (14.-15.12.2004): Open point confirmed.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(7)	*continued* Vol. 3, B.7.3, Residue definition		plant commodities must be considered PENDING, waiting for results of hydrolysis studies.	Open point still open.
3(8)	Vol. 3, B.7.3 pag 26 Definition of the residue	Aug 04 ES: RMS has proposed in the DAR Captan as residue definition for plants and animal commodities. According the results of the metabolism studies some metabolites (THPI and THPAM) appeared at levels that should be considered significant. The non-relevance of these metabolites in the residue definition should be clarified.	Sept 04 RMS: In domestic animals captan is rapidly metabolised following oral administration. The metabolism of captan in domestic animals and in rat was similar. The breakdown of the trichloromethyl moiety to elemental carbon is of no toxicological significance. The metabolites from the imide portion of the molecule are rapidly excreted. There is no evidence that these metabolites accumulate in tissues. From their presence in the rat metabolism studies, it can be inferred that the metabolites formed were also generated following administration in the orally-dosed toxicology studies, i.e. the *in vivo* toxicology studies and *in vitro* mutagenicity studies, where there was metabolic activation. There were no indications of adverse effects on short-term, medium term, long-term or reproductive toxicity. The metabolites arising from the imide portion of the molecule doesn't seem therefore of toxicological concern. Therefore, the most appropriate definition of	See open points in comments 3(7) and 3(9)

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3(8)	*continued* Vol. 3, B.7.3 pag 26 Definition of the residue		the residue in domestic animals is captan alone (see also point 9).	
3(9)	Vol. 3, B.7.3, Residue definition	Aug 04 EFSA: Animal products : The residue definition for animal products as currently proposed does not seem appropriate as captan is not an indicator compound due to its extensive metabolisation. The metabolite 3-OH THPI represents a better candidate for residue definition in animal products (except for poultry were THPI is more relevant).	Sept 04 RMS: See point 8 Moreover, we don't think that any captan metabolite should be a good indicator for captan in animal commodities. No THPI, because it is a major metabolite in hen (but captan is not used on any crops which are fed to hens) but not in goat, no 3-OH or 5-OH because they seem transient metabolites rapidly transformed into hydroxilated THP metabolites and incorporated into natural products.	Open point. MSs to discuss in an expert meeting the residue definition for animal products. Open point. RMS to provide in an addendum informations in column 3 of comments 3(8) and 3(9) for support of discussion Evaluation Meeting (14.-15.12.2004): Open points confirmed. Open points still open.
3(10)	Vol. 3, B.7.6.1, residue trials in pome fruits	Aug 04 EFSA: We suppose that apples were frozen as whole fruits.	Sept 04 RMS: Yes	Addressed.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(11)	Vol 3, B.7.6., residues resulting from supervised trials	Aug 04 UK: It would be more transparent if all the residue trials were included in the DAR and then a clear indication of those not to be considered valid would be presented together with the justifications. Although, the 8.0 mg/kg residue on apple is considered by the RMS an outlier, the DAR indicates that this was a valid trial. In the absence of any reason to do otherwise, this residue must be considered as a true residue, i.e. one that was (and could be) found from such a use. In the Southern Member State use on apples, a residue of 8.0 mg/kg has been stated to be an outlier. However, we consider that this residue should only be excluded if a valid reason or problem has been identified with the trial (for example double application). In the absence of such information, it is unclear why this should be considered anything other than a real situation. Were the apples of very small size perhaps because the residues at 21 days were also significantly higher than the other trials	Sept 04 RMS: 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) (see Vol 1, "Summary of critical residue data"). There is no obvious reason to exclude the 8 mg/kg value, however, this value is clearly out of step with all other residue values in apples and pears in north and south EU.	Open point MSs to discuss the reliability of the residue of 8.0 mg/kg in pome fruits in an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(12)	Vol 3, B.7.6.1, Residues resulting from supervised trials, pome fruit	Aug 04 UK: Trials for apple and pear in the North should be separated for clarity. There are a total of 10 trials for apple and pear in the North. Eight of the trials are for apple with 2 trials for pear.	Set 04 RMS: Noted	Addressed. RMS to provide a corrigendum/addendum or to consider in a revised DAR where results for pears and apples are clearly identified.
3(13)	Vol 3, B.7.6.1, Residues resulting from supervised trials, pome fruit	Aug 04 UK: There are only 5 trials for apple in South EU. This is the critical GAP and therefore a further 3 trials for Southern Member States are required.	Set 04 RMS: For apple and pear were used extrapolations to the whole group, according to EU regulations (EC document 7039/VI/95 EN, Appendix D). We feel there are enough data for MRL and STMR calculations and we do not think there is a need for further SRTs for pome fruits.	Addressed
3(14)	Vol 3, B.7.6.1, Residues resulting from supervised trials, pome fruit	Aug 04 UK: There are only 3 trials for Pear in Southern Member States. Extrapolation from apple trials in SEU would support the pear use. However, residues in the limited number of pear trials were much lower than seen in the 5 apple trials. Like apple, but based on an even more limited data set (2 NMS plus 3 SMS trials), residues in southern MS pears were slightly higher than the North	Set 04 RMS: See point 13	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(15)	Vol 3, B.7.6., residues resulting from supervised trials	Aug 04 UK: We consider that the choice of residue from each trial requires further consideration. Some trials have been omitted without justification and in some trials samples taken at slightly longer PHI's gave higher residues and in such cases the highest residue, not residue closest to intended GAP should be used. We have appended suggested residues values for assessment and they are highlighted **bold and underlined**. In many cases they are the same as suggested by the RMS. This is consistent with EFSA advice received in relation to the metrafenone DAR. Clearly any change in the residue values used to reflect GAP in the trials will have an effect on other areas, risk assessment and MRLs. We append our proposals for the STMR, HR, $R_{(max)}$, $R_{(ber)}$, and subsequent MRL in the hope this will be of assistance to the RMS	Sept 04 We have omitted only trials not performed according to intended GAPs and we provided always a (brief) justification for omissions (see texts, Vol 3, B.7.6). Our understanding of regulations (EC document 7039/VI/95 EN, Appendix I) for MRL and STMR calculation, is that residue values closest to the intended GAPs should be used. We have no problems, following specific advice from EFSA, to change our interpretation, however it doesn't seem that this would change the figure. Among 34 values, in 29 cases UK proposes the same as suggested by us, and in the remaining 5, there is only 1 case were the difference is"significant" (6.3 instead of 4.9 mg/kg in peaches). For the moment we will keep results from our previous calculations.	Addressed

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3(16)	Vol. 3, B.7.6.4, Stability of residues prior to analysis.	Aug 04 EFSA: Strong indications are present showing that captan is not always stable under storage. The rapporteur should update his conclusions about study under point a) (McKay, JC 1990) when recovery data for captan and THPI separately will be available.	Sept 04 RMS: Stability of captan in raw and processed commodities is an important point. As reported in Vol 3 (below table B.7.6.4.1) from the original study submitted by the Notifier it is not clear if stability data refer to captan or to the sum captan plus THPI. Notifier is request to clarify stability data for captan in raw and processed commodities, providing stability data for captan and THPI separately . If not available new experimental data are required.	Data requirement. 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 also comments 3(17), 3(18) and 3(19). Evaluation Meeting (14.-15.12.2004): The notifier will provide a clarification by mid of April 2005 to the RMS. Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(17)	Vol. 3, B.7.6.4, Stability to residues prior to analysis, a (Captan and THPI …), page 36 and 37	Aug 04 AT: The claimed completeness of the storage stability study (various crops), "McKay, JC 1990, II A, 6.3/01", is not designated in Vol. 1, Level 4, point 4.7 (Residue data), page 49	Sept 04 RMS: As reported in Vol 3 (below table B.7.6.4.1) the storage stability study submitted is INCOMPLETE. We failed to report it in Vol 1 Level 4	See data requirement in comment 3(16)
3(18)	Vol 3, B.7.6.4c, stability of residues prior to analysis-peaches	Aug 04 UK: The finding that captan residues were stable in peaches when not in contact with the juice suggests the juice is reacting in some way. Captan is not stable in alkaline media – was any evidence presented on the pH of peach juice?	Sept 04 RMS: No. pH values were not presented.	See data requirement in comment 3(16)
3(19)	Vol. 3, B.7.6.5, Summary assessment.	Aug 04 EFSA: Conclusions given about the storage stability in particular for processed products from apples and tomatoes are not acceptable for the time being without demonstration by experimental data.	Sept 04 RMS: Correct. See point 16 and point 17.	See data requirement in comment 3(16)
3(20)	Vol. 3, B.7.7, Effects of processing.	Aug 04 EFSA: Metabolite THPI was determined in all submitted processing studies and results should be reported in the DAR. This metabolite may be present at high	Sept 04 RMS: See point 7. When hydrolysis studies will be available, a residue definition for processed commodities will be formulated and new	Open point. RMS to provide an addendum with summary table of the processing studies where TPHI data are included to be

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(20)	*continued* Vol. 3, B.7.7, Effects of processing.	levels in commodities resulting from a process involving a heating step. The relevance of establishing a specific residue definition or specific processing or yield factors for these commodities should be addressed.	tables proposed	discussed in an expert meeting Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
3(20a)	Vol. 3, B.7.7 (effects of industrial processing), B.7.7.1 (effects on the nature of the residue), page 43	Aug 04 AT: According to the mentioned data requirements - especially after integration of the results of specific processing studies - a terminal residue definition will be possible. Maybe a recalculation (e.g. including of risk relevant metabolite in the provisional residue definition) of the risk assessment is necessary. For terminal determination of the residue definition a complete data set (also including from relevant processed food) is needed. In the list of endpoints (Vol. 1, appendix 3, chapter 4) the residue definition should be stated as provisional.	Sept 04 RMS: Correct. See point 7 If changes will be introduced, RA will be recalculated accordingly.	Open point. RMs to discuss on how the risk assessment specifically for processed commodities is to be carried out in an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(21)	Vol 3, B.7.7, effects of industrial processing	UK: For processing studies where residues are below the limit of quantification, it is difficult to derive precise processing factors.	Sept 04 RMS: When values are below the LOD, we think appropriate to consider value = LOD	Open point. 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. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
3(22)	Vol. 1, 4.7, and Vol 3, B.7.7.1 effects of processing on the nature of the residue	Aug 04 NOT :The DAR Volume 1 concludes that a hydrolysis study in representative hydrolytic conditions is required. It is concluded that sufficient data already exist to predict the effect of processing hydrolysis on the nature of the residue and therefore new studies are not required. Several hydrolysis studies with captan and THPI have already been conducted. The	Sept 04 RMS: Specific hydrolysis studies are required in specific pH and temperature conditions. Such studies, in such conditions, are not available and therefore are still required. See also comment from EFSA, point 4. We will examine the mentioned position paper when available.	Open point; 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)"** Evaluation Meeting (14.-15.12.2004):

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(22)	*continued* Vol. 1, 4.7, and Vol 3, B.7.7.1 effects of processing on the nature of the residue	studies cover a range of pH values and include high temperatures. The studies already conducted are considered to be adequate to evaluate the effects of processing. In the studies, captan degraded rapidly to THPI, and THPI was stable to hydrolysis under acid conditions. Further studies under simulated processing conditions would only provide data on the rate of formation of the known degradation products, the route of degradation will not be affected. Therefore, it is concluded that during simulated processing studies conducted at acid pH potentially toxic metabolites of captan will not be formed and additional studies are not required. The requirement for a new study and the response to the data requirement is fully addressed in the following position paper: **"Captan. Position Paper on Effects on the Nature of the Residue (2004)".** Will be included in the addendum to be submitted to the RMS.		see data requirement (i) under comment 3(4)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(23)	Vol. 3, B.7.7.2, Effects on the residue levels, Table B.7.7.2.3 (Residue of captan in processed apple …Germany 1991) and Table B.7.7.2.4 (Residue of captan in processed apple …USA 1986), page 46 (linked to page 44)	Aug 04 AT: With regard to Table B.7.7.2.3: Available PHI-data should be included in the graphical presentation [and text, page 44, paragraph 2 (“In Germany in 1991 …..”)]. With regard to Table B.7.7.2.4, head, column 2 (“Application”), subcolumn 3 [“residue (mg/kg)”]: In context with page 44, paragraph 3 (“In the USA in 1986 …”) the above mentioned subcolumn should be titled as ”**kg a.s./ha**” instead of “**residue (mg/kg)**”.	Sept 04 RMS: Correct. The table will be amended (minor point)	Addressed. RMS to provide a corrigendum/addendum or to consider a revised DAR
3(24)	Vol. 3, B.7.7.2, Effects on the residue levels, page 48	Aug 04 AT: Page 48 is not staffed. Maybe a formatting error?	Sept 04 RMS: Noted	Addressed
3(25)	Vol. 3, B.7.7.2, Effects on the residue levels, Table B.7.7.2.6 (Transfer factor values …processed apple …) and succeeding text, page 49	Aug 04 AT: The left and right side of the mentioned table and the succeeding text (left part) are such destructed, so the information is imperfect. Editorial error!	Sept 04 RMS: Noted	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(26)	Vol. 3, B.7.7.2, Effects on the residue levels, page 49, last paragraph ("In two studies in Germany in 1991 …")	Aug 04 AT: There is a great difference between the residue values of captan in cold pomace ["..up to 81 % of residues from the washed fruit .." (apples)] and in warm pomace ["..up to 1.2 % of residues from the washed fruit .." (apples)], which should be explained. Page 49, last paragraph, last sentence: Instead of "Up to 38 % of residues ……(Table B.7.7.2.7)", it should be written "Up to 38 % of residues ……(**Table B.7.7.2.8**)" See also next page 50, paragraph 1 and 2 (each last sentence): The cited Tables should be corrected.	Sept 04 RMS: The production of cold juice/cold pomace involves centrifugation. Since captan residues are predominantly on the skin, they remain in the pomace. The production of warm juice involves boiling which converts the captan to THPI. THPI is extracted from the skin and equally distributed into juice and pomace. Agree with the other comments	Addressed RMS to provide a corrigendum/addendum or to consider a revised DAR including the comments in column 3.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(27)	Vol. 3, B.7.7.2, Effects on the residue level.	Aug 04 EFSA: In table B.7.7.2.3, it should be clarified what must be understood as 'warm apple juice' and 'cold juice'	Sept 04 RMS: In report R-7588/ TMN-0572 (IIA 6.5.2/ 05): 'Warm' juice was obtained from apples using a steam juice extractor by boiling with water and then draining the juice leaving the 'warm' pomace. 'Cold' juice was obtained by a Braun juice extractor. The centrifuged juice was collected leaving the 'cold' pomace	Addressed RMS to provide a corrigendum/addendum or to consider a revised DAR including the comments in column 3.
3(28)	Vol. 1, 4.7, and Vol 3, B.7.7.2 effects of processing on residue levels	Aug 04 NOT: The DAR Volume 1 concludes that new processing studies (1 balance plus 1 follow up study) in tomato are required. New processing studies are available, Report RF A3154 (balance study), Report RF A3156 (follow-up study) and Report RF A3153 (validation of the analytical method in tomato processed fractions). In the new studies, there was no evidence of accumulation of residues of captan in the processed edible commodities. The new studies are listed below: **"Faessel, V. (2004). Residue study in and**	Sept 04 RMS: Summary of the new studies have been submitted very recently. They will be examined when the original studies will be presented.	Open point. Notifier/RMS to indicate whether THPI was analyzed in the new studies in the evaluation meeting. RMS to provide an evaluation of these studies in an addendum to be considered in an expert meeting. Evaluation Meeting (14.-15.12.2004): see data requirement (ii) under comment 3(4)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(28)	*continued* Vol. 1, 4.7, and Vol 3, B.7.7.2 effects of processing on residue levels	**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."** **"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."** Will be included in the addendum to be submitted to the RMS.		
3(29)	Vol. 1, 4.7, and Vol 3, B.7.7.2 effects of processing on residue levels	Aug 04 NOT: The DAR Volume 1 concludes that new processing studies (1 balance plus 3 follow up studies) in peaches/nectarines are required. It is concluded that existing data on the effect of canning on residues of captan in apple can be used to predict residues in canned peaches and so the requirement can be	Sept 04 RMS: 1 balance study and 3 follow-up studies are still required for PF calculation. Moreover we remember that definition of residues in processed commodities is provisional. Therefore we recommend to perform the studies after terminal definition of the nature of the residue in processed commodities.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(29)	*continued* Vol. 1, 4.7, and Vol 3, B.7.7.2 effects of processing on residue levels	reduced to 1 balance study plus 1 follow up study in peaches/nectarines. 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 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.		
3(30)	Vol. 3, B.7.8, Livestock feeding studies	Aug 04 EFSA: Calculations of the potential exposure of animals should also be performed in mg/kg bw unit. More details should also be given about the calculations leading to the conclusion that no residues of captan and of its metabolites are expected in	Sept 04 RMS: Calculations will be detailed in a Table in addendum	Open point. RMS to include calculations of the potential exposure of animals by consumption of apple pomace in an addendum to be considered in expert meeting.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(30)	*continued* Vol. 3, B.7.8, Livestock feeding studies	products of animal origin.		Note 1: with regard to the question about residue definition in animal products, intake of THPI present in dry pomace should also be considered. Note 2: considering comment 3(11), calculation should be carried out considering a MRL of 10 mg/kg as worst scenario. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(31)	Vol 3, B.7.8, Livestock feeding studies	Aug 04 UK: The use of the existing EU MRL for apple (3 mg/kg) in the estimation of dietary burden for livestock should be re considered in light of the residues seen in the trials. Residues in supervised trials for apple for example exceed 3 mg/kg on a number of occasions in both Northern and Southern MS trials.	Sept 04 RMS: Correct. Calculations mentioned above (see point 30) will be performed using an MRL value of 5 mg/kg for apple	See open point in comment 3(30)
3(32)	Vol. 3, B.7.12, Proposed EU MRLs	Aug 04 EFSA: Results of Rber and Rmax calculations supporting the proposals should be given. In addition the proposal of 5 mg/kg for peaches and nectarines seems too low, considering the results of residue trials.	Sept 04 RMS: Calculations are reported in Vol 3. For MRL of peaches and nectarines see point 1	See open point in comment 3(1)
3(33)	Vol 3, B.7.12, proposed EU MRLs	Aug 04 UK: The data suggest the MRL for peaches/nectarines proposed at 5 mg/kg will be exceeded in practice. Consideration should be given to a higher MRL [$R_{(max)}$ is 8.6 and $R_{(ber)}$ is 10.6].	Sept 04 RMS: For MRL of peaches and nectarines see point 1	See open point in comment 3(1)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(34)	Vol 3, B.7.12, proposed EU MRLs	Aug 04 UK: It seems likley that the MRL for apples will be higher than 5 (we should not ignore the 8.0 mg/kg residue). Taking the HR of 8.0 mg/kg, the TMDI is likely to be >100% of the ADI. However, the NEDI calculation using the STMR will still be within the ADI even when the highest residue in the group is 8 and not 4.2 mg/kg. [$R_{(max)}$ for apple North is 4.4 and $R_{(ber)}$ is 5.1 whilst $R_{(max)}$ for apple South is 14.5 and $R_{(ber)}$ is 12.2]	Sept 04 RMS: Considering the value 8 mg/kg an outlier (see 11) all values are below 5 mg/kg. We consider the MRL of 5 mg/kg appropriate	See open point in comment 3(11)
3(35)	Vol 3, B.7.12, proposed EU MRLs	Aug 04 UK: It seems likely that the proposed MRL for tomato is supported by the data, however, the MRLs for the other crops may well need to be amended once the trials are re-examined.	Sept 04 RMS: See points 1 and 34	See open points in comments 3(1) and 3(11)
3(36)	Vol. 1, 2.4.4, and Vol 3, B.7.12 Proposed MRLs	Aug 04 NOT: The DAR proposes a MRL of 5 mg/kg for peaches/nectarines. MRL calculations to Commission Guidelines indicate 10 mg/kg is appropriate. A MRL	Sept 04 RMS: See point 1	See open point in comment 3(1)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(36)	*continued* Vol. 1, 2.4.4, and Vol 3, B.7.12 Proposed MRLs	of 10 mg/kg is proposed. The MRL for peaches is based on residue trials conducted according to the GAP which led to residues in the fruit ranging from 2.1 to 5.6 mg/kg (n = 8). Calculations according to Commission Guidelines (see Appendix 5, page 270 to 271 of DAR Volume 3) gave values of 7.5 mg/kg (Calculation Method I) and 9.6 mg/kg (Calculation Method II). Both calculations therefore indicate that a MRL of 10 mg/kg is appropriate.		
3(37)	Vol. 3, B.7.15, Estimation of potential and actual dietary exposure.	Aug 04 EFSA: On page 65 the rapporteur states that 'the TMDI for toddlers using the UK dietary model exceeds the ADI…', although the figure mentioned in table B.7.15.6 is 91% of the ADI.	Sept 04 RMS: This was a misprint. We missed to correct a previous version of the Draft: the TMDI for toddler, according to UK model, was less than the ADI. But, changing the MRL for peaches/nectarines to 10 mg/kg will change also the TMDI for toddler that will exceed the ADI. However the risk assessment will not change because the NEDI will remain lower than the ADI (new calculations will be provided in the addendum). A a final RA will be possible only when all the data will be available.	See comment open point in 3(1)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(38)	Vol. 3, B.7.15, Estimates of potential and actual dietary exposure through diet and other means, page 66 (acute exposure)	Aug 04 AT: An estimation of acute dietary risk assessment is required as an ARfD of 0.1 mg/kg b.w. is proposed.	Sept 04 RMS: An estimate of the acute dietary risk will be submitted in addendum if all the needed data will be available A preliminary estimation of acute dietary risk assessment shows NESTI values exceeding the ARfD for apple and peach/nectarines in toddler using the UK model (about 250% for apple and 400% for peach).	Open point RMS to include acute intake calculation in an addendum to be considered in an expert meeting. Note: for pome fruits calculations should be also made with 8.0 as extreme value as worst case scenario (see point 3(11)) Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(39)	Vol 3, B.7.15, Estimates of dietary exposure	Aug 04 UK: Clearly the response to suggested amendments above will impact on the risk assessments as well as considerations of potential residues in animal tissues. The UK would welcome the opportunity to comment on the amended risk assessments/MRL proposals	Sept 04 RMS: Apart the changes of TMDI, due to the change of MRL for peaches/nectarines to 10 mg/kg, for the moment the RA remains unchanged. Moreover, even taking into account values as proposed by UK, NEDI for toddler (the critical value) would not exceed 60% of the ADI. Any change would not therefore modify substantially the RA. For animals we feel captan alone the best definition of residues. However, since the definition of the residue for processed commodities is pending and the data set is incomplete, the Risk assessment presented in the DAR must be considered PROVISIONAL and a final RA will be possible only when all the needed data will be available.	See open point in comment 3(1)
3(40)	Vol. 3, B.7.15, Estimation of potential and actual dietary exposure.	Aug 04 EFSA: Estimations of acute dietary risk must be provided as soon as possible.	Sept 04 RMS: See point 38	See open point in comment 3(38)

4. Environmental fate and behaviour

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(1)	Vol 1. List of end points. PEC soil. p. 73. Application rate.	Aug 04 EFSA: GAP is 9 applications of 1.25 kg a.s./ha no 1.5 kg a.s. / ha. Please clarify and amend.	Sept 04 RMS: It is not clear. In our document the data is 1.25 kg a.s./ha We will change the text	Open point RMS to amend list of end points and clarify application rate used to calculate PEC soil. Evaluation Meeting (14.-15.12.2004): The list of end points has been amended accordingly. Open point fulfilled.
4(2)	Vol 1. List of end points. PEC ground water. p 76.	Aug 04 EFSA: Results from PELMO and PESTLA modelling should be removed since they are not relevant for the proposed GAPs and do not use agreed FOCUS scenarios. Only FOCUS PELMO results should be maintained in the list of end points.	Sept 04 RMS: See comment 80 (NOT)	Open point RMS to update list of end points with respect to PEC gw. See data requirement in comment 4(80). Evaluation Meeting (14.-15.12.2004): Open point confirmed.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(2)	*continued* Vol 1. List of end points. PEC ground water. p 76.			Open point still open.
4(3)	Vol. 1 2.5.2 Fate and behaviour in soil	Aug 04 SI: See comment 39A.	Sept 04 RMS: see point 16	See data requirements in comment 4(16)
4(4)	Vol. 1 2.5.3 Fate and behaviour in water	Aug 04 SI: See comment 39A.	Sept 04 RMS: see point 16	See data requirements in comment 4(16)
4(5)	Vol.1 List of end point – PEC (soil)	Aug 04 (SI) PECsoil calculations are in line with guidance for first tier assessment. For the method of calculation it will be sufficient to mention that first order kinetics were assumed.	Sept 04 RMS: We agree We will amend he text.	Open point 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. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(6)	Vol. 1, level 3, proposed decision	Aug 04 NL: neutral soils are widely spread in Northern Europe, in the Netherlands especially fruit trees are normally grown on more neutral (clay) soils. Therefore inclusion of annex I regarding the leaching risk of THPAM should be treated with care.	Sept 04 RMS: We agree. See comment 16	This is rather an issue of risk management than risk assessment.
4(7)	Vol.1, Annex 3, list of endpoints	Aug 04 NL: for the degradation rate we prefer individual values with the mean. If ranges are provided at least the mean and the number of values (soils) should be reported.	Sept 04 RMS: We agree. See coment 16	Open point RMS to amend the list of end points to include individual values of DT_{50} with the mean. See also comment (16) Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(8)	Vol.1, Annex 3, list of endpoints	Aug 04 NL: for sorption values the same remark as made above for the degradation rate; we prefer individual values with the mean. If ranges are provided at least the mean and the number of values (soils) should be reported. PH dependence of THPAM; absorbed should be adsorbed. Better wording is increased sorption at decreased pH.	Sept 04 RMS: We agree. See comment 69 and 78. List endpoint will be amended after the new results	Open point 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 also comment 4(68) Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
4(9)	Vol.1, Annex 3, list of endpoints	Aug 04 NL: route and rate of degradation; information about the amount of THPI in the sediment is missing. THPI was detected in sediment extracts >10% PECsed should be calculated for this metabolite	Sept 04 RMS:. See comment 78	Open point PEC sed for THPI should be included in the list of end points. Evaluation Meeting (14.-15.12.2004):

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(9)	*continued* Vol.1, Annex 3, list of endpoints			Open point confirmed. Open point still open.
4(10)	Vol. 1, appendix 3, list of end points	Aug 04 FR: because 2 label positions were used, mineralization and non-extractable residues should be reported for each moiety.	Sept 04 RMS: Text corrected	Addressed
4(11)	Vol. 1, appendix 3, list of end points	Aug 04 FR: the max. amounts of THPI and THPAM (relevant metabolites) should be reported in the end points.	Sept 04 RMS: Text corrected	Addressed
4(12)	Vol. 1, appendix 3, list of end points	Aug 04 FR: typing error : the max. DT50 for THPAM is 7 d.	Sept 04 RMS: Text corrected	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(13)	Vol. 1, appendix 3, list of end points	Aug 04 FR: the main hydrolysis products of captan should be reported in the end points.	Sept 04 RMS: We agree	Open point RMS to report main hydrolysis products in the end points list. See data requirement in comment 4(64) See also comment 4(61) Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
4(14)	Vol. 1, appendix 3, list of end points	Aug 04 FR: the max. amounts of metabolites in water and in sediment should be reported in the end points, and where possible the DT50 values.	Sept 04 RMS: We agree.	Open point RMS to report the max. amounts of metabolites in water and in sediment and DT50 if available. Evaluation Meeting (14.-15.12.2004): Open point confirmed.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(14)	*continued* Vol. 1, appendix 3, list of end points			Open point still open.
4(15)	Vol. 1, appendix 3, list of end points	Aug 04 FR: values of the input parameters (DT50 and Koc) used for PECgw calculation should be reported in the end points.	Sept 04 RMS: See comment 84	Open point RMS to include input parameters of the FOCUS PEC gw calculations in the end points list. See data requirement in comment 4(80) and open point in comment 4(84) Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
4(16)	Vol 3. B.8.1 Route and rate of degradation in soil. B.8.1.1 Aerobic studies.	Aug 04 EFSA: Studies under this section have major drawbacks and are not adequate to estimate the rate of degradation neither of the parent nor of the main metabolites.	Sept 04 RMS: Route and rate of degradation in soil-aerobic studies- general comments: In data described under B.8.1.3 the degradation rate at numerous field sites	Data requirement Two new laboratory aerobic soil degradation studies. These studies should cover the ranges of pH 4.5 to 5 and pH 8.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(16)	*continued* Vol 3. B.8.1 Route and rate of degradation in soil. B.8.1.1 Aerobic studies.	Some problems are listed below: - Soils employed are very similar in characteristics and particularly in pH. The tree soils are within the pH range of 6 to 7. Rages of 4,5 to 5, 5 and 8 must be addressed with additional studies (Annex II 7.1). Furthermore, only two DT_{50}, in closely related soils, may be derived from the studies available. The rate degradation should be provided for three soil types additional to the soil investigated for the route (Annex II 7.1.1.2.1). - Initial parent concentrations in soil investigated in the studies are between six to ten times those intended by the representative uses. Degradation seems to be concentration dependent, being slower at lower concentrations. Additional studies may be needed to address concentrations closer to intended ones. -Adequate information on kinetic employed and goodness of fitting should be provided.	appears to be independent of soil type due to the rapid degradation. Nevertheless we agree that the field studies are carried out in USA and the influence of environmental conditions in particular, soil moisture and soil pH may not be sufficiently clarified with these studies. Adequate information both on the relevance of the USA field for European locations and on the methodology are needed. This is important especially for the PEC calculation of captan and all major metabolites. Recalculation could be provided (in particular for all metabolites). The list of end point will be updated with new data.	Metabolites THCY and THPAI should be addressed as well with separate studies if necessary. Data requirement Adequate kinetic analysis of degradation data should be provided for the soil degradation studies (kinetic model employed, goodness of fitting). Data requirement Relevance of field USA study with respect to EU conditions should be assessed. See also data requirement in 4(55) See also comments in 4(17), 4(18), 4(19), 4(20), 4(23), 4(25), 4(26), 4(27), 4(33), 4(34), 4(35), 4(36), 4(37), 4(38), 4(39), 4(40), 4(51), 4(52) and 4(54).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(16)	*continued* Vol 3. B.8.1 Route and rate of degradation in soil. B.8.1.1 Aerobic studies.			Evaluation Meeting (14.-15.12.2004): Data requirement (Two new laboratory aerobic soil degradation studies): The notifier will provide arguments by mid of March 2005. Data requirement (Adequate kinetic analysis of degradation data): The notifier will provide arguments by mid of March 2005. Data requirement (Relevance of field USA studie with respect to EU conditions): The notifier will provide a position paper by mid of March 2005. Data requirements still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(17)	General comments	Aug 04 ES: there is not sufficient amount of information in DAR with regard to the methodology followed in the studies and in the estimation of the rate of degradation For example there is not information with regard to the R^2 and the model followed for the estimation and if they are reliable for modelling Clarification in these point should be required for a good assessment of Captan and its metabolites	Sept 04 RMS: See comment 16	See data requirements in comment 4(16)
4(18)	Vol.3, B8.1.1. route and rate of degradation in soil Aerobic studies	Aug 04 ES: The degradation of the parent compound has been studied at pH≅ 7. However, this is not the worst case for Captan since the degradation is pH dependant. Besides, the in tended use in apples, tomatoes and peaches that can be cultivated under acidic conditions.	Sept 04 RMS: See comment 16	See data requirements in comment 4(16)
4(19)	Vol.3, B8.1.1. route and rate of degradation in soil Aerobic studies	Aug 04 ES: the recoveries in the study c are out of range (>110% TAR)	Sept 04 RMS: See comment 16	See data requirements in comment 4(16)

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4(20)	Vol.3, B8.1.1. route and rate of degradation in soil Anaerobic studies	Aug 04 ES: the recoveries in the study a are out of range (>110% TAR and < 90% TAR) In the study c there are loses between a 8 and 25% TAR in the identification of metabolites	Sept 04 RMS: See comment 16	See data requirements in comment 4(16)
4(21)	Vol.3, B8.1.1. route and rate of degradation in soil rate of degradation studies (laboratory studies)	Aug 04 ES: The DT_{50} values estimated in the studies for the metabolites THPI and THPAM are based on Timme and Fresh model and they should not be considered relevant for modelling.	Sept 04 RMS: We agree. Recalculation should be provided	Data requirement DT_{50} values estimated in the laboratory studies for the metabolites THPI and THPAM using first order kinetics should be provided for modelling purposes. Evaluation Meeting (14.-15.12.2004): The notifier will provide the recalculation by mid of March 2005. Data requirement still open.

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4(22)	Vol.3, B8.1.1. route and rate of degradation in soil rate of degradation studies (field studies)	Aug 04 ES: THPAM was not monitored and in the ground water modelling is found at levels > 0.1 µg/l	Sept 04 RMS: We agree. Calculation should be provided	See data requirement in comment 4(80)
4(23)	Vol.3, B8.1.1. route and rate of degradation in soil rate of degradation studies (field studies)	Aug 04 ES: The field studies were carried out in the USA. There is not information in the DAR if the field conditions are equivalent to that ones in Northern and Southern Europe.	Sept 04 RMS: See comment 16	See data requirements in comment 4(16)
4(24)	Vol. 3, B.8.1., route and rate of degradation	Aug 04 NL: in the aerobic degradation study there is a textual incorrectness as the description of the degradation behaviour is repeated.	Sept 04 RMS: We require clarification of this comment.	NL to clarify the comment (please indicate pg in pdf file and study reference).
4(25)	Vol 3. B.8.1 Route and rate of degradation in soil. B.8.1.2 Supplementary studies. Anaerobic degradation.	Aug 04 EFSA: Soil and ground water relevance of major metabolites under anaerobic conditions (THCY and THPAI) should be addressed.	Sept 04 RMS: We agree. Recalculation should be provided	Se data requirements in comments 4(16) and 4(80).

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4(26)	Vol 3. B.8.1 Route and rate of degradation in soil. B.8.1.2 Supplementary studies. Aerobic degradation of metabolite THPI.	Aug 04 EFSA: The tree soils employed are very similar. Only pH range 6 to 7 is covered. Does Timme and Frehse model mean first order in this case?. Goodness of fit should be provided and evaluated.	Sept 04 RMS: As comment 25	See data requirements in comment 4(16).
4(27)	Vol 3. B.8.1 Route and rate of degradation in soil. B.8.1.2 Supplementary studies. Aerobic degradation of metabolite THPAM.	Aug 04 EFSA: The tree soils employed are very similar. Only pH range 6 to 7 is covered. Does Timme and Frehse model mean first order in this case?. Goodness of fit should be provided and evaluated	Sept 04 RMS: As comment 25	See data requirements in comment 4(16).
4(28)	Vol. 3, B.8.1.2, Supplementary studies, Anaerobic metabolism	Aug 04 FR: the anaerobic degradation studies Lay (1992) and Pack et al. (1988b) should not be used (unacceptable recoveries and significant deviation from guideline, respectively)	Sept 04 RMS:Clarification on significant deviation from guideline required.	Data requirement Notifier to provide clarification on deviations of the anaerobic degradation studies(Lay (1992) and Pack et al. (1988b)) Open point RMS to assess if these studies are acceptable and essential for the risk assessement. Evaluation Meeting (14.-15.12.2004):

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4(28)	*continued* Vol. 3, B.8.1.2, Supplementary studies, Anaerobic metabolism			Data requirement still open. The notifier will provide a clarification mid of March 2005. Data requirement still open. Open point: 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 comment 4(29) Open point still open.

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4(29)	Vol. 3, B.8.1.2, Supplementary studies, Anaerobic metabolism	Aug 04 FR: the max. amounts of THPI (21.2 %) and THPAM ((34.4 %) reported in the end points do not match the values in Table B.8.1.2.6 (46.4 % and 36.4 %, respectively).	Sept 04 RMS: The maximum amounts of the metabolites THPI and THPAM observed in the study (IIA, 7.1.1.1.2/03) as shown in Table B.8.1.2.4 are 46.45 AR after 7 days and 36.4 AR after 49 days, respectively. Endpoint list to be corrected to following: "Captan rapidly degraded to THCY (max 20.8% after 112 days), THPI (max 46.4% after 7 days), THPAM (max 36.4% after 49 days) and THPAI (max 21.6% after 256 days)."	Open point If anaerobic studies are finally considered not acceptable and not essential this information should be removed from the end points list. Evaluation Meeting (14.-15.12.2004): Relates to comment 4(28).

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4(30)	Vol. 3, B.8.1.2, Supplementary studies, Anaerobic metabolism	Aug 04 FR: the study Pack et al (1979) seems to provide information on aerobic degradation of THCY. If acceptable, this information should be included in the end points.	Sept 04 RMS: We agree	Open point RMS to considere if information from study Pack et al (1979) should be included in the end points list. Evaluation Meeting (14.-15.12.2004): This open point was removed. It is covered by comment 4(48). Point closed.
4(31)	Vol. 3, B.8.1.2, Supplementary studies, Soil photolysis	Aug 04 FR: results from the studies Ruzo et al. (1988a and 1998b) should be summarized in the end points (THPI and THCY major for both dark and light conditions, no effect of light).	Sept 04 RMS: the text will be amended as follows: Captan is rapidly degraded on a soil surface under both illuminated and dark conditions, i.e. no significant effect of light. Two significant (i.e. >10% AR) degradation products are observed, THPI (max 51.0% after 4 days) and THCY (max 15.3% after 4 days)."	Addressed

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4(32)	Vol 3. B.8.1.3 Field studies. a).	Aug 04 EFSA: RMS should clarify if this study is considered essential for the assessment.	Sept 04 RMS: Study can be removed	Addressed RMS to include for the field study under a) a statement "not reliable and not essential" in a revised DAR or addendum/ corrigendum
4(33)	Vol 3. B.8.1.3 Field studies. b).	Aug 04 EFSA: Goodness of fit should be provided for the DT50 calculated.	Sept 04 RMS: We agree see comment 16	See data requirements in comment 4(16)
4(34)	Vol 3. B.8.1.3 Field studies. c).	Aug 04 EFSA: Goodness of fit should be provided for the DT50 calculated. Visual examination of data shows that no reliable DT50 may be calculated from this study.	Sept 04 RMS: We agree see comment 16	See data requirements in comment 4(16)
4(35)	Vol 3. B.8.1.3 Field studies. d).	Aug 04 EFSA: Goodness of fit should be provided for the DT50 calculated.	Sept 04 RMS: see comment 16	See data requirements in comment 4(16)
4(36)	Vol 3. B.8.1.3 Field studies. e).	Aug 04 EFSA: Goodness of fit should be provided for the DT50 calculated.	Sept 04 RMS: see comment 16	See data requirements in comment 4(16)

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4(37)	Vol 3. B.8.1.3 Field studies. f).	Aug 04 EFSA: Goodness of fit should be provided for the DT50 calculated. Why is it stated that soil with a pH = 4.9 is neutral?	Sept 04 RMS: Soil pH for study is 6.9 (not 4.9) and is therefore considered approximately neutral.	See data requirements in comment 4(16) RMS to amend DAR or provide a corrigendum with the actual soil pH of field study under f)
4(38)	Vol 3. B.8.1.3 Field studies. General.	Aug 04 EFSA: Reliability of degradation rates derived from these studies seem doubtful. No calculation of DT_{50} for metabolite THPI is attempted or reported. All the studies are performed in USA and the relevance for European locations has not been assessed. However, it seems clear that half life of Captan under field conditions is longer than could be envisaged from previous laboratory studies. Influence of environmental conditions and soil pH may not be clarified with these studies.	Sept 04 RMS: We agree. Recalculation should be provided. See comment 16	See data requirements in comment 4(16)

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4(39)	Vol. 3 B.8.1.3 Field studies	Aug 04 (SI) It should be discussed whether the field studies in the USA can be representative for conditions in Europe. The slower degradation in field studies compared to laboratory studies are probably the result of dry conditions at the sites in the USA. This has to be considered when calculating PECsoil and PECgroundwater.	Sept 04 RMS: see comment 16	See data requirements in comment 4(16)
4(40)	Vol. 3, B.8.1.3, Field studies.	Aug 04 FR: R^2 values corresponding to DT50f for captan should be reported. It is agreed that soil moisture is a more important factor than soil pH. Concentrations of THPI were measured. Would it be possible to derive DT50f values for this metabolite (apparent DT50f could be about 4-17 d for n=5 and 36 d for the acidic dry soil in Oregon, using linear 1st order $R^2 > 0.89$).	Sept 04 RMS: We agree	See data requirements in comment 4(16)

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4(41)	Vol 3. B.8.2.1. Adsorption, desorption and mobility in soil. a)	Aug 04 EFSA: It is stated that literature data is used to estimate a "mean" Koc = 200 mL / g for CAPTAN. However, references to the literature data and assessment of the reliability of this literature data is missing both in the dossier and the DAR.	Sept 04 RMS: We agree. The reference should be provided	Data requirement Literature data and references to support Captan Koc must be provided and assessed. See also comment 4(42) and 4(44) Evaluation Meeting (14.-15.12.2004): The notifier informs the meeting that has already provided the requested data. RMS needs to confirm. Data requirement still open.
4(42)	Vol.3, B8.2 .1 Adsorption and desorption	ES: The KOC of Captan could not be estimated due to the rapid degradation of the active substance. An leaching column study should be performed according to 95/35/CEE	Sept 04 RMS: Agree. Recalculation shoud be provided	See data requirement in comment 4(41) and open point in comment 4(46)

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4(43)	Vol. 3, B.8.2.1, Adsorption and desorption	Aug 04 FR: in Tables B.8.2.1.4 and .5, the pH value for the East Anglia soil (soil 2) is 8.1 (typing error). Influence of pH on adsorption of THPAM is thus confirmed. The Freundlich adsorption parameters should be preferably used and reported in the end points.	Sept 04 RMS: the typing error will be corrected. We suggest inclusion of following revised text: K_F/K_{OC} : "Captan: K_F = not estimated. THPAM: K_F = 0.14 to 1.2 mL/g (6 soils, 1/n = 0.99 to 1.26, R^2 = >0.97.). THPI: K_F = 0.14 to 0.17 mL/g "	Addressed RMS to consider in a revised DAR or corrigendum.
4(44)	Vol.3 B.8.2.1 Adsorption and desorption	Aug 04 (SI) For captan values for Koc of 33 – 600 mL/kg from a database are used for risk assessment and therefore crucial. More information on the background of the database used is required to judge if these data are reliable.	Sept 04 RMS: as point 41	See data requirement in comment 4(41)
4(45)	Vol.3 B.8.2.1 Adsorption and desorption	Aug 04 (SI) It should be noted that the Koc for THPI in the Lilly field soil is unreliable as the Freundlich coefficient 1/n is only 0.37. This value should not be mentioned when concluding on adsorption behaviour.	Sept 04 RMS: Agree. Suggest DAR modified throughout (also effects comment No. 43.).	Addressed RMS to consider in a revised DAR or corrigendum

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4(46)	Vol 3. B.8.2.2.1. Column leaching studies.	Aug 04 EFSA: Captan seems to be considerably more stable in these soils than any of the ones employed in the degradation studies: 59 1%, 51% and 20. 5 % of parent remains unchanged at the end of the study (30 d). These results should be taken into consideration when revising the degradation rate of Captan. Also it seems that, under some circumstances, captan is stable enough to obtain reliable adsorption / desorption parameters.	Sept 04 RMS: Noted	Open point 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 also comments in 4(42) and 4(47) Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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4(47)	Vol. 3, B.8.2.2.1, Column leaching	Aug 04 FR: the main results (amounts of compounds in soils after the ageing period, amounts of compounds in soil columns and leachates after elution) should be reported in the end points to confirm that captan has a low potential for mobility contrary to THPI and THPAM. The high DT50 observed for the ageing period is clearly linked to soil moisture.	Sept 04 RMS: we agree	See open point in comment 4(46)
4(48)	Vol 3. B.8.2.3 Summary and assessment. Line 3 form the bottom in p. 115	Aug 04 EFSA: Please clarify where in the dossier it is demonstrated that anaerobic metabolite THCY is rapidly degraded to THPA under aerobic conditions.	Sept 04 RMS:This information is included in the dossier under Point IIA, 7.1.1.1.2/03 and is mentioned in the DAR. The actual study report does not contain any additional details.	Open point RMS to clarify on the information available on the degradation of anaerobic metabolite THCY under aerobic conditions. Evaluation Meeting (14.-15.12.2004): See comment 4(30). Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(49)	Vol 3. B.8.2.3 Summary and assessment. Line 1from the top in p. 116.	Aug 04 EFSA: The fact the one DT50 in one soil is 20 days for THPI is omitted here without apparent justification.	Sept 04 RMS: Recalculation should be provided	Open point RMS to clarify which DT_{50} are relevant of the risk assessment of metabolite THPI. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
4(50)	Vol 3. B.8.2.3 Summary and assessment. Line 3 from the top in p. 116.	Aug 04 EFSA: Here degradation half life of metabolites THPI and THPAM from a study not included in the dossier is introduced in the discussion. Report Verhaar, H.J.M. (1999) should be required and assessed if results in it are used in the risk assessment presented in the DAR.	Sept 04 RMS: The report should be provided	Data requirement 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. Evaluation Meeting (14.-15.12.2004): The notifier will provide the report by mid of March 2005.

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4(50)	*continued* Vol 3. B.8.2.3 Summary and assessment. Line 3 from the top in p. 116.			Data requirement still open.
4(51)	Vol 3. B.8.2.3 Summary and assessment. Line 22 from the top in p. 116.	Aug 04 EFSA: Here an unknown separated document is quoted (actually quote 2 is missing in the foot notes to the summary) where it seems that comparability of USA field studies with EU situation is discussed. This document must be submitted and incorporated in the dossier and assessed by RMS in an addendum.	Sept 04 RMS: The report should be provided	See 3rd data requirement in comment 4(16).
4(52)	Vol 3. B.8.2.3 Summary and assessment. Line 26 from the top in p. 116.	Aug 04 EFSA: Here a DT50 for metabolite THPI calculated with data in field studies is introduced. It seems that this DT50 is derived in the same missed reference quoted in line 22. This document must be submitted and incorporated in the dossier and assessed by RMS in an addendum.	Sept 04 RMS: The report should be provided	See data requirements in comment 4(16).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(53)	Vol 3. B.8.2.3 Summary and assessment. Lines 30-32 from the top in p. 116.	Aug 04 EFSA: Reason given here for not measuring metabolite THPAM in field studies has not any support in EU assessment current procedure and should be removed from this summary.	Sept 04 RMS: We agree and suggest removal but see also comment 22	Addressed RMS to consider in a revised DAR or corrigendum
4(54)	Vol. 3, B.8.2.3, summary and assessment	Aug 04 NL: Information on the laboratory soil degradation rate is missing here and should be included as these are the values that should be used in groundwater modelling	Sept 04 RMS: See comment 16. Recalculation are requested	See data requirements in comment 4(16)
4(55)	Vol 3. PEC soil.	Aug 04 EFSA: Since DT50s of captan in soil are not fully reliable it is recommended to use worst case field for PEC soil calculation. The value of DT50 = 24 days is further supported by the results of the column leaching study Verity, A.A., Harvey, B and Simmons, N.D., 1995 and may be envisaged as a realistic worst case in the lack of more reliable data. Therefore, new PEC soil with field worst case DT_{50} must be provided.	Sept 04 RMS: We agree . Recalculation are requested See comment 16	Data requirement New PEC soil with worst case field DT_{50} should be calculated in the lack of more reliable data (see data requirements in 4(16)). See also comments 4(56), 4(57) and 4(58). Evaluation Meeting (14.-15.12.2004): Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(56)	Vol3, B8.3 Predicted environmental concentrations in soil	Aug 04 ES: The PECs in soil is not based in the worst DT50 value but in the mean of the DT50 values seen in the field studies. The PEC in soil should be recalculated and they should collect the PEC for the main metabolites THPI and THPAM	Sept 04 RMS: see point 55	See data requirement in comment 4(55).
4(57)	Vol. 3, B.8.3, PECs	Aug 04 FR; as first approach, the max. DT50f should be used.	Sept 04 RMS: see point 55	See data requirement in comment 4(55).
4(58)	B.8.3 Predicted environmental concentrations in soil	Aug 04 See comment 39A.	Sept 04 RMS: see point 55	See data requirement in comment 4(55).
4(59)	B.8.3 Predicted environmental concentrations in groundwater	Aug 04 See comment 39A	Sept 04 RMS: see point 84	See data requirement in comment 4(80).

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4(60)	B.8.3 Predicted environmental concentrations in surface water	Aug 04 (SI) The metabolites THPI and THPAM are stable in water and accumulation has to be considered when calculating the PIEC for multiple applications.	Sept 04 RMS: We agree. Recalculation should be provided	Data requirement New initial PEC sw, taking into account multiple applications must be provided for metabolites THPI and THPAM. See also comment 4(85). Evaluation Meeting (14.-15.12.2004): Data requirement still open.
4(61)	Vol 3. B.8.4.1. Aqueous hydrolysis. Figure B.8.4.1.1	Aug 04 EFSA: The proposed route of degradation of captan by hydrolysis should include metabolite THPC (S-(tetrahydrophtalamido)thiocarbonate).	Sept 04 RMS: We agree.	See open point in comment 4(13)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(62)	Vol 3. B.8.4.1. Aqueous hydrolysis. Lee, K.S. 1989b.	Aug 04 EFSA: The hydrolysis rates calculated from the degradation of the ring labelled Captan should be calculated and provided.	Sept 04 RMS: We agree.	Data requirement Notifier to calculate the hydrolysis rate from the ring labelled captan (Lee, K.S. 1989b.) Evaluation Meeting (14.-15.12.2004): The notifier will provide the data by mid of March 2005. Data requirement still open.
4(63)	Vol. 3, B.8.4.1, Aqueous hydrolysis	Aug 04 NL: Study e is with THPAM. However, the text about dosage and the tables mention THPI.	Sept 04 RMS: Noted	Addressed RMS to consider in a revised DAR or corrigendum.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(64)	Vol3 B8.4.1 Hydrolysis studies	Aug 04 ES: Accumulation of THPI and THPC is observed in the study c. According to 95/35/CEE information with regard to the hydrolysis metabolites above 10% should be reported. On the other hand the studies in for THPI and THPAM cannot be considered valid since they were carried out at temperatures of 50,60 and 70 ºC and no identification of the metabolites was made. Finally no information with regarding THPC is given	Sept 04 RMS: We agree. According to 95/35/CEE information with regard to the hydrolysis metabolites above 10% should be reported also if not relevant in the aquatic environment.	Data requirement Hydrolysis of metabolites THPI, THPC and THPAM should be provided according EEC guidelines. Metabolites should be reported. See also open point in 4(13) and comment 4(65). Evaluation Meeting (14.-15.12.2004): The notifier stated that the studies have been conducted. EFSA stated that the temperature in the studies was not correct and for THPC there is no study available. The notifier will submit the requested data by mid of March 2005. Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(65)	Vol3 B8.4.1 Hydrolisis studies	Aug 04 ES: The route of hydrolysis seems not to meet the experimental results since THPC appears before than THPI. It seems if as Captan degrades to THPC and then to THPI and sodium thiocarbonate	Sept 04 RMS: as point 64	See data requirement in comment 4(64)
4(66)	Vol 3. B.8.4.3. Ready biodegradability.	Aug 04 EFSA: Ready biodegradability should be assessed with available information or test required.	Sept 04 RMSA: Study is required	Data requirement Readily biodegradability test. See also comment 4(67). Evaluation Meeting (14.-15.12.2004): There is a biodegradability study for folpet available, which covers also captan. The notifier will submit the requested data mid of March 2005. Data requirement still open.

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4(67)	Vol3 B8.4.3 Ready biodegradability	Aug 04 ES: No information was submitted and in the DAR no argumentation was found. Therefore, a study should be required.	Sept 04 RMS: see comment 66	See data requirement in comment 4(66)
4(68)	Vol 3. B.8.4.4. Water sediment system.	Aug 04 EFSA: In both water sediment systems studied water has an alkaline pH (pH 8.1 and 7.8). Since hydrolysis of captan is enhanced under alkaline conditions these systems do not represent worst case. However, they represent a worst case respect the metabolite THPAM.	Sept 04 RMS: Whilst the study was conducted with 2 water/sediment systems with alkaline pH's and cannot therefore be considered a worst-case, captan is degraded extremely rapidly via hydrolysis at all pH's (DT_{50} at pH 5 < 18.8 hrs) even under sterile conditions. Therefore, conducting a further study under mildly acidic conditions would not provide any useful additional information.	Addressed See also open point in comment 4(70)
4(69)	Vol. 3, B.8.4.4, water/sediment systems	Aug 04 NL: the DT_{50} value of the metabolite THPI can be determined in accurately in one of both systems. To our opinion this calculation should be included and not just an approximate value.	Sept 04 RMS: We agree. Calculation should be provided. See also comment 78	Data requirement DT_{50} value of the metabolite THPI in the water sediment system. Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data by mid of March 2005. Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(70)	Vol3 B8.4.4 Water sediment studies	Aug 04 ES: It seems as if THPC had not been monitored. This is one of the main metabolites found in the hydrolysis studies. On the other hand, in the table 8.4.4.3 the mass balance is not closed. There is not information with regard to the radioactivity extracted in the sediment . Finally loses between 4 and 11% TAR has been detected in the Virginia System	Sept 04 RMS: THPC is formed, under sterile conditions, at alkaline pH in hydrolysis studies. In water/sediment studies (i.e. biotic conditions) THPC is not observed. As THPC is an intermediate metabolite of THPI (which is observed at levels of ca 80% at 0 day), it is assumed that, if formed, THPC is rapidly degraded to THPI under non-sterile conditions.	Open point 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 also comment 4(68) Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
4(71)	Vol 3. B.8.6. PEC ground water. A) Merpan 80 WDG. Burden, A.N. and Ridge, M.A. 1999.	Aug 04 EFSA: This study should only be considered as additional information and no conclusion with respect to the representative uses should be derived. (FOCUS not used and parameters may require adjustment)	Sept 04 RMS: See comment 84	See data requirement in comment 4(80)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(72)	Vol 3. B.8.6. PEC ground water. B) Malvin WG. Hayes, S.E. and Travis, K.Z. 1996.	Aug 04 EFSA: This study should only be considered as additional information and no conclusion with respect to the representative uses should be derived. (FOCUS not used and parameters may require adjustment)	Sept 04 RMS: See comment 84	See data requirement in comment 4(80)
4(73)	Vol 3. B.8.6. PEC ground water. FOCUS scenarios.	Aug 04 EFSA: FOCUS ground water exercise reported at the end of the section in the DAR is not found in the dossier. Please clarify.	Sept 04 RMS: See comment 84	See data requirement in comment 4(80)
4(74)	Vol 3. B.8.6. PEC ground water. FOCUS scenarios.	Aug 04 EFSA: FOCUS ground water scenarios need to be recalculated with reliable parameters (eg. DT50 of parent Captan).	Sept 04 RMS: See comment 84	See data requirement in comment 4(80)
4(75)	Vol. 3, B.8.6, PEC groundwater	Aug 04 NL: The Koc value for THPI and the Lillyfield soil should not be included because of the low organic matter content and the low Freundlich coefficient with bad fit of the data. This however wil probably not be of great influence to the results.	Sept 04 RMS: See comment 45	See data requirement in comment 4(80)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(76)	Vol. 3, B.8.6, PEC groundwater	Aug 04 NL: The conclusion of the modelling with the Dutch standard scenario and the PESTLA model can never be that the risk to groundwater from THPI and THPAM is low. Because the model results obtained by PESTLA require a safety factor of 100 the concentration in the upper groundwater clearly exceeds 0.1 µg/L.	Sept 04 RMS: See comment 84	See data requirement in comment 4(80)
4(77)	Vol. 3, B.8.6, PEC groundwater	Aug 04 NL: table B.8.6.9; the method for normalisation of the DT50 values should be given (reference to FOCUS).	Sept 04 RMS: See comment 83	See data requirement in comment 4(80)
4(78)	Vol. 3, B.8.6, PEC sediment	Aug 04 NL: calculation for PECsed are missing. Metabolite THPI is detected in the sediment.	Sept 04 RMS: Calculation should be provided	Data requirement PEC sed for metabolites THPI and THPAI must be provided. See also comment 4(78) Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data by mid of March 2005. Data requirement still open

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(79)	Vol. 3, B.8.6, Predicted concentrations in groundwater	Aug 04 UK: In neutral/alkaline pH soils, THPAM has predicted groundwater concentrations of above 0.1µg/l in several FOCUS gw scenarios – particularly in N EU. (In acidic soils it is ok). Is this metabolite relevant according to the EU guidance? We were unable to find an assessment of relevance of THPAM by the RMS in the DAR?	Sept 04 RMS: See comment 83	Open point RMS to assess relevance of ground water metabolite THPAM if enough data available or identify data gaps. See also data requirement in comment 4(80) Evaluation Meeting (14.-15.12.2004): The notifier stated that a new FOCUS ground water modelling is available. The open point was confirmed by the meeting. Open point still open.
4(80)	Vol. 1, 2.5.3, and Vol 3, B.8.6 Predicted environmental concentrations in groundwater	Aug 04 NOT: The DAR Volume 1 concludes that in acidic soil types, captan can be used throughout the EU without an unacceptable risk to groundwater. The results also indicate that in neutral and alkaline soils some safe uses do exist in	Sept 04 RMS: The results show many PEC value>0.1 µg/l. for THPAM.	Data requirement Notifier to provide new PEC GW modelling consistent with GAPs and reliable input parameters. Metabolites THCY and THPAM should be assessed.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(80)	*continued* Vol. 1, 2.5.3, and Vol 3, B.8.6 Predicted environmental concentrations in groundwater	southern EU states. NOT: A new groundwater modelling study consistent with the GAP is available which demonstrates that safe usage scenarios have been identified for all notified uses, in the context of Annex 1 listing.		Open point RMS to prepare new addendum with new information of potential groundwater contamination. See open points in comments 4(2), 4(79) and 4(81). See also comments 4(22), 4(25), 4(59), 4(71), 4(72), 4(73), 4(74), 4(75), 4(76),4(77) and 4(84). <u>Evaluation Meeting (14.-15.12.2004):</u> Data requirement: The notifier stated that the metabolite THCY is not relevant and will submit an argumentation on this issue. The data requirement was reworded:

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(80)	*continued* Vol. 1, 2.5.3, and Vol 3, B.8.6 Predicted environmental concentrations in groundwater			Notifier to provide new PEC GW modelling consistent with GAPs and reliable input parameters. Metabolites should be assessed according SANCO/221/2000-rev 10.. Data requirement still open. Open point confirmed. Open point still open.
4(81)	Vol. 3, B.8, Definition of the residue in groundwater	Aug 04 SE: A definition of the residue in groundwater is missing. We suggest that it include both metabolites THPI and THPAM. As a consequence valid methods of analysis in groundwater should be presented for both metabolites.	Sept 04 RMS: We agree. Calculation should be provided. See comment 84	Open point RMS to revise the residue definition in ground water. See data requirement in comment 4(80). Monitoring analytical methods will need to be provided for the new metabolites added to the residue defintion. Evaluation Meeting (14.-15.12.2004):

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(81)	*continued* Vol. 3, B.8, Definition of the residue in groundwater			Open point confirmed. Open point still open.
4(82)	Vol 3. B.8.6. PEC surface water.	Aug 04 EFSA: It should be clarified where the DT_{50} (2.6 h at 25 °C) employed for captan PEC SW calculation comes from.	Sept 04 RMS: We agree. Calculation should be provided.	Data requirement PEC FOCUS sw taking into account run off and drainage must be provided. Input parameters should be clearly justified. See also comments 4(83) and 4(85). Evaluation Meeting (14.-15.12.2004): The notifier will provide a new position paper including a new calculation on PEC FOCUS sw in March 2005. Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(83)	Vol 3. B.8.6. PEC surface water.	Aug 04 EFSA: To address loading to surface water by run-off and drainage, FOCUS SW scheme is recommended.	Sept 04 RMS: We agree. Calculation should be provided.	See data requirement in comment 4(82).
4(84)	Vol3 B8.6 Predicted environmental concentration in surface and in ground water	Aug 04 ES: There is not sufficient information with regard to the PECgw modelling in the DAR. The average DT50 value used in the modelling has not taken into account the worst case found in the field studies . Besides, the DT50 of the metabolites used in the modelling are not based in first order kinetics. The rate of application is not based in the maximum of the GAPs	Sept 04 RMS: We agree. The new study submitted has to be evaluated. The results indicate many scenarios with THPAM PEC value >0.1 µg/l	See data requirements in comment 4(80)
4(85)	Vol. 3, B.8.6, Surface water	Aug 04 FR: PECsw should be calculated for the metabolites in case of multiple applications.	Sept 04 RMS: We agree. Calculation should be provided	See data requirements in comments 4(60) and 4(83)
4(86)	Vol. 3, B.8.6, Surface water	Aug 04 FR: PECsed should be calculated for THPI (max. 41 % in sediment on day 0) and THPAI (max. 11.3 % in sediment after 30 d).	Sept 04 RMS: as for comment 78	See data requirement in comment 4(78)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(87)	Vol 3. B.8.7. Fate and behaviour in air.	Aug 04 EFSA: Soil metabolite thiophosgene should be considered to be relevant to the air compartment. Higher apparent volatility of trichloromethyl ^{14}C- Captan (in Pack, D.E. 1987 c) could be due to depletion of this toxic metabolite.	Sept 04 RMS: We agree. Calculation should be provided	Data requirement Relevance of depleted thiophosgen in air should be assessed. See also comment 4(89) Analytical method for monitoring thiophosgene may be needed if finally included in the residue definition in air. Evaluation Meeting (14.-15.12.2004): The notifier will present the requested data in a position paper in March 2005. Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(88)	Vol3 B8.7 rate of degradation in air	Aug 04 ES: The rate of degradation in air according to Atkinson model should be required.	Sept 04 RMS: We agree. Calculation should be provided	Data requirement Rate of degradation in air must be provided. Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data by mid of March 2005. Data requirement confirmed. Data requirement still open.
4(89)	Vol 3. B.8.9 Definition of the residue.	Aug 04 EFSA: Thiophosgene may need to be considered for the definition of residue in air.	Sept 04 RMS: as for comment 87	See data requirement in comment 4(87)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(90)	Vol 3. B.8.10 Monitoring data.	Aug 04 EFSA: Report quoted is not found in the dossier.	Sept 04 RMS: Noted	Data requirement Report with the monitoring data should be provided and assessed in an addendum by RMS. Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data by mid of March 2005. Data requirement still open.
4(91)	Vol 3. B.8.11 List of references relied on. P. 156..	Aug 04 EFSA: The six first references of this page (p.156) are repeated from the previous page. Please remove.	Sept 04 RMS: Noted	Addressed RMS to consider in a revised DAR or corrigendum

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(92)	New open point Based on comments from DE			Evaluation Meeting (14.-15.12.2004): The request of a lysimeter study to be discussed in an expert meeting. New open point set.
4(93)	New open point			Evaluation Meeting (14.-15.12.2004): New open point: DT90 in water < 3 days needs to be confirmed in an expert meeting and to communicate to the experts of the phys-chem section. New open point set.

5. Ecotoxicology

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(1)	Vol. 1, List of endpoints, Effects on bees.	Aug 04 EFSA: Preferably also the results of the study with the a.s. are listed in the list of endpoints. Results are given for a study with Malvin WG while in the DAR no study with this formulation is discussed.	Sept 04 RMS: The endpoints document lists the endpoints for oral and contact toxicity from a study conducted both with the active substance and a formulation. The inclusion of toxicity endpoints for the formulation in the endpoints document was omitted because the formulation (Captan 83 WP) is not being supported and only the oral toxicity data was generated in accordance with the EU guideline. The hazard quotients for Merpan 80 WDG are based on endpoints from the study with the technical material or with Captan 83 WP as detailed in the DAR (B.9.4.2.2). The origin of the toxicity endpoint in the hazard quotient table in the endpoints document will be included to increase clarity.	See data requirement in comment 5(31). Open point: RMS to amend the list of endpoints regarding the toxicity values for bees. See also comment 5(37). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5(2)	Vol. 1, List of endpoints, Effects on other arthropod species	Aug 04 EFSA: Preferably results of the studies on NTA are not reported as IOBC classifications but exact effect percentages should be given. Readability would be enhanced if an indication of the study type is given (e.g. laboratory or extended laboratory)	Sept 04 RMS: A revised risk assessment and a summary of endpoints (exact effect percentages) on NTAs will be presented in the Addendum to the dossier (in preparation).	Open point: RMS to amend the list of endpoints regarding NTA (indicating exact effect percentages and study type). See also comment 5(3).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(2)	*continued* Vol. 1, List of endpoints, Effects on other arthropod species			Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5(3)	Vol. 1 2.6.3 Effects on other arthropods and bees	Aug 04 (SI) According to authors of the ESCORT 2 report the trigger of 30% for worst case laboratory studies should be applied to the separate endpoints (mortality, reproduction, parasitation, food consumption) and not to the overall effect.	Sept 04 RMS: The endpoint document will be amended to clarify that the 14-day LC50 839 mg captan/kg result was based on the test with an 83% WP. However, the test with the active substance resulted in a 14-day LC50 of greater than 519.3 mg/kg, which was not worst-case nor used in the risk assessment accordingly. The worst-case endpoint only was listed.	See open point in comment 5(2).
5(4)	Vol. 1, List of endpoints, Effects on earthworms	Aug 04 EFSA: Please indicate that the acute LC50 of 839 mg as/kg was obtained from a study with an 83% WP formulation. In addition the results of the acute toxicity study with the a.s. should be mentioned as well.	Sept 04 RMS: The endpoint document will be amended to clarify that the 14-day LC50 839 mg captan/kg result was based on the test with an 83% WP. However, the test with the active substance resulted in a 14-day LC50 of greater than 519.3 mg/kg, which was not worst-case nor used in the risk assessment accordingly. The worst-case endpoint only	Open point: RMS to amend the list of endpoints regarding the acute toxicity to earthworms. Evaluation Meeting (14.-15.12.2004):

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	continued		was listed.	Open point confirmed.
5(4)	Vol. 1, List of endpoints, Effects on earthworms			Open point still open.
5(5)	Vol. 1, List of endpoint, Toxicity data for aquatic species	Aug 04 SE: The list of endpoints, table with data on toxicity to aquatic species, should be supplemented with the lowest, most sensitive, endpoints derived from short- and long-term studies with the different organism groups. At present, the table only shows the data selected for risk assessment. For convenience, the table should also include data on the two metabolites.	Sept 04 RMS: The list of endpoints will be amended with the lowest endpoint for each aquatic group. Endpoints for the metabolites will also be included.	Open point: RMS to amend the list of endpoints regarding the data on toxicity to aquatic organisms. See also comment 5(9). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5(6)	Vol. 1, 2.6.5 Risk to soil micro-organisms	Aug 04 (SI) See comment 12.	Sept 04 RMS:	See comment 5(52).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(7)	Vol.1 List of end points – Effects on terrestrial vertebrates	Aug 04 (SI) Please report the LC50 and NOEC for birds also as daily dose as this is the endpoints to be used for risk assessment of birds according to the latest EU guidance.	Sept 04 RMS: A revised risk assessment for birds and mammals will be presented in the Addendum (in preparation). The endpoints document will be amended accordingly (including toxicity endpoints as daily doses).	Open point: RMS to amend the list of endpoints regarding the LC_{50} and NOEC for birds. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5(8)	Vol.1, level 2	Aug 04 NL: the points mentioned above regarding Volume 3 apply of course also to the corresponding points of Volume 1 and some points have consequences for the endpoint list (TER calculations).	Sept 04 RMS: Level 2 Vol.1 will be amended according to changes in Vol 3	Addressed.
5(9)	Vol. 1, List of endpoint, Toxicity data for aquatic species, p. 79	Aug 04 AT: The table in the list of endpoints shows only the data on toxicity to species which were used for the risk assessment. The results for the most sensitive species from each group of organisms should be added to the table (eg. the lowest 96h EC_{50} value for rainbow trout = 50 µg ai/L). For	Sept 04 RMS: Please see comment above in point 5	See open point in comment 5(5).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(9)	*continued* Vol. 1, List of endpoint, Toxicity data for aquatic species, p. 79	completeness and a better overview the table should also include data on the two metabolites THPI and THPAM.		
5(10)	Vol. 1, 2.6.1, and Vol 3, B.9.1 and B.9.3	Aug 04 NOT: In response to a request from the RMS, a revised risk assessment for birds and wild mammals has been conducted (Norman, S. and Wyness, L. (2003)), in accordance with the 'Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC' (SANCO/4145/2000); 25 September 2002. This concludes that overall, there is a low risk to birds and mammals.	Sept 04 RMS: The revised risk assessment for terrestrial vertebrates is currently under evaluation. Results will be presented in the Addendum (in preparation).	Open point: RMS is proposed to prepare an addendum with a revised risk assessment for birds and mammals according to SANCO/4145/2000. See also comments 5(12), 5(14), 5(15), 5(16), 5(17), 5(18), 5(19), 5(20), 5(33), 5(34) and 5(35). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(11)	Vol.3 B.9.1.1 Acute toxicity to birds	Aug 04 (SI) As substance resembling the dose material was found in the study with mallards the resulting LD_{50} should be considered as unreliable. The study should not be mentioned in the risk assessment.	Sept 04 RMS: The LD50 for both test species was greater than 2,000 mg captan/kg bw. Therefore, the potential drawback with emesis in the study with the mallard has no consequence to the outcome of the risk assessment. The amended risk assessment does not make specific reference to the mallard or quail study and so a comment on the invalidity of the LD50 from the mallard study seems not essential.	Open point: MS to discuss the acceptability of the acute toxicity study to mallards in an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5(12)	Vol.3 B.9.1.1 Acute toxicity to birds	Aug 04 (SI) The paragraph on Annex III requirements is based on the risk assessment in B.9.1.4. It should be either reported in B.9.1.4 or it can be deleted as it is not relevant for dossier requirements but not for the actual risk assessment.	Sept 04 RMS: Please refer to a revised risk assessment for birds and mammals which will be presented in the Addendum to the dossier (in preparation)	See open point in comment 5(10).
5(13)	Vol. 3, B.9.1.3, Effects on birds	Aug 04 EFSA: It is noted that for both reproduction studies the validity criterion of OECD Guideline 206 with regard to the number of 14 day old survivors per hen in the control is not met.	Sept 04 RMS: In the study with the mallard duck, the number of 14-day old survivors per hen exceeded the OECD 206 validity criterion of 15 (16 were reported). For bobwhite quail the number reported was 11 versus the validity criterion of 12. This minor	Addressed.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(13)	*continued* Vol. 3, B.9.1.3, Effects on birds		discrepancy and that there were sufficient numbers for a valid statistical analysis and that the study was conducted before the guideline was published, and for reasons of animal welfare (unnecessary testing) further testing would seem unnecessary. The bobwhite quail results are clear in terms of no treatment-related effects of the test substance on any reproduction parameter and are deemed suitable for use in the risk assessment.	
5(14)	Vol. 3, B.9.1.4, Risk to birds	Aug 04 EFSA: Preferably also the risk to birds and mammals via exposure to contaminated drinking water is assessed.	Sept 04 RMS: The comment is fully noted. however, the principal potential exposure route is through ingestion of insects carrying residues. This has been addressed in monograph addendum. Omission of the potential drinking water route (which is considered unlikely) does not influence the outcome of the assessment.	See open point in comment 5(10).
5(15)	Vol. 3, B.9.1.4, Risk assessment to birds	Aug 04 NL: In the risk assessment the Guidance Document regarding Birds and mammals is not followed. Also multiple application has not been taken into account. At least the dry weight/wet weight factor and the multiple application factor have to be taken into account in the risk assessment.	Sept 04 RMS: See points 7, 10	See open point in comment 5(10).

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5(16)	Vol. 3, B.9.1.4, Risk assessment to birds	Aug 04 DK agrees with the comments on these points from France, UK and the Netherlands.	Sept 04 RMS	See open point in comment 5(10).
5(17)	Vol. 3, Annex B, point B.9.1.4, risk assessment to birds.	Aug 04 FR: captane is intended to be used for a period ranging from 4 weeks to up to 12 weeks in some crops (e.g. pome fruit). It is not sure that the risk arising from repeated exposure over a 1 to 3-month period is addressed by the proposed calculations.	Sept 04 RMS: See point 7, 10	See open point in comment 5(10).
5(18)	Vol. 3, Section 9.1.4 'Risk to birds'& Section 9.3.1 'Risk to terrestrial vertebrates other than birds':	Aug 04 UK: Daily intakes for small (<100g) and large (> 100g) birds / mammals are estimated in Table B.9.1.4.2 assuming daily consumption levels equivalent to 30% and 10% of their respective bodies weights (from Kenaga, 1973). However, these estimates are based on dry weight consumption figures. Before they are used in the risk assessment they should be corrected to fresh weights. Aug 04 The UK uses a correction factor of 2.4 for this, resulting in wet weight food consumption levels of 72% and 24% of body weight for small and large vertebrates.	Sept 04 RMS: See point 7, 10	See open point in comment 5(10).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(19)	Vol. 3, Section 9.1.4 'Risk to birds'& Section 9.3.1 'Risk to terrestrial vertebrates other than birds'	Aug 04 UK: In relation to the long-term risk to herbivorous mammals consideration is required in the refined risk assessment of the likely rates of break down of residues in foliage based on foliar residue data, with some quantification of risk e.g. by comparing the toxicity endpoint with 7 day time weighted residues (this being the minimum interval between applications). For insectivorous mammals which are considered in the refined risk assessment to consume typically 60% of their diet as insects, the possible pesticide contamination of other components in the diet needs to be taken into account in estimate exposure levels.	Sept 04 RMS: See point 7, 10	See open point in comment 5(10).
5(20)	Vol. 3, Annex B 9.1.4. and B 9.3.1., Risk to birds and Risk to mammals	Aug 04 AT: In our opinion the risk assessment for birds and mammals should be performed according to SANCO/4145/2000. It seems that in the TERlt calculations presented multiple application scenarios (possible sum-up of residues on plants) have not been taken into account. If captan break-down on vegetation is rapid and	Sept 04 RMS: See point 7, 10	See open point in comment 5(10).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(20)	*continued* Vol. 3, Annex B 9.1.4. and B 9.3.1., Risk to birds and Risk to mammals	therefore no sum-up of residues can be expected, this should be illustrated with representative residue data. However, in the estimation of HQ`s for non-target arthropods a MAF (multiple application factor) of 2.6 is considered.		
5(21)	Vol. 3, B.9.2.6, Risk to aquatic organisms	Aug 04 EFSA: Given the comments on the PECsw and the water sediment study in the section on Fate and behaviour, a revision of the aquatic risk assessment may be necessary.	Sept 04 RMS: The RMS will take due account of any changes to the PECsw in the risk assessment for aquatic organisms. A revised risk assessment will be presented in the next addendum	Open point: 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. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5(22)	Vol.3 B.9.2.6 Risk to aquatic organisms	Aug 04 (SI) For rainbow trout the lowest reported LC_{50} of 50 microgram/L is below the lowest reported NOEC of 56 mirogram/L. This raises questions about the safety of an	Sept 04 RMS: The LC50 of 50 microgram\L was based on a 96-hour flow-through test design. The NOEC of 56 microgram/L was based on a 21-day flow-through test design and was	Open point: MS to discuss the aquatic risk assessment in an expert meeting;

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5(22)	*continued* Vol.3 B.9.2.6 Risk to aquatic organisms	EAC of 19.92 microgram/L but it is not mentioned in the risk assessment.	based on mortality only. The two endpoints were generated from different studies and slight differences are expected when studies are carried out at different times. The NOEC from the 28-day semi-static test, used in the risk assessment was fully justified based on the semi-static test design as related to the behaviour of captan in water.	See also comments 5(23), 5(24), 5(25) and 5(26). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Discussion in an expert meeting taking into account the written comments from DE (29-10-2004). Open point still open.
5(23)	Vol.3 B.9.2.6 Risk to aquatic organisms	Aug 04 (SI) It is not correct to simply state that using the endpoints from the flow-through studies will overestimate the risk. Sl: If the effect of captan is reversible an approach can be to compare the end points from the flow-through studies with an appropriate PECtwa in stead of the initial PEC. Which time period is appropriate should be determined by the time to onset of effects as pointed out in the Guidance document on aquatic ecotoxicology.	Sept 04 RMS: If a PECtwa is used, then the risk will be underestimated because the initial peak concentration will not be taken into account. Also, in a flowthrough study, the exposure profile in the study (continuous, at a constant concentration) does not match the likely exposure in the field (short pulse followed by rapid hydrolytic degradation). The RMS considers the most logical approach is to use endpoints from static or semi-static toxicity studies and initial PEC values.	See open point in comment 5(22).

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5(24)	Vol. 3, B.9.2.6, Risk assessment to aquatic organisms	Aug 04 NL: According to HARAP it is possible to reduce the safety factor with an order of magnitude, when enough data are available, as done in the risk assessment by the RMS. But the remaining safety factor of 10 has to be applied on the lowest toxicity value. In this case the LC50-value of 98 µg/L (Brown trout) must be chosen as the relevant endpoint. Together with a safety factor of 10 the PNEC = 9.8 µg/L. NL: An alternative is to use the HC5-value of 24.2 µg/L. NL is of the opinion that no additional safety factor is necessary on this HC5-value, but is has to be proven that the multiple exposure does not enhance the toxicity. In this case there is a semi-static 28-day study available for Rainbow trout. From this study it appeared that the toxicity was not higher after the pulsed exposure in comparison with the acute study. So the HC5-value can be used.	Sept 04 RMS: RMS agrees with the comment that the risk assessment should be based on the LC50 of 98 µg/l, together with an uncertainty factor of 10. The RMS also agrees with the alternative proposal to use a HC5 of 24.2 µg/l as derived from the species sensitivity distribution (SSD). It is proposed by the RMS, that for Member States which support the use of SSD's in risk assessments at national level, the PNEC (predicted no effect concentration) of 24.2 µg/l can be used.	Open point: RMS to prepare an addendum with a revised risk assessment to fish (based on the LC_{50} of 98 µg/L). See open point in comment 5(22). See also comments 5(25), 5(26), 5(27) and 5(28). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5(25)	Vol. 3, Annex B, point B. 9.2.6., risk to aquatic organisms.	Aug 04 DK recognises a high risk to fish from the use of captan. In our opinion, the LC50 value of 93 µg/l for the most sensitive fish, brown trout	Sept 04 RMS: RMS agrees that LC50 of 98 µg/l for brown trout should be used in the risk assessment. RMS considers the TER trigger of 10 to be protective, and the approach is in	See open points in comments 5(22) and 5(24).

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5(25)	*continued* Vol. 3, Annex B, point B. 9.2.6., risk to aquatic organisms.	(*Salmo trutta*) should be used in the acute risk assessment. The appropriate safety factor should be discussed. We agree with RMS, that results from static tests mimic the real exposure situation best, but it seems strange to use results from a 28 days semi-static chronic test with rainbow trout in acute risk assessment, more so since NOEC = LC50 = 199,2 µg/l. According to the results from acute static test with rainbow trout, NOEC = 30,1 µg/l and LC50 = 205 µg/l, the dose/response curve is not so steep as in the 28 days semi-static test with the same species. In stead the LC50 value of 93 µg/l for the most sensitive fish, brown trout (*Salmo trutta*) should be used in the acute risk assessment. We would hesitate to accept a safety factor of 10, because this is based solely on acute effects (5 fish species) and the intended use is continuous for up to 3 months.	accordance with HARAP and p 25-26 of EU guidance document on aquatic ecotoxicology. This reduction in uncertainty factor is based on acute studies for 6 species. These studies show the range of sensitivity to be narrow. In addition, multiple applications will not lead to continuous exposure in the field as the DT50 is very short (3.84 hours). Hence, the risk assessment should only be based on acute effects. The possible impact of multiple acute exposures on the same fish has been addressed in a 28 day semi-static study on rainbow trout, where there was no accumulation of adverse effects from several exposures.	

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5(26)	Vol. 3, Annex B, point B. 9.2.6., risk to aquatic organisms	Aug 04 FR: it is not understood why acute (including static) studies with fish might over-estimate the risk to fish (acute risk is assessed based on the 28-day chronic study with rainbow trout), while the acute toxicity study with *Daphnia magna* is considered relevant for invertebrates. Data are available from test performed under static conditions: a total of 6 tests under static conditions have been made, giving the brown trout (*Salmo trutta*) as the most sensitive species with a LC50 of 0.098 mg/l, that may be used to assess acute risk. Moreover, data with rainbow trout and common carp show a difference ranging from a 2-fold to 4-fold factor for LC50 measured under flow through or static conditions, which is not so high. It is therefore the opinion of France that a specific acute risk assessment can be made for fish. In this frame, it is proposed in the DAR to re-assess risks based on a probabilistic approach. We are not convinced that a safety factor of 10 is sufficient as the assessment remains based on acute effects. Moreover it is not clear how this safety	Sept 04 RMS: RMS clarifies that it is not proposed that acute static studies might overestimate the risk, only acute flowthrough. Acute static studies are considered the relevant tests on which to base the acute risk assessment. The RMS agrees with the comment from FR, that the LC50 of 98 µg/L may be used in the risk assessment. The RMS considers the TER trigger of 10 to be protective, and the approach is in accordance with HARAP and p 25-26 of EU (SANCO) guidance document on aquatic ecotoxicology. This reduction in uncertainty factor is based on acute studies for 6 species. These studies show the range of sensitivity to be narrow. In addition, multiple applications will not lead to continuous exposure in the field as the DT50 is very short (3.84 hours). Hence, the risk assessment should only be based on acute effects. The possible impact of multiple acute exposures on the same fish has been addressed in a 28 day semi-static study on rainbow trout, where there was no accumulation of adverse effects from several exposures. Potential for run-off is a generic issue which is to be addressed at Member State level, as	See open points in comments 5(22) and 5(24).

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5(26)	*continued* Vol. 3, Annex B, point B. 9.2.6., risk to aquatic organisms	factor was introduced into calculations. In addition, it is not so sure that under field conditions a chronic exposure would not occur since risk of run-off was envisaged in the fate section, and because application occur each week during up to 3 months. Finally, THPI and THPAM are not so transient as the active substance and PEC calculation should consider multi-applications.	the EU level assessment for list 2 reviews should be based on spray drift. Also, considering the short DT50 of captan in soil (8.9 days), significant run-off is considered unlikely. The comment on THPI and THPAM is noted. However, TER's are very much higher than the triggers. Hence, the outcome of the assessment would not be affected.	
5(27)	Vol 3, Section B.2.6 Risk to aquatic organisms:	Aug 04 UK: A risk to aquatic life (in particular fish) has been identified. Additional species data on a total of six species of fish have been used to reduce the acute TER 'acceptability trigger' from 100 to 10. In line with current guidance (Section 5.3 of SANCO/3268/2001 October 2002), this is considered acceptable providing the reduced trigger is applied to the toxicity value for the most sensitive tested species - i.e. the brown trout (*S. trutta*) with an EC50 of 0.098 mg a.s./l. The current refined risk assessment uses a toxicity endpoint relating to the rainbow trout which would appear to be	Sept 04 RMS: RMS agrees with the comments from UK. The LC50 of 98 µg/L for brown trout should be used in the risk assessment, together with an uncertainty factor of 10. TERs values will be recalculated accordingly.	See open point in comment 5(24).

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5(27)	*continued* Vol 3, Section B.2.6 Risk to aquatic organisms:	approximately two times less sensitive than the brown trout. We have concluded that calculated TERs in Table B.9.2.6.18 under-estimate the potential risk and should be re-calculated using the brown trout acute toxicity data, with the indicated 'low risk' /acceptable buffer zones amended accordingly.		
5(28)	Vol. 3, Annex B, point B. 9.2.6., risk to aquatic organisms, p. 170 - 211	Aug 04 AT: Brown trout (*Salmo trutta*) is the most sensitive species (LC_{50} = 98 µg ai/L). The argument that the results of tests conducted under flow through conditions would lead to an overestimation of the risk is not valid for brown trout since the test with brown trout was conducted under static conditions. Therefore it is not necessary to use the result of the long term study with rainbow trout (semi static test conditions) for the acute risk assessment.	Sept 04 RMS: The RMS clarifies that the comment on overestimation of the risk does not apply to the static study on brown trout. The 28 day semi-static study on rainbow trout effectively included multiple acute exposures, which is why it was included in the assessment. However, on the basis of comments from several Member States, the RMS now agrees to base the overall risk assessment on the LC50 for brown trout (with an uncertainty factor of 10).	See open point in comment 5(24).
5(29)	Vol. 3, B.9.2, Effects on aquatic organisms	Aug 04 EFSA: The measured concentrations of the freshly prepared stock solutions or measure concentrations at the start of test were far below 80% of the nominal for the following studies: acute toxicity to	Sept 04 RMS: Agreed	Open point: RMS to prepare an addendum to revise the endpoints for aquatic organisms (based on measured concentrations if appropriate) and revise the

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	continued	rainbow trout of a 83% WP formulation (Kent, 1993a) and acute toxicity to *Daphnia magna* of a 83% WP formulation (Kent, 1993b). Nevertheless the results of these studies are expressed in nominal concentrations which could underestimate the risk. Preferably the results of these studies are expressed in initial measured concentrations.		aquatic risk assessment if necessary. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5(29)	Vol. 3, B.9.2, Effects on aquatic organisms			
5(30)	Vol. 3, B.9.2.6, Risk to aquatic organisms	Aug 04 EFSA: It is noted that not all studies are summarized in Table B.9.2.6.4 on p. 203. Is this because those studies are regarded as not acceptable?	Sept 04 RMS: The summary table B.9.2.6.4 will be amended to include all aquatic toxicity studies.	Addressed. RMS to provide a corrigendum/addendum or to consider in a revised DAR.
5(31)	Vol. 3, B.9.2.6, Risk to aquatic organisms	Aug 04 EFSA: It is noted that for the risk assessment of the lead formulation Malvin **WG**, studies with Merpan 83 **WP** are used. A statement on the comparability of these formulations is considered necessary.	Sept 04 RMS: RMS will ask the notifier a statement on the comparability of various formulations used for ecotox studies	Data requirement: Notifier to submit the composition of the tested formulations to proof their comparability to the lead formulations. See also comments 5(36), 5(40), 5(45), 5(52) and 5(53).

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5(31)	*continued* Vol. 3, B.9.2.6, Risk to aquatic organisms			Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data by mid of April 2005. Data requirement still open.
5(32)	Vol. 3, B.9.2.6, Risk to aquatic organisms	Aug 04 EFSA: Also THPAI is a major metabolite in the sediment. An argumentation concerning the necessity of a study with this metabolite is considered necessary.	Sept 04 RMS: An argumentation concerning this point is already reported in the DAR (B.9.2.4Effects on sediment dwelling organisms (Annex IIA 8.2.7). The chronic semistatic toxicity study on Daphnia is representative of the low toxicity (> 1mg/l) of THPAI for invertebrates since the rapid hydrolysis of captan in water leading to the formation of THPAI during the test. A study with sediment dwelling organisms is not required .	Open point: RMS to prepare an addendum regarding the risk of the metabolite THPAI to sediment dwelling organisms (THPAI was not tested on aquatic invertebrates). Evaluation Meeting (14.-15.12.2004): Open point confirmed. To be discussed in an expert meeting. Open point still open.

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5(33)	Vol.3 B.9.3.1 Risk to terrestrial vertebrates other than birds	Aug 04 SI) A quantified refinement of the long term risk to mammals is to be preferred over a qualitative statement. Data on the residue decline on plants can be used to refine with a PECtwa.	Sept 04 RMS: See points 7,10	See open point in comment 5(10).
5(34)	Vol. 3, Annex B, point B.9.3.1, risk assessment to mammals.	Aug 04 FR: captane is intended to be used for a period ranging from 4 weeks to up to 12 weeks in some crops (e.g. pome fruit). It is not sure that the risk arising from repeated exposure over a 1 to 3-month period is addressed by the proposed calculations. Long term risks are assessed on the basis of the NOEC of 25 mg/kg/day, from the study of Benson (1982). From the same study the NOEC of 12.5 mg/kg/day is proposed to cover toxic effects on pups. Toxic effects on pups should also be considered in the risk assessment.	Sept 04 RMS: See points 7,10	See open point in comment 5(10).

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5(35)	Vol.3, B.9.3.1, Risk to mammals	Aug 04 NL: For the long-term risk assessment to mammals the long-term NOEC has been converted from mg/kg bw/day to mg/kg food. But why not using the toxicity value in mg/kg bw/day conform the guidance document and using the PEC-values from table B.9.3.1.2. The TERlt-values will then be somewhat lower than mentioned in table B.9.3.1.3. Besides this also the multiple application factor has to be taken into account in the risk assessment.	Sept 04 RMS: See points 7,10	See open point in comment 5(10).
5(36)	Vol. 3, B.9.4, Effects on bees	Aug 04 EFSA: On p. 217 it is stated that the toxicity to bees for the lead formulation Malvin **WG** can be based on a study with a 50% **WP** formulation. A more extensive argumentation of the comparability of both formulations is considered necessary.	Sept 04 RMS: See point 31	See data requirement in comment 5(31).
5(37)	Vol 3, Annex B, point B.9.4.2.2., risk assessment to bees	Aug 04 FR: table B.9.4.2.2.1 gives an oral LC50 of > 169.3 µg/bee while in the test it is given at > 100 µg/bee.	Sept 04 RMS: See point 1. The endpoint for oral toxicity was taken from the study with 'Merpan' 83 WP (> 169.3µg a.s./bee) rather than from the study with the technical material.	See open point in comment 5(1).

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5(38)	Vol. 1, 2.6.3, and Vol 3, B.9.5	Aug 04 NOT: Additional studies have been undertaken on *Aphidius rhopalosiphi* (Moll, M. (2004)) and *Coccinella septempunctata* (Moll, M. and Bützler, B. (2004)) which cover the proposed rates and the ESCORT 2 multiple application factor. In both new studies, effects were less than the ESCORT 2 trigger of 50% at the maximum rate tested (6.75 kg a.s./ha). The new studies confirm the low risk to non-target arthropods in-field and off-field.	Sept 04 RMS: The new studies and revised risk assessment are under evaluation. Data and results will be presented in the Addendum (in preparation)	Open point: RMS to prepare an addendum to revise the risk assessment for NTA. See also comments 5(41), 5(42), 5(43) and 5(44). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5(39)	Vol. 3, B.9.5, Effects on other arthropod species	Aug 04 EFSA: It is noted that the fecundity in the control during the laboratory study with *T. pyri* was rather low. EFSA: Mean eggs per female was 2 while in the Guidelines to evaluate side-effects of plant protection products to non-target arthropods (Candolfi *et al.*, 2000) a minimum of 4 is set as a validity criterion	Sept 04 RMS: See point 38 .	Open point: MS to discuss the acceptability of the laboratory toxicity test with *T. pyri* in an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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5(40)	Vol. 3, B.9.5, Effects on other arthropod species	Aug 04 EFSA: A more extensive argumentation regarding the comparability of the tested formulations to both lead formulations is considered necessary.	Sept 04 RMS: See point 31	See data requirement in comment 5(31).
5(41)	Vol. 3, B.9.5, Risk to other arthropod species	Aug 04 EFSA: On which data is the assumption of a DT_{50} of 1.64 x the spray interval based. Furthermore the spray interval is not mentioned in the summary of intended uses.	Sept 04 RMS: See point 38	See open point in comment 5(38). Open point: RMS to amend the list of endpoints regarding the list of representative uses (spray interval should be included). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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5(42)	Vol. 3, B.9.5, Risk to other arthropod species	Aug 04 EFSA: A more elaborated statement on the representativeness of the number of applications and the use rate in the field studies to the intended use in pome fruit for southern Europe is considered necessary.	Sept 04 RMS: See point 38	See open point in comment 5(38).
5(43)	Vol.3 B.9.5.2 Risk to other arthropods	Aug 04 (SI) It should be mentioned that most laboratory studies cannot be used for risk assessment as the applied dose is (far) below the application rate specified in the table with intended uses.	Sept 04 RMS: See point 38	See open point in comment 5(38).
5(44)	Vol. 3, Annex B 9.5.2., risk to other arthropods	Aug 04 AT: In the tier 2 assessment of in-field risk with respect to *A. rhopalosiphi* it is stated that "the LR_{50} of captan to *A. rhopalosiphi* is considered to be significantly higher than the highest application rate tested". We think that this extrapolation from the data of Schuld (1999) is not feasible. The dose-mortality curve can not be predicted from the figures available and may well be exponential. The highest dose tested was 1.868 kg ai/ha (single application) and thus significantly below the intended rate	Sept 04 RMS: See point 38	See open point in comment 5(38).

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5(44)	*continued* Vol. 3, Annex B 9.5.2., risk to other arthropods	of 4 times 2.5 kg ai/ha. Therefore we think that higher tier data on *A. rhopalosiphi* which also take into account the multiple use scenario are indispensable before a conclusion on the acceptability of effects on non-target arthropods can be drawn. It should be kept in mind that *A. rhopalosiphi* is a representative of the whole arthropod fauna. Furthermore, the HQ for *A. rhopalosiphi* has been calculated with a LR_{50} which is derived from an extended laboratory study. As the HQ assessment has been validated for glassplate-derived LR_{50}`s, this should at least be seen as a "Tier 2 HQ". Because the in-field HQ>2 one additional species has to be tested. We think that the data on *P. melanarius* and *T. rapae* also do not sufficiently take into account the potential effects of multiple applications.		
5(45)	Vol. 3, B.9.6, Risk to earthworms	Aug 04 EFSA: A more extensive argumentation regarding the comparability of the tested formulation to both lead formulations is considered necessary.	Sept 04 RMS: See point 38	See data requirement in comment 5(31).

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5(46)	Vol. 3, B.9.6, Risk to earthworms	Aug 04 EFSA: Pending on the outcome of the discussion on the PECs in the section on Fate and behaviour, a revision of the risk to earthworms may be necessary.	Sept 04 RMS: A revision of the earthworm risk assessment will be conducted based on any changes to the PECs.	Open point: Pending on the discussion of the PECs in the section on Fate and behaviour, a revision of the risk to earthworms may be necessary. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5(47)	Vol. 3, Annex B 9.6.3., Risk to earthworms	Aug 04 AT: In the tier 1 assessment it was missed by the Rapporteur Member State to divide the LC50- and NOEC-value by the factor 2 where $logK_{ow}$ is greater than 2 (in accordance to the "Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC", SANCO/10329/2002 rev 2 final). The $logK_{ow}$ for captan is 2.5. Furthermore, in the tier 2 assessment the 28-day time weighted average exposure concentration was used. This value is not in accordance with the Guidance Document on	Sept 04 RMS: Agreed, a revised earthworm risk assessment will be done.	Open point: RMS to prepare an addendum to revise the risk assessment for earthworms. See also comments 5(48), 5(49) and 5(51). Evaluation Meeting (14.-15.12.2004): Open point confirmed.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(47)	*continued* Vol. 3, Annex B 9.6.3., Risk to earthworms	Terrestrial Ecotoxicology under Council Directive 91/414/EEC", (SANCO/10329/ 2002 rev 2 final). In case of repeated applications, the PEC after the last application is relevant. Therefore the relevant TER_{lt} will be 1.6.		Open point still open.
5(48)	Vol 3, Annex B, point B.9.6.3., risk assessment to earthworms	Aug 04 FR: toxicological endpoints should be divided by 2 (log P>2). In addition, the use of twaPEC for long term risk assessment is not justified since dissipation of the a.s. within time was already considered in the reproduction test. Moreover, this is not conservative when considering repeated uses of captane. If PEC had to be time-weighted, it should rather be done over a 7 days interval (interval between applications) which would be more representative of the expected exposure of soil organisms. Moreover, it is proposed that metabolites are covered by the risk assessment with the parent, but this is not true anymore if PEC are time-weighted.	Sept 04 RMS: See point 47	See open point in comment 5(47).

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5(49)	Vol.3, B.9.6.3, Risk to earthworms	Aug 04 NL: In the Tier 2 long-term risk assessment to earthworms a time-weighted average concentration has been taken for the PEC. But because the sublethal studies are static studies it is not appropriate to us a PECtwa. The maximum PEC of 3.449 must be used for the long-term risk assessment. A further refinement of the long-term risk to earthworms is then necessary.	Sept 04 RMS: See point 47	See open point in comment 5(47).
5(50)	Vol.3 B.9.6.3 Risks to earthworms	Aug 04 (SI) The calculation of PEC in soil has been described in B.8.3. A reference to this section is preferred. It should be avoided to present PEC calculations in the Ecotoxicology section without the underlying fate studies.	Sept 04 RMS: Noted	Addressed.
5(51)	Vol.3 B.9.6.3 Risks to earthworms	Aug 04 (SI) The use of a PECtwa of 28 days is not appropriate as the NOEC is based on the PIEC in a test with fast degradation of captan and as such the decline in exposure has already been taken into account.	Sept 04 RMS: See point 47 .	See open point in comment 5(47).

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5(51)	*continued* Vol.3 B.9.6.3 Risks to earthworms	Aug 04 Sl: It should be recognised that the use of a PECtwa may overlook effects that result from exposure that occurred early on in the exposure period. If a PECtwa is used in the refinement it should be done with a PECtwa based on the time to onset of effects		
5(52)	Vol. 3, B.9.8, Effects on soil non-target micro-organisms	Aug 04 EFSA: A more extensive argumentation regarding the comparability of the tested formulation to both lead formulations is considered necessary.	Sept 04 RMS: See point 31	See data requirement in comment 5(31).
5(53)	Vol.3 B.9.8 Effects on soil non-target micro-orgnisms	Aug 04 (SI) The test with Pseudomonas putida is relevant for effects on sewage water treatment and not for effects on soil non-target micro-organisms. Consequently, it is not acceptable to refer to this study with the active to conclude on safe uses for the formulations ‘Merpan’ WDG and ‘Malvin’ WG. Unless it can be argued that the results of the study with the 83% WP formulation are representative for the formulations ‘Merpan’ WDG and ‘Malvin’ WG separate studies are required.	Sept 04 RMS: See point 31. The results from the study with the 83% WP formulation were considered to be relevant for an assessment of risk from formulations ‘Merpan’ WDG and ‘Malvin’ WG.	See data requirement in comment 5(31).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(54)	Vol. 3, B.9.9, Effects on other fauna and flora	Aug 04 EFSA: Data supporting the statement made in this section is considered necessary. Furthermore data on the pesticidal activity of the major groundwater metabolites are considered necessary.	Sept 04 RMS: No specific data have been submitted but there are no reported evidences of adverse effects . Many scenarios give PECgw <0.1, so data on pesticide screening are not required. Exposure via surface water is expected to be higher than via ground water and os the risk assessment for surface water, which takes account of metabolites, is sufficient.	Data requirement: Notifier to address the risk to other non-target fauna and flora. See also comment 5(55). Open point: 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. Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data by mid of April 2005. Data requirement still open. Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(55)	Vol. 3, B.9.9, Effects on other non-target organisms believed to be at risk	Aug 04 NL: It is not clear if data has been submitted with regard to this point. If data has been submitted, the evaluation of the data should be more clear.	Sept 04 RMS: No data have been submitted	See data requirement in comment 5(54).
5(56)	Vol. 3, B.9.10, Sewage treatment	Aug 04 EFSA: Pending on the discussion of the PECsw in the section in Fate and behaviour, the need for a study on the effects on methods for sewage treatment may need to be revised.	Sept 04 RMS: Captan is not a probable risk for sewage treatment plants if used in accordance with the GAP due to the rapid hydrolysis in the water environment. Furthermore data on *Pseudomonas putida* (see Point 53) indicate a low risk. Data should be evaluated at MS level.	Open point: MS to discuss the need for further data to address the risk to sewage treatment in an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.