PEER REVIEW REPORT ON **CAPTAN** 21.03.2006

TABLE OF CONTENTS

	Document	**File Name**
00	Cover page	00 captan cover.doc
01	**All comments received on the DAR**	**01 captan all comments.doc**
02	Reporting table all sections	02 captan rep table rev.1-3.doc
03	All reports from EPCO Expert Meetings	03 captan all reports.doc
04	Evaluation table	04 captan eval table rev.2-1.doc

Comments on the Draft Assessment Report on captan (EAS)

RMS IT

End of commenting period: 18.08.2004 (MS, NOT)

Date	Supplier	File
26.07.2004 05.08.2004	France	01 captan comments FR 2004-07-26 ecotox.doc 01 captan comments FR 2004-08-05 fate.doc
03.08.2004	United Kingdom	02 captan comments UK 2004-08-03.doc 02 captan comments UK addendum residues.doc
05.08.2004	Spain	03 captan comments ES 2004-08-05.doc
17.08.2004 19.08.2004	The Netherlands	04 captan comments NL 2004-08-17.doc 04 captan comments NL 2004-08-19 physchem.doc
17.08.2004	Germany	05 captan comments DE 2004-08-17.doc
17.08.2004	Makhteshim	06 captan comments NOT 2004-08-17.doc
19.08.2004	Denmark	07 captan comments DK 2004-08-19.doc
18.08.2004	Sweden	08 captan comments SE 2004-08-18.doc
19.08.2004	Slovenia	09 captan comments SI 2004-08-19.doc
25.08.2004	Austria	10 captan comments AT 2004-08-25.doc
01.09.2004	EFSA	11 captan comments EFSA 2004-08-31.doc

5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 3, Annex B, point B.9.1.4, risk assessment to birds.	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.	
(2)	Vol. 3, Annex B, point B. 9.2.6., risk to aquatic organisms	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	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
		sufficient as the assessment remains based on acute effects. Moreover it is not clear how this safety 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.	
(3)	Vol. 3, Annex B, point B.9.3.1, risk assessment to mammals.	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.	
(4)	Vol 3, Annex B, point B.9.4.2.2., risk assessment to bees	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.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(5)	Vol 3, Annex B, point B.9.6.3., risk assessment to earthworms	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.	

section 4. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.8.1.2, Supplementary studies, Anaerobic metabolism	FR: the anaerobic degradation studies Lay (1992) and Pack et al. (1988b) should not be used (unacceptable recoveries and significant deviation from guideline, respectively)	
(2)	Vol. 3, B.8.1.2, Supplementary studies, Anaerobic metabolism	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).	
(3)	Vol. 3, B.8.1.2, Supplementary studies, Anaerobic metabolism	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.	
(4)	Vol. 3, B.8.1.2, Supplementary studies, Soil photolysis	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).	
(5)	Vol. 3, B.8.1.3, Field studies.	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 1^{st} order $R^2 > 0.89$).	
(6)	Vol. 3, B.8.2.1, Adsorption and desorption	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.	

section 4. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(7)	Vol. 3, B.8.2.2.1, Column leaching	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.	
(8)	Vol. 3, B.8.3, PECs	FR; as first approach, the max. DT50f should be used.	
(9)	Vol. 3, B.8.6, Surface water	FR: PECsw should be calculated for the metabolites in case of multiple applications.	
(10)	Vol. 3, B.8.6, Surface water	FR: PECsed should be calculated for THPI (max. 41 % in sediment on day 0) and THPAI (max. 11.3 % in sediment after 30 d).	
(11)	Vol. 1, appendix 3, list of end points	FR: because 2 label positions were used, mineralization and non-extractable residues should be reported for each moiety.	
(12)	Vol. 1, appendix 3, list of end points	FR: the max. amounts of THPI and THPAM (relevant metabolites) should be reported in the end points.	
(13)	Vol. 1, appendix 3, list of end points	FR: typing error : the max. DT50 for THPAM is 7 d.	
(14)	Vol. 1, appendix 3, list of end points	FR: the main hydrolysis products of captan should be reported in the end points.	
(15)	Vol. 1, appendix 3, list of end points	FR: the max. amounts of metabolites in water and in sediment should be reported in the end points, and where possible the DT50 values.	
(16)	Vol. 1, appendix 3, list of end points	FR: values of the input parameters (DT50 and Koc) used for PECgw calculation should be reported in the end points.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 3, B.2.1, Physical and chemical properties of the active substance	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.	
(2)	Vol 3, B.2.1, Physical and chemical properties of the active substance	UK: Where cases have been made for classification purposes, the RMS should indicate where these are considered acceptable or otherwise.	
(3)	Vol. 3, B.2.1.1 & B.2.1.3, Boiling point and temperature of decomposition	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 decomposition. Thus we would suggest decomposition temperature is requested. Decomposition should be observed up to 360°C.
(4)	Vol 3, B.2.1.10, UV etc spectra (impurities)	UK: The DAR states that none of the impurities present are of concern. However, there is a [redacted] and folpet 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.)	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol 3, B.2.2.10a, pH for Captan 80 WDG	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 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.
(6)	Vol 3, B.2.2.16a, Wettability for Captan 80 WDG	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'.	
(7)	Vol 3, B.2.2.18a, Suspensibility for Captan 80WDG	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.	
(8)	Vol 3, B.2.2.25, friability and attrition for Captan 80WDG	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.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(9)	Vol 3, B.2.2.10, pH of 1% aqueous suspension for Malvin WG	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.	
(10)	Vol 3, B.2.2.16b, wettability for Malvin WG	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'.	

section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.10, Summary of mammalian toxicology and proposed ADI, AOEL and ARfD	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 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).
(2)	Vol. 3, B.6.10, Summary of mammalian toxicology and proposed ADI, AOEL and ARfD	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.
(3)	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)	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.	

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section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(4)	Vol. 3, B.6.14.1.2, text below Table B.6.14.1.3.1	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.	
(5)	Vol. 3, B.6.14..2, bystander exposure	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.	
(6)	Vol. 3, B.6.14..3.1, estimation of worker exposure, 2nd paragraph	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.	
(7)	Vol. 3, B.6.14..3.1, estimation of worker exposure	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.	

section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(8)	Vol. 3, B.6.14..3.1, estimation of worker exposure	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.	
(9)	Vol. 3, B.6.14..3.2, measurement of worker exposure	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).	

section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(10)	Vol. 3, B.6.14..3.3, overall assessment of worker exposure	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 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.	

section 3 - Residues (B.7)

3. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol 3, B.7.1, metabolism, distribution and expression of residues in plants	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, 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	
(2)	Vol 3, B.7.6.4c, stability of residues prior to analysis-peaches	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?	
(3)	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.	

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section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(4)	Vol 3, B.7.6., residues resulting from supervised trials	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
(5)	Vol 3, B.7.6.1, Residues resulting from supervised trials, pome fruit	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.	
(6)	Vol 3, B.7.6.1, Residues resulting from supervised trials, pome fruit	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.	
(7)	Vol 3, B.7.6.1, Residues resulting from supervised trials, pome fruit	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.

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section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(8)	Vol 3, B.7.6., residues resulting from supervised trials	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.
(9)	Vol 3, B.7.8, Livestock feeding studies	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.	
(10)	Vol 3, B.7.12, proposed EU MRLs	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].	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(11)	Vol 3, B.7.12, proposed EU MRLs	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]
(12)	Vol 3, B.7.12, proposed EU MRLs	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.	
(13)	Vol 3, B.7.15, Estimates of dietary exposure	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.

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

4. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.8.6, Predicted concentrations in groundwater	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?	

5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 3, Section 9.1.4 'Risk to birds'& Section 9.3.1 'Risk to terrestrial vertebrates other than birds':	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.	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.
(2)	Vol. 3, Section 9.1.4 'Risk to birds'& Section 9.3.1 'Risk to terrestrial vertebrates other than birds'	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.	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(3)	Vol 3, Section B.2.6 Risk to aquatic organisms:	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 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.

Addendum to UK comments on captan residues

Table B.7.6.1.1: Residues of captan in apples and pears following applications of WG and WP formulations of captan in northern EU

Location Year Trial Crop	Application					Portion analysed	PHI (days)	Captan residue (mg/kg)	Ref.
	Formulation (type and a.s. content)	No.	Method	kg a.s./ha	kg a.s./hL				
Germany 1993 RS-9312-B1 apple	WP 830 g/kg	10	motorised knapsack mist-blower	1.494	0.5	fruit	0 3 7 14 20	7.0 8.4 6.7 2.1 **2.3**	RJ 1592B (IIA 6.3/21)
Germany 1993 RS-9312-B1 apple	WG 750 g/kg	10	motorised knapsack mist-blower	1.494	0.5	fruit	0 3 7 14 20	9.4 8.3 7.4 **2.5** 2.4	
Germany 1993 RS-9312-B2 apple	WP 830 g/kg	10	motorised knapsack mist-blower	1.494	0.5	fruit	0 3 7 13 20	6.3 6.6 2.4 **2.7** 1.8	
Germany 1993 RS-9312-B2 apple	WG 750 g/kg	10	motorised knapsack mist-blower	1.494	0.5	fruit	0 3 7 13 20	5.5 5.3 2.8 **3.5** 1.7	
Germany 1993 RS-9312-G1 pear	WP 830 g/kg	10	motorised knapsack mist-blower	1.494	0.5	fruit	0 3 7 14 20	3.7 1.4 1.8 **1.3** 0.67	
Germany 1993 RS-9312-G1 pear	WG 750 g/kg	10	motorised knapsack mist-blower	1.494	0.5	fruit	0 3 7 14 20	3.4 1.7 0.88 **1.2** 0.23	
Germany 1993 RS-9312-K1 apple	WP 830 g/kg	10	motorised knapsack mist-blower	1.494	0.1	fruit	0 3 7 13 20	1.6 1.4 0.81 0.71 **0.89**	
Germany 1993 RS-9312-K1 apple	WG 750 g/kg	10	motorised knapsack mist-blower	1.494	0.1	fruit	0 3 7 13 20	2.7 2.6 1.3 **1.3** 0.97	
.Germany 1994 N°4211 apple	WP 830 g/kg	12	foliar airblast	1.245	0.12	fruit	0 2 3 7 14	2.0 2.1 1.4 0.84 **0.76**	R-7784 (IIA 6.3/05)

Germany 1994 N°4212 apple	WP 830 g/kg	12	foliar airblast	1.245	0.12	fruit	0 2 3 7 14	4.5 4.1 2.0 2.0 **1.3**	

Table B.7.6.1.2: Residues of captan in apples following applications of a WG or WP formulation of captan in southern EU

Location Year Trial	Application					Portion analysed	PHI	Captan residue (mg/kg)	Ref.
	Formul-ation (type and a.s. content)	No.	Method	kg a.s./ ha	kg a.s./ hL				
Portugal 1991 Turcifal	WP, 830 g/kg	10	Airblast	2.4	0.29	fruit	0 10 14 21	6.2 3.0 **2.9*** **2.9**	R-6778 (IIA 6.3/11
S.France 2000 Grenade sur Garonne (31330)	WG, 800 g/kg	11	Backpack sprayer	2.4 - 2.6	0.15	fruit	7 14 21	1.7 **2.3** 2.1	TMN-0577A (IIA 6.3/12)
Spain 2000 Gualta	WG, 800 g/kg	11	Backpack sprayer	2.3 - 2.9	0.15	fruit	10 13 21	2.5 **1.5** 0.81	
Italy 2000 Brignano Frascata	WG, 800 g/kg	12	Backpack sprayer	2.3 - 2.5	0.125	fruit	7 14 21	7.5 **4.2** 1.3	
Italy 2000 Brignano Frascata	WG, 800 g/kg	12	Backpack sprayer	2.3 - 2.5	0.125	fruit	7 14 21	7.8 **8.0** 5.6	

Table B.7.6.1.3: Residues of captan in pears following applications of a WG or WP formulation of captan in southern EU

Location Year Trial	Application					Portion analysed	PHI	Captan residue (mg/kg)	Ref.
	Formuln (type, content)	No.	Method	kg a.s./ ha	kg a.s./ hL				
Italy 1997 Francolino	WG, 800 g/kg	9	airblast	2.56	0.128	fruit	0 7 14	2.9 1.6 **1.3**	R-10068 (IIA 36.3/13)
S.France 2000 Grenade sur Garonne (31330)	WG, 800 g/kg	11	back-pack sprayer	2.4 - 2.6	0.15	fruit	7 14 21	2.4 **0.54** 0.37	TMN-0660B (IIA 6.3/14)
Spain 2000 Gualta	WG, 800 g/kg	11	back-pack sprayer	2.3 - 2.7	0.15	fruit	10 15 20	0.86 0.79 **1.0**	

Table B.7.6.2.1: Residues of captan in tomatoes following applications of a WG formulation of captan in southern EU

Location Year Trial	Application					Portion analysed	PHI (days)	Captan residue (mg/kg)	Ref.
	Formuln (type, content)	No.	Method	kg a.s./ ha	kg a.s./ hL				
Spain 2000 PA1 Lebrija, (41740 Seville)	WG, 800 g/kg	4	foliar; knap-sack	1.70 - 1.90	0.15	whole fruit	9	0.23	TMN-0695A (IIA 6.3/15)
							14	0.06	
							21	**0.07**	
Spain 2000 PA2 Lebrija, (41740 Seville)	WG, 800 g/kg	4	foliar; knap-sack	1.73 - 1.94	0.15	whole fruit	10	0.24	
							14	**0.09**	
							21	0.05	
Greece 2000 GR1, Xechasmeni, (Veria)	WG, 800 g/kg	4	foliar; knap-sack	1.86 - 2.19	0.125	whole fruit	8	0.02	
							15	**0.03**	
							21	< 0.01	
Greece 2000 GR2, Xechasmeni, (Veria)	WG, 800 g/kg	4	foliar; knap-sack	1.77 - 2.06	0.125	whole fruit	8	0.63	
							14	**0.33**	
							21	< 0.01	
Spain 2001 PA1 Peñaflor (41740)	WG, 800 g/kg	4	foliar; knap-sack	1.84 - 2.06	0.15	whole fruit	14	**0.56**	TMN-0695B (IIA 6.3/16)
							21	0.18	
Spain 2001 PA2 Lebrija, (41740)	WG, 800 g/kg	4	foliar; knap-sack	1.75 - 1.88	0.15	whole fruit	14	**1.1**	
							21	0.29	
Greece 2001 GR1 Kavasila	WG, 800 g/kg	4	foliar; knap-sack	1.76 - 2.06	0.125	whole fruit	14	**0.28**	TMN-0695C (IIA 6.3/16)
							21	0.16	
Greece 2001 GR2 Skilitsi	WG, 800 g/kg	4	foliar; knap-sack	1.90 - 2.07	0.125	whole fruit	13	**0.15**	
							19	0.13	

Table B.7.6.3.1: Residues of captan in peaches and nectarines following applications of WG and WP formulations of captan in southern EU

Location Year Trial	Application					Portion analysed	PHI (days)	Captan residue (mg/kg)	Ref.
	Formuln (type, content)	No.	Method	kg a.s./ ha	kg a.s./ hL				
Peaches									
S.France 2000 TL1 Grenade sur Garonne, (31330)	WG, 800 g/kg	4	foliar; knap-sack	3.06 - 3.52	0.25	whole fruit	7	**3.5**	TMN-0651A (IIA 6.3/17)
							13	1.3	
							21	0.56	
Spain 2000 PA1 Lora del Rio (41440)	WG, 800 g/kg	4	foliar; knap-sack	2.96 - 3.27	0.15	whole fruit	11	4.9	
							15	**6.3**	
							22	2.2	
Spain 2000 ES1 Gualta (17257)	WG, 800 g/kg	4	foliar; knap-sack	3.05 - 3.17	0.15	whole fruit	9	**3.7**	
							14	2.8	
							21	1.7	
S. France 2001 Vacquiers (31340)	WG, 800 g/kg	4	foliar; knap-sack	2.94 - 3.08	0.25	whole fruit	8	**4.4**	TMN-0652 (IIA 6.3/20)
							13	1.6	
							20	0.66	
Nectarines									
Greece 1999 GR1 Veria (59100)	WP, 830 g/kg	4	foliar; knap-sack	2.80 - 2.99	0.125	whole fruit	7	**5.6**	TMN-0643 (IIA 6.3/18)
							14	4.1	
							21	1.5	
Greece 1999 GR2 Naoussa (59100)	WP, 830 g/kg	4	foliar; knap-sack	2.85 - 3.00	0.125	whole fruit	7	**3.1**	
							14	2.3	
							21	0.90	
Spain 1999 ES1 Gualta (17257)	WP, 500 g/kg	4	foliar; knap-sack	2.84 - 3.03	0.15	whole fruit	7	**2.1**	
							11	1.8	
							21	0.62	
Spain 1999 ES2 Pals (Girona, 17256)	WP, 500 g/kg	4	foliar; knap-sack	2.98 - 3.02	0.15	whole fruit	7	**2.5**	
							11	1.3	
							21	0.43	

Residue value calculations for various crops using appropriate residues in the DAR.

HR =	3.500	1.300	8.000	1.300	1.100	6.300	
STMR =	1.800	1.250	2.900	1.000	0.215	3.600	
R(max) =	5.039	3.107	14.544	3.877	1.467	8.557	
R(ber) =	5.300	#NUM!	12.200	#NUM!	1.005	10.600	

	Residue Values in mg/kg						
	1	2	3	4	5	6	7
n	apple N	Pear N	apple S	Pear S	Tomato S	Peach S	
1	2.30	1.30	2.90	1.30	0.07	3.50	
2	2.50	1.20	2.30	0.54	0.09	6.30	
3	2.70		1.50	1.00	0.03	3.70	
4	3.50		4.20		0.33	4.40	
5	0.89		8.00		0.56	5.60	
6	1.30				1.10	3.10	
7	0.76				0.28	2.10	
8	1.30				0.15	2.50	

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

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, Appendix 3, listing of endpoints, Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured:	ES: [redacted] please a clarification is needed	
(2)	Vol 1, Level 1 pag 7. 1.3.9 Specific ation of purity of the ac tive substance (A nne x IIA 1.9)	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.	
(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)	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] 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	As [redacted] it is assumed that this [redacted] is inactive as phytosanitary.

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(4)	Vol. 1, Appendix 3, listing of endpoints, Minimum purity of the active substance…	ES: The purity of the active substance should be expressed in g/Kg	
(5)	Vol. 1, Appendix 3, listing of endpoints, Melting point	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.	
(6)	Vol. 1, Appendix 3, listing of endpoints, Relayive density	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.	
(7)	Vol. 1, Appendix 3, listing of endpoints, Vapour pressure	ES: On listing of endpoints two vapour pressure values at two different temperatures are reported but the purity of test substance is not indicated.	
(8)	Vol. 3, B.2.1.10, Spectra of the impurities…	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.	
(9)	Vol. 3, B.3.3.2, Procedures for destruction or decontamination	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%”	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(10)	Vol. 3, B.3.4.6, Procedures for destruction or decontamination of the plant protection product	ES: On page 50 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%"	
(11)	Vol. 3, B.5.1.2, Methods for determination of impurities	ES: Confirmatory methods for impurities folpet, perchloromethylmercaptan, carbon tetrachloride, and [redacted] are necessary since the primary methods are not highly specific.	

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section 2 - Mammalian toxicology (B.6)

Section 2 - Mammalian toxicology (B.6)
No comments at the momment

section 3 - Residues (B.7)

Section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.3 pag 26 Definition of the residue	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.	

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

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	General comments	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	
(2)	Vol.3, B8.1.1. route and rate of degradation in soil Aerobic studies	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.	
(3)	Vol.3, B8.1.1. route and rate of degradation in soil Aerobic studies	ES: the recoveries in the study c are out of range (>110% TAR)	
(4)	Vol.3, B8.1.1. route and rate of degradation in soil Anaerobic studies	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	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol.3, B8.1.1. route and rate of degradation in soil rate of degradation studies (laboratory studies)	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.	
(6)	Vol.3, B8.1.1. route and rate of degradation in soil rate of degradation studies (field studies)	ES: THPAM was not monitored and in the ground water modelling is found at levels > 0.1 µg/l	
(7)	Vol.3, B8.1.1. route and rate of degradation in soil rate of degradation studies (field studies)	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.	
(8)	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	
(9)	Vol3, B8.3 Predicted environmental concentrations in soil	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	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(10)	Vol3 B8.4.1 Hydrolisis studies	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	
(11)	Vol3 B8.4.1 Hydrolisis studies	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	
(12)	Vol3 B8.4.3 Ready biodegradability	ES: No information was submitted and in the DAR no argumentation was found. Therefore, a study should be required.	
(13)	Vol3 B8.4.4 Water sediment studies	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	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(14)	Vol3 B8.6 Predicted environmental concentration in surface and in ground water	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	
(15)	Vol3 B8.7 rate of degradation in air	ES: The rate of degradation in air according to Atkinson model should be required.	

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section 5 - Ecotoxicology (B.9)

Section 5 - Ecotoxicology (B.9)
No comments at the momment

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

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

NL: no comments.

section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 1, appendix 3, list of end points, ADME studies	NL: ADME studies: Please present the extent of absorption.	
(2)	Vol. 1, appendix 3, list of end points, long-term toxicity	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).	
(3)	Vol. 1, appendix 3, list of end points, summary	NL: Please mention the studies and applied safety factors, used to derive the ADI, AOEL and ARfD.	
(4)	Vol. 3, B.6.3.2 Oral 90-day study rat	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.	

section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(5)	Vol. 3, B.6.3.2 Oral 90-day study dog	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.	
(6)	Vol. 3, B.6.3.3, other routes, 90-day inhalation rat	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. Therefore, the observed hyperplasia in the larynx in the two lowest dose groups should be considered toxicologically relevant.	

section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(7)	Vol. 3, B.6.4.3, summary of genotoxicity studies	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.	
(8)	Vol. 3, B.6.10, Summary and proposed ADI, AOEL, **ARfD**	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.	
(9)	Vol. 3, B.6.10, Summary and proposed ADI, AOEL, ARfD; **mode of oncogenic activity in the mouse**	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.	
(10)	Vol. 3, B.6.12 Dermal absorption, study a), the *in vivo* study	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.	

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section 2 - Mammalian toxicology (B.6)

Classification and labelling (B.4), part mammalian toxicology
No comments.

section 3 - Residues (B.7)

3. Residues (B.7)

NL: no comments.

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

4. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.8.1., route and rate of degradation	NL: in the aerobic degradation study there is a textual incorrectness as the description of the degradation behaviour is repeated.	
(2)	Vol. 3, B.8.2.3, summary and assessment	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	
(3)	Vol. 3, B.8.4.1, Aqueous hydrolysis	NL: Study e is with THPAM. However, the text about dosage and the tables mention THPI.	
(4)	Vol. 3, B.8.4.4, water/sediment systems	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.	
(5)	Vol. 3, B.8.6, PEC groundwater	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.	
(6)	Vol. 3, B.8.6, PEC groundwater	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.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(7)	Vol. 3, B.8.6, PEC groundwater	NL: table B.8.6.9; the method for normalisation of the DT50 values should be given (reference to FOCUS).	
(8)	Vol. 3, B.8.6, PEC sediment	NL: calculation for PECsed are missing. Metabolite THPI is detected in the sediment.	
(9)	Vol. 1, level 3, proposed decision	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.	
(10)	Vol.1, Annex 3, list of endpoints	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.	
(11)	Vol.1, Annex 3, list of endpoints	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.	
(12)	Vol.1, Annex 3, list of endpoints	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.

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5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.1.4, Risk assessment to birds	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.	
(2)	Vol. 3, B.9.2.6, Risk assessment to aquatic organisms	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.	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.
(3)	Vol.3, B.9.3.1, Risk to mammals	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.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(4)	Vol.3, B.9.6.3, Risk to earthworms	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.	
(5)	Vol. 3, B.9.9, Effects on other non-target organisms believed to be at risk	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.	
(6)	Vol.1, level 2	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).	

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

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. C, 1.11, Makhteshim	NL: The content of the impurity folpet in one of 5 batches (1.02%) exceeded the maximum specification of 1.0%.	
(2)	Vol. C, 4.1.2, Makhteshim	NL: On which principle is the commercial moisture meter method to determine water based? Is there any validation data for this method?	
(3)	Vol. C, 4.1.3.1, Makhteshim	NL: Specificity should be adequately addressed for all impurities.	
(4)	Vol. C, 4.1.3.2, Makhteshim	NL: There is no information on linearity for the [redacted]	
(5)	Vol. C, 4.1.3.3, Makhteshim	NL: 4.1.2/02: the fortification levels in terms of % w/w are needed to assess whether the relevant range was validated.	
	Vol. C, 4.1.3.4, Makhteshim	NL: 4.1.2/02: what is the (fortification) level at which RSD for carbon tetrachloride was determined?	
(6)	Vol. C, 4.1.3.5, Makhteshim	NL: Validation was incomplete: linearity and specificity for certain impurities not addressed.	
(7)	Vol. C, 1.9 & 1.10, Tomen	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.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(8)	Vol. C, 1.10, Tomen	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).	
(9)	Vol. C, 1.10, Tomen	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.	
(10)	Vol. C, 1.11, Tomen	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.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(11)	Vol. C, 1.11, Tomen	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).	
(12)	Vol. C, 1.11, Tomen	NL: Composition statement: the maximum level of [redacted] is higher than the FAO specification [redacted]	
(13)	Vol. C, 4.1.2, Tomen	NL: On which principle is the commercial moisture meter method to determine water based? Is there any validation data for this method?	
	Vol. C, 4.1.3.1, Tomen	NL: Specificity should be adequately addressed for all impurities.	
(14)	Vol. C, 4.1.3.2, Tomen	NL: There is no information on linearity of most impurities.	
(15)	Vol. C, 4.1.3.3, Tomen	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.	
(16)	Vol. C, 4.1.3.3, Tomen	NL: Recovery data should be provided for all impurities from the specification.	
(17)	Vol. C, 4.1.3.4, Tomen	NL: Repeatability data should be provided for all impurities from the specification.	
(18)	Vol. C, 4.1.3.5, Tomen	NL: Validation was incomplete: specificity, linearity, recovery and repeatability for certain impurities not addressed.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(19)	Vol. 3, B.2.1	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..	
(20)	Vol. 3, B.2.1.3	NL: The temperature of decomposition must also be determined.	
(21)	Vol. 3, B.2.2.10, Merpan 80 WDG	NL: What is the explanation for the very different pH values found in the two experiments?	
(22)	Vol. 3, B.2.2.14, Merpan 80 WDG	NL: Is the value given the bulk or the tap density?	
(23)	Vol. 3, B.2.2.15, Merpan 80 WDG	NL: Was the physical stability examined in the accelerated storage stability test?	
(24)	Vol. 3, B.2.2.15, Merpan 80 WDG	NL: Was the physical stability examined in the shelf life study?	
(25)	Vol. 3, B.2.2.18, Merpan 80 WDG	NL: Prior to and after ambient storage testing for 24 months, suspensibility was <60%. Should this not be addressed by the notifier?	
(26)	Vol. 3, B.2.2, Malvin WG	NL: A justification should be provided why the test results performed with the “similar” formulation Captan 80 WG are valid for Malvin WG.	
(27)	Vol. 3, B.2.2.15, Malvin WG	NL: Was the physical stability fully examined in the accelerated storage stability test (flowability only is not sufficient)?	

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No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(28)	Vol. 3, B.2.2.15, Malvin WG	NL: The wettability of Captan 80 WDG was not acceptable (3 minutes and 40 seconds). Does this not trigger further testing?	
(29)	Vol. 3, B.5.1.2	NL: See comments on vol. C pertaining to methods of analysis of impurities; there are several data gaps.	
(30)	Vol. 3, B.5.2.1	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 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.	
(31)	Vol. 3, B.5.2.2	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.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(32)	Vol. 3, B.5.5	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.	
(33)	Vol. 1, level 2, 2.2.1	NL: See comments on vol. C pertaining to methods of analysis of impurities; there are several data gaps.	
(34)	Vol. 1, level 2, 2.2.3	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.	
(35)	Vol. 1, level 3, 3.2	NL: Captan should not be included.	
(36)	Vol. 1, level 3, 3.3	NL: There are data gaps concerning analytical methods as listed in level 4.	
(37)	Vol. 1, level 4, 4.2	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..	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	**General Remark**	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.	
(2)	Vol. 3, B.5.2.1, Analytical methods (residue) for plant material	DE: Data Requirement: For determination of captan in commodities with high water content a confirmatory method is missing and should be provided.	
(3)	Vol. 3, B.5.2.1, Analytical methods (residue) for plant material	DE: Data Requirement: For determination of captan in commodities with high water content an independent laboratory validation is missing and should be provided.	
(4)	Vol. 3, B.5.3.2, Analytical methods (residues) for water	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.
(5)	Vol. 3, B.5.4.1 Analytical methods for body fluids and tissues(Annex IIA 4.2.5; Annex IIIA 5.2)	DE: Data Requirement: For determination of captan in human body tissues a confirmatory method is missing and should be provided.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	Vol. 3, B.5.4.1 Analytical methods for body fluids and tissues(Annex IIA 4.2.5; Annex IIIA 5.2)	DE: Data Requirement: For determination of captan in human body fluids a sufficiently validated method is missing and should be provided.	
(7)	Vol. 3, B.5.4.1 Analytical methods for body fluids and tissues(Annex IIA 4.2.5; Annex IIIA 5.2)	DE: Data Requirement: For determination of captan in human body fluids a confirmatory method is missing and should be provided.	

2. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.1.4, Classification and labelling	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.
(2)	Vol. 1, 2.3.2, ADI	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).
(3)	Vol. 1, 2.3.4, AOEL	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.
(4)	Vol. 1, 2.3.6, Impact on human and animal health and Vol.3, B.6.14, Exposure data	DE: On the basis of the proposed dermal absorption rate of 9 % and a systemic AOEL of 0.1 mg/kg bw/day [see (3) and (6)] 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 operator exposure are presented using the German BBA model only.”)..

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(5)	Vol. 1, Level 4, Further information and demand point 4.6	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.	
(6)	Vol. 3, B.6.12, Dermal absorption	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.	In the in vivo study, dermal absorption was followed for 8 hours. Although the exposure time is appropriate, the sampling time is not. According to the EU guidance document, serial non-detects in excreta are required to prove that test material possibly retained in skin is actually not absorbed further. The argument that the radiaoactivity in the excreta/carcass/cage wash between 4 and 8 hours after dosing did not increase, is not convincing. Thus, on one hand, it cannot be excluded that a significant amount might remain in the skin. On the other hand, in vitro data clearly suggest a lower permeability of human skin as compared to rat skin by at least 3 times. To avoid additional animal testing, it is considered a possible approach not to include the in vivo:in vitro correction factor of 3 in the calculation as a surrogate for the unknown amount retained in skin. This calculation would result in a worst-case assumption of 9 % as established in vivo. In a 1999 U.S.EPA evaluation, a dermal absorption rate of 0.4% per hour was mentioned. The basis for this assumption is not known, however, over 24 hours, it would result in a total absorption of nearly 10 %. Again, since the amount retained in skin is not given, a 24 hour value should be used instead of a calculation for 8 hours only.

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 4.5, and Vol 3, B.5.2.1, methods of analysis in plants, plant products	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.	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 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

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			the results 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 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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
			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 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)".** Will be included in the addendum to be submitted to the RMS.
(2)	Vol. 1, 4.5, and Vol 3, B.5.2.2, methods of analysis in animal tissues and milk	The DAR volume 1 concludes that independent laboratory validation and a confirmatory assay are required. 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.	The report of Tilkes described under Annex Point IIA, 4.2.1/05 was included to demonstrate that the standard multi-residue 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. It is considered appropriate to retract the original claim in the dossier that

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
			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 the following position paper: **"Captan. Position Paper on Residue Analytical Methods (April 2004)".** Will be included in the addendum to be submitted to the RMS.
(3)	Vol. 1, 4.5, and Vol 3, B.5.3.2, methods of analysis in water	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.	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 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

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			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)".** Will be included in the addendum to be submitted to the RMS.
(4)	Vol. 1, 4.5, and Vol 3, B.5.3.3, methods of analysis in air	The DAR volume 1 concludes that for air, validation and a confirmatory method are required. It is concluded that the requirements of the Commission Directive 96/48/EC, in terms of method validity, have been adequately met and the method presented is suitable for monitoring. It is considered unnecessary to conduct further work on confirmation when there are numerous existing chromatographic conditions available.	Specificity: As described in the dossier, the specificity of the method has been confirmed (blank samples contained no captan or interferences above 5% of the fortified values). Linearity: Linearity is not defined as a requirement for residue analytical methods either in the Commission Directive 96/46/EC or SANCO/825/00 guidance document. Method validation design: The method has been validated by fortification experiments - three replicate recovery values were determined at each of three concentrations. Current guidance for validation of analytical methods (SANCO/825/00) recommends that five replicate recovery values are determined at two concentrations.

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
			The method was validated before the current guidance was available, but 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 the minor deviation in the size of the sample set compared to the current guidance is not significant. There is no scientific basis on which to reject the results 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. Confirmatory procedure A specific confirmatory assay is not provided in the report. However, residues in air samples may be confirmed using the many other chromatographic conditions presented for captan residue determination in other substrates (crops, soil, water 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. 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 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)”.**

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
			Will be included in the addendum to be submitted to the RMS.
(5)	Vol. 1, 4.5, and Vol 3, B.5.4, methods of analysis in body fluids and tissues	The DAR volume 1 concludes that a validated method is required. A study is planned.	

2. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 1, 4.6, and Vol 3, B.6.6 reproductive toxicity	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. Based on several factors (see column 3), we believe no useful information would be gained from further developmental toxicity studies conducted with captan.	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 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

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

section 2 - Mammalian toxicology (B.6)

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
			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). 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.
(2)	Vol. 1, 2.3.1	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. Therefore, we request that this statement is removed.	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, the statement should be removed.

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No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(3)	Vol. 1, 2.3.3	An ARfD of 0.1 mg/kg bw is proposed. We propose that, based on an evaluation of the toxicology database for captan, an ARfD for captan is not needed.	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**. 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 13763 (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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
			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.
(4)	Vol. 3, B.6.1	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 intermediate) 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 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

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			(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-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.

section 3 - Residues (B.7)

3. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 1, 4.7, and Vol 3, B.7.7.1 effects of processing on the nature of the residue	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 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.
(2)	Vol. 1, 4.7, and Vol 3, B.7.7.2 effects of processing on residue levels	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: **"Veronique, F. (2004). Residue study in and on tomatoes following 4 applications of the test item Malvin WG. Anadiag report R A3154."** **"Veronique, F. (2004). Residue study in and on tomatoes following 4 applications of the test item Malvin WG. Anadiag report R A3156."** **"Veronique, F. (2004). Validation study of the analytical method for the determination of captan and tetrahydrophthalimide (THPI) in**

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section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
			tomato processed fractions. Anadiag report R A3153." Will be included in the addendum to be submitted to the RMS.
(3)	Vol. 1, 4.7, and Vol 3, B.7.7.2 effects of processing on residue levels	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 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.
(4)	Vol. 1, 2.4.4, and Vol 3, B.7.12 Proposed MRLs	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 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.

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

4. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.5.3, and Vol 3, B.8.6 Predicted environmental concentrations in groundwater	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 southern EU states. 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.	Captan, THPI and THPAM have been modelled using FOCUS PELMO, for the uses and rates notifed in the EU review. The conclusions of the new modelling are as follows: Tomatoes: All PEC values for captan, THPI and THPAM were <0.1 µg/l. Peaches/Nectarines: All PEC values for captan and THPI were <0.1 µg/l. For THPAM, 3 out of 4 scenarios give PEC values <0.1 µg/l. Pome fruit (North EU): All PEC values for captan and THPI were <0.1 µg/l. For THPAM, 3 out of 5 scenarios give PEC values <0.1 µg/l. Pome fruit (South EU): All PEC values for captan and THPI were <0.1 µg/l. For THPAM, 3 out of 4 scenarios give PEC values <0.1 µg/l. Safe usage scenarios have been identified for all notified uses, in the context of Annex 1 listing. The new study is listed below: **"Price, O and Mackay, N. (2003). Predicted Environmental Concentrations of captan and its degradation products in groundwater in the EU using the Focus groundwater ccenarios. Cambrideg Environmental Assessments – ADAS, unpublished report number CEA.019"** 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.

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5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.6.1, and Vol 3, B.9.1 and B.9.3	In response to a request from the RMS, a revised risk assessment for birds and wild mammals has been conducted, 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.	The revised risk assessment 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, concludes that overall, there is a low risk to birds and mammals. The risk assessment is presented in the paper below: **"Norman, S. and Wyness, L. (2003). Captan: Response to Rapporteur Member State request for a revised avian and mammalian risk assessment in accordance with EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000)."** Will be included in the addendum to be submitted to the RMS.
(2)	Vol. 1, 2.6.3, and Vol 3, B.9.5	Additional studies have been undertaken on *Aphidius rhopalosiphi* and *Coccinella septempunctata* 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.	Data have been reviewed by the RMS on toxicity to non-target arthropods. These studies indicated a general low toxicity to arthropods. The application rates tested in the laboratory and extended laboratory studies do not cover the highest rates notified in the EU review. Hence, additional studies have been undertaken on *Aphidius rhopalosiphi* and *Coccinella septempunctata* which cover the proposed rates, and also the ESCORT 2 multiple application factor. *A. rhopalosiphi* was chosen for testing as previous glass plate studies identified this as the most sensitive species. *C. septempunctata* was selected as it is a recommended additional test species under ESCORT 2. 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.

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
			The new studies and the updated risk assessment are listed below: **"Moll, M. (2004). Effects of 'Merpan' 80 WDG on the parasitoid *Aphidius rhopalosiphi*, extended laboratory study - aged residue test. IBACON, unpublished report No. 18191003 (Company file: R-16397)."** **"Moll, M. and Bützler, B. (2004). Effects of 'Merpan' 80 WDG on the ladybird beetle *Coccinella septempunctata*, extended laboratory study - aged residue test. IBACON, unpublished report No. 18193013 (Company file: R-16399)."** **"Norman, S. (2004). Non-target arthropods: Updated risk assessment incorporating new extended laboratory studies at higher application rates than previously tested."** The new studies (and Tier 2 summaries of the new studies) and the new risk assessment paper will be included in the addendum to be submitted to the RMS.

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

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

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

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section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.5.3 Summary of long-term toxicity and carcinogenicity	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.

section 3 - Residues (B.7)

3. Residues (B.7)

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

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

4. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		DK agrees with the comments from France, UK and the Netherlands	

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section 5 - Ecotoxicology (B.9)

5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.1.4, Risk assessment to birds	DK agrees with the comments on these points from France, UK and the Netherlands.	
(2)	Vol. 3, Annex B, point B. 9.2.6., risk to aquatic organisms.	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 (*Salmo trutta*) should be used in the acute risk assessment. The appropriate safety factor should be discussed.	DK: 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.
(3)	Vol.3, B.9.3.1, Risk to mammals	DK agrees with the comments on these points from France, UK and the Netherlands.	

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

4. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.8, Definition of the residue in groundwater	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.	

section 5 - Ecotoxicology (B.9)

5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, List of endpoint, Toxicity data for aquatic species	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.	

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

4. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1 2.5.2 Fate and behaviour in soil	See comment 4.	
(2)	Vol. 1 2.5.3 Fate and behaviour in water	See comment 4.	
(3)	Vol.1 List of end point – PEC (soil)	(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.	
(4)	Vol. 3 B.8.1.3 Field studies	(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.	
(5)	Vol.3 B.8.2.1 Adsorption and desorption	(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.	
(6)	Vol.3 B.8.2.1 Adsorption and desorption	(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.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(7)	B.8.3 Predicted environmental concentrations in soil	See comment 4.	
(8)	B.8.3 Predicted environmental concentrations in groundwater	See comment 4.	
(9)	B.8.3 Predicted environmental concentrations in surface water	(SI) The metabolites THPI and THPAM are stable in water and accumulation has to be considered when calculating the PIEC for multiple applications.	

5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 1 2.6.3 Effects on other arthropods and bees	(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.	
(2)	Vol. 1, 2.6.5 Risk to soil micro-organisms	(SI) See comment 12.	
(3)	Vol.1 List of end points – Effects on terrestrial vertebrates	(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.	
(4)	Vol.3 B.9.1.1 Acute toxicity to birds	(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.	
(5)	Vol.3 B.9.1.1 Acute toxicity to birds	(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.	
(6)	Vol.3 B.9.2.6 Risk to aquatic organisms	(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 EAC of 19.92 microgram/L but it is not mentioned in the risk assessment.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(7)	Vol.3 B.9.2.6 Risk to aquatic organisms	(SI) It is not correct to simply state that using the endpoints from the flow-through studies will overestimate the risk.	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.
(8)	Vol.3 B.9.3.1 Risk to terrestrial vertebrates other than birds	(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.	
(9)	Vol.3 B.9.5.2 Risk to other arthropods	(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.	
(10)	Vol.3 B.9.6.3 Risks to earthworms	(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.	
(11)	Vol.3 B.9.6.3 Risks to earthworms	(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.	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.

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(12)	Vol.3 B.9.8 Effects on soil non-target micro-orgnisms	(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.	

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

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

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

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section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.6)

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

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section 3 - Residues (B.7)

3. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 1, Appendix 3 (listing of end points), chapter 4 (residues), summary of critical residues data (… MRL, STMR), page 69	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 compounds are considered similar. (Maybe caused by different speed of metabolic pathway and therefore different determined metabolites.)
(2)	Vol. 3, Figure B.7.2.1.1, Proposed metabolic pathway of captan in domestic animals, page 25	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**"	
(3)	Vol. 3, B.7.6.4, Stability to residues prior to analysis, a (Captan and THPI …), page 36 and 37	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	

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section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(4)	Vol. 3, B.7.7 (effects of industrial processing), B.7.7.1 (effects on the nature of the residue), page 43	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.
(5)	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)	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)**”.	
(6)	Vol. 3, B.7.7.2, Effects on the residue levels, page 48	AT: Page 48 is not staffed.	Maybe a formatting error?

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section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(7)	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	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!
(8)	Vol. 3, B.7.7.2, Effects on the residue levels, page 49, last paragraph ("In two studies in Germany in 1991 …")	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.
(9)	Vol. 3, B.7.15, Estimates of potential and actual dietary exposure through diet and other means, page 66 (acute exposure)	AT: An estimation of acute dietary risk assessment is required as an ARfD of 0.1 mg/kg b.w. is proposed.	

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

4. Environmental fate and behaviour (B.8)

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

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5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 3, Annex B 9.1.4. and B 9.3.1., Risk to birds and Risk to mammals	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 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.	
(2)	Vol. 3, Annex B, point B. 9.2.6., risk to aquatic organisms, p. 170 - 211	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.	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(3)	Vol. 1, List of endpoint, Toxicity data for aquatic species, p. 79	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 completeness and a better overview the table should also include data on the two metabolites THPI and THPAM.	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(4)	Vol. 3, Annex B 9.5.2., risk to other arthropods	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 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.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(5)	Vol. 3, Annex B 9.6.3., Risk to earthworms	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 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.	

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

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	General comment	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.	
(2)	Vol. 1, p. 57, List of endpoints, FAO specification	EFSA: For clarification, the given FAO specification should be read as 910 g/kg ± 30 g/kg.	
(3)	Vol. 1, p. 57, List of endpoints, minimum purity	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).	
(4)	Vol. 1, p. 57, List of endpoints, Identity of relevant impurities	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.	
(5)	Vol. 1, p. 57, List of endpoints, melting point	EFSA: Clarification is needed why the result of the study of Wollerton and Husband (1995b) is not mentioned.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	Vol. 1, 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.	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.	
(7)	Vol. 1, p. 58, List of endpoints, relative density	EFSA: Clarification is needed why the result of the study of Wollerton and Husband (1995b) is not mentioned.	
(8)	Vol. 1, p. 58, List of endpoints, solubility in water	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.	
(9)	Vol. 1, p. 58, List of endpoints, partition coefficient	EFSA: Clarification is needed why the result of the study of Schlesinger (1987a) is not mentioned.	
(10)	Vol. 1, p. 60, Summary of intended uses	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.	
(11)	Vol. 1, p. 61, List of endpoints, classification and labelling in relation to Vol. 3, p. 51, B.4	EFSA: The hazards classification T and N should be mentioned and not only the risk phrases.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(12)	General comment to Volume 3	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 is captan or [redacted]	
(13)	Vol. 3, p. 15, B.2.1.20 Flammability and auto-flammability	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.	
(14)	Vol. 3, p. 16, B.2.2 Physical, chemical and technical properties of the ppp	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.	
(15)	Vol. 3, p. 21f, B.2.2 Physical, chemical and technical properties of the ppp	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.	
(16)	Vol. 3, p. 17, B.2.2.10 pH value	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?	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(17)	Vol. 3, p. 53f, B.5.1.3 Methods for the determination of active ingredient in plant formulation	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.	
(18)	Vol. 3, p. 55ff, B.5.2 Analytical methods (residue)	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).	
(19)	Vol. 3, p. 55ff, B.5.2 Analytical methods (residue)	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.	
(20)	Vol. 3, p. 61ff, B.5.2 Analytical methods (residue) soil, water, air	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.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(21)	Vol. 3, p. 65, B.5.4 Analytical methods (residue) for body fluids and tissues	EFSA: It should be noted, that neither the Directive nor the guidance document SANCO/825/00 requires analytical 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.	
(22)	General comment to Volume 4	EFSA: Clarification is needed regarding the discrimination between captan [redacted] Captan is the international harmonised name for N-(trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide (IUPAC). The chemical name does not comprise any indication of the stereochemistry.[redacted]	

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No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		and captan. The consequence of the given discrimination would be that the compound named in volume 4 as captan is not captan, but only the *cis*-isomer, [redacted] 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.	
(22)	Vol. 4, p. 6, 1.8 Method of manufacture	EFSA: Data concerning the identity of the starting material (source, purity) are missing.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(24)	Vol. 4, p. 11, Composition statement	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.	
(25)	Vol. 4, p. 8 and 27, 1.10 Identity of isomers, impurities and additives	EFSA: Clarification is needed regarding the pattern of impurities. Taken both synthesis pathways into account, the different pattern is not reliable.	
(26)	Vol. 4, p. 12 and 41, 4. Analytical methods in relation to Volume 3, p. 53ff, B.5.1 Analytical methods for formulation analysis.	EFSA: The applicability or non-applicability of CIPAC method(s) was not mentioned.	

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section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.6)

No comments are available at this stage.

section 3 - Residues (B.7)

3. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, level 2, 3 and 4	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.	
(2)	Vol. 1, level 4, 4.7, Residue data	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 balance study and 3 follow-up studies for canned peaches/nectarines	
(3)	Vol. 3, B.7.2, Metabolism in livestock	EFSA: As general remark, the exposure rate of animals should also be expressed in mg/kg bw/d.	
(4)	Vol. 3, B.7.3, Residue definition	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.	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol. 3, B.7.3, Residue definition	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).	
(6)	Vol. 3, B.7.6.1, residue trials in pome fruits	EFSA: We suppose that apples were frozen as whole fruits.	
(7)	Vol. 3, B.7.6.4, Stability of residues prior to analysis.	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.	
(8)	Vol. 3, B.7.6.5, Summary assessment.	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.	
(9)	Vol. 3, B.7.7, Effects of processing.	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 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.	

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section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(10)	Vol. 3, B.7.7.2, Effects on the residue level.	EFSA: In table B.7.7.2.3, it should be clarified what must be understood as ‘warm apple juice’ and ‘cold juice’	
(11)	Vol. 3, B.7.8, Livestock feeding studies	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 products of animal origin.	
(12)	Vol. 3, B.7.12, Proposed EU MRLs	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.	
(13)	Vol. 3, B.7.15, Estimation of potential and actual dietary exposure.	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.	
(14)	Vol. 3, B.7.15, Estimation of potential and actual dietary exposure.	EFSA: Estimations of acute dietary risk must be provided as soon as possible.	

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

4. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 1. List of end points. PEC soil. p. 73. Application rate.	EFSA: GAP is 9 applications of 1.25 kg a.s./ha no 1.5 kg a.s. / ha. Please clarify and amend.	
(2)	Vol 1. List of end points. PEC ground water. p 76.	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.	
(3)	Vol 3. B.8.1 Route and rate of degradation in soil. B.8.1.1 Aerobic studies.	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. 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	

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

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		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.	
(4)	Vol 3. B.8.1 Route and rate of degradation in soil. B.8.1.2 Supplementary studies. Anaerobic degradation.	EFSA: Soil and ground water relevance of major metabolites under anaerobic conditions (THCY and THPAI) should be addressed.	
(5)	Vol 3. B.8.1 Route and rate of degradation in soil. B.8.1.2 Supplementary studies. Aerobic degradation of metabolite THPI.	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.	
(6)	Vol 3. B.8.1 Route and rate of degradation in soil. B.8.1.2 Supplementary studies. Aerobic degradation of metabolite THPAM.	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	
(7)	Vol 3. B.8.1.3 Field studies. a).	EFSA: RMS should clarify if this study is considered essential for the assessment.	NO degradation parameters neither for the parent or metabolites are derived from this study.
(8)	Vol 3. B.8.1.3 Field studies. b).	EFSA: Goodness of fit should be provided for the DT50 calculated.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(9)	Vol 3. B.8.1.3 Field studies. c).	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.	
(10)	Vol 3. B.8.1.3 Field studies. d).	EFSA: Goodness of fit should be provided for the DT50 calculated.	
(11)	Vol 3. B.8.1.3 Field studies. e).	EFSA: Goodness of fit should be provided for the DT50 calculated.	
(12)	Vol 3. B.8.1.3 Field studies. f).	EFSA: Goodness of fit should be provided for the DT50 calculated. Why is it stated that soil with a pH = 4.9 is neutral?	
(13)	Vol 3. B.8.1.3 Field studies. General.	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.	
(14)	Vol 3. B.8.2.1. Adsorption, desorption and mobility in soil. a)	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.	

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

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(15)	Vol 3. B.8.2.2.1. Column leaching studies.	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.	
(16)	Vol 3. B.8.2.3 Summary and assessment. Line 3 form the bottom in p. 115	EFSA: Please clarify where in the dossier it is demonstrated that anaerobic metabolite THCY is rapidly degraded to THPA under aerobic conditions.	
(17)	Vol 3. B.8.2.3 Summary and assessment. Line 1from the top in p. 116.	EFSA: The fact the one DT50 in one soil is 20 days for THPI is omitted here without apparent justification.	
(18)	Vol 3. B.8.2.3 Summary and assessment. Line 3 from the top in p. 116.	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.	
(19)	Vol 3. B.8.2.3 Summary and assessment. Line 22 from the top in p. 116.	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.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(20)	Vol 3. B.8.2.3 Summary and assessment. Line 26 from the top in p. 116.	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.	
(21)	Vol 3. B.8.2.3 Summary and assessment. Lines 30-32 from the top in p. 116.	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.	
(22)	Vol 3. PEC soil.	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.	
(23)	Vol 3. B.8.4.1. Aqueous hydrolysis. Figure B.8.4.1.1	EFSA: The proposed route of degradation of captan by hydrolysis should include metabolite THPC (S-(tetrahydrophtalamido)thiocarbonate).	
(24)	Vol 3. B.8.4.1. Aqueous hydrolysis. Lee, K.S. 1989b.	EFSA: The hydrolysis rates calculated form the degradation of the ring labelled Captan should be calculated and provided.	
(25)	Vol 3. B.8.4.3. Ready biodegradability.	EFSA: Ready biodegradability should be assessed with available information or test required.	

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

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(26)	Vol 3. B.8.4.4. Water sediment system.	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.	
(27)	Vol 3. B.8.6. PEC ground water. A) Merpan 80 WDG. Burden, A.N. and Ridge, M.A. 1999.	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)	
(28)	Vol 3. B.8.6. PEC ground water. B) Malvin WG. Hayes, S.E. and Travis, K.Z. 1996.	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)	
(29)	Vol 3. B.8.6. PEC ground water. FOCUS scenarios.	EFSA: FOCUS ground water exercise reported at the end of the section in the DAR is not found in the dossier. Please clarify.	
(30)	Vol 3. B.8.6. PEC ground water. FOCUS scenarios.	EFSA: FOCUS ground water scenarios need to be recalculated with reliable parameters (eg. DT50 of parent Captan).	
(31)	Vol 3. B.8.6. PEC surface water.	EFSA: It should be clarified where the DT_{50} (2.6 h at 25 ^{o}C) employed for captan PEC SW calculation comes from.	
(32)	Vol 3. B.8.6. PEC surface water.	EFSA: To address loading to surface water by run-off and drainage, FOCUS SW scheme is recommended.	

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No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(33)	Vol 3. B.8.7. Fate and behaviour in air.	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.	
(34)	Vol 3. B.8.9 Definition of the residue.	EFSA: Thiophosgene may need to be considered for the definition of residue in air.	
(35)	Vol 3. B.8.10 Monitoring data.	EFSA: Report quoted is not found in the dossier.	
(36)	Vol 3. B.8.11 List of references relied on. P. 156..	EFSA: The six first references of this page (p.156) are repeated from the previous page. Please remove.	

section 5 - Ecotoxicology (B.9)

5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, List of endpoints, Effects on bees.	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.	
(2)	Vol. 1, List of endpoints, Effects on other arthropod species	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)	
(3)	Vol. 1, List of endpoints, Effects on earthworms	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.	
(4)	Vol. 3, B.9.1.3, Effects on birds	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.	
(5)	Vol. 3, B.9.1.4, Risk to birds	EFSA: Preferably also the risk to birds and mammals via exposure to contaminated drinking water is assessed.	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	Vol. 3, B.9.2.6, Risk to aquatic organisms	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.	
(7)	Vol. 3, B.9.2, Effects on aquatic organisms	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 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.	
(8)	Vol. 3, B.9.2.6, Risk to aquatic organisms	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?	
(9)	Vol. 3, B.9.2.6, Risk to aquatic organisms	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.	
(10)	Vol. 3, B.9.2.6, Risk to aquatic organisms	EFSA: Also THPAI is a major metabolite in the sediment. An argumentation concerning the necessity of a study with this metabolite is considered necessary.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(11)	Vol. 3, B.9.4, Effects on bees	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.	
(12)	Vol. 3, B.9.5, Effects on other arthropod species	EFSA: It is noted that the fecundity in the control during the laboratory study with *T. pyri* was rather low.	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.
(13)	Vol. 3, B.9.5, Effects on other arthropod species	EFSA: A more extensive argumentation regarding the comparability of the tested formulations to both lead formulations is considered necessary.	
(14)	Vol. 3, B.9.5, Risk to other arthropod species	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.	
(15)	Vol. 3, B.9.5, Risk to other arthropod species	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.	
(16)	Vol. 3, B.9.6, Risk to earthworms	EFSA: A more extensive argumentation regarding the comparability of the tested formulation to both lead formulations is considered necessary.	
(17)	Vol. 3, B.9.6, Risk to earthworms	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.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(18)	Vol. 3, B.9.8, Effects on soil non-target micro-organisms	EFSA: A more extensive argumentation regarding the comparability of the tested formulation to both lead formulations is considered necessary.	
(19)	Vol. 3, B.9.9, Effects on other fauna and flora	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.	
(20)	Vol. 3, B.9.10, Sewage treatment	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.	